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CALL FOR PAPERS

The expression "call for papers" is familiar to scientists, as their professional societies plan conferences on major selected topics. We think the expression is most appropriate for IDEA, whose pages report those problems which lie at the interface between the law and technology.

Therefore, our Editorial Board solicits, from authors in legal, scientific, innovative and technological disciplines, manuscripts for possible publication in IDEA. Each will be reviewed by our Editorial Advisory Board for its appropriateness to these pages and, if accepted, put into print as soon as the publication schedule permits.

It should be noted that IDEA welcomes papers that express viewpoints which may be controversial. We hope this policy will stimulate the expression of alternative views, in other manuscripts submitted for publication in the future.

The Use of Cultural Anthropology in Patent Litigation: An Unexpected Synergism

Myles Hopper Ph.D.*

This paper[1] suggests that certain orientations and research techniques in cultural anthropology might be of value in formulating persuasive arguments in patent law litigation and therefore in maximizing the consistency and clarity of judicial interpretations of patent validity. The central topic analyzed is the difficulty in advancing a comprehensive argument in support of either the obviousness or non-obviousness of an innovation. The discussion will demonstrate that anthropologists are also concerned with the issue of the obviousness or non-obviousness of innovations and that their approach in assessing this quality is useful and adaptable to the needs of patent attorneys. The examination of this relationship between anthropology and patent law will focus not on the initial granting of a patent but on the actions of the courts when asked to weigh the claims of disputants regarding the validity or protectability of a patent.

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[1] The author would like to express his appreciation to Thomas G. Field, Jr., for his encouraging advice and to Catherine Smiltneek and Joan Gilmore for their editorial assistance. In particular, suggestions offered by Robert M. Viles were especially helpful in the formulation of the final draft and his efforts are gratefully acknowledged.

When performing these functions, courts will view the process of innovation as one which involves both individual creative acts and social responses to those acts. This view is not unique to the field of intellectual and industrial property.[2] Thus, other disciplines have contributions to make to the debate of such issues as what is an innovation, how does it occur, when should it be legally protected, and why is this type of protection of value to our society? These types of questions have long been a central concern of cultural anthropology and other social sciences. This paper relies upon anthropological literature in particular because of the training and special interests of the author. However, the terms "social science" and "social scientist" are used instead of the relatively more narrow terms "cultural anthropology" or "cultural anthropologist" when matters are discussed which are not unique to anthropology.

The analysis which follows consists of several interrelated topics. First, a brief explanation of cultural anthropology is offered which focuses on the psycho-social phenomenon of innovation. Second, several recurrent themes of patent law are discussed, particularly the issue of obviousness or non-obviousness and the difficulty of the proof of same in patent law litigation. Third, a well-known recommendation for the proper structure of judicial inquiry in patent litigation is analyzed and its deficiencies suggested in light of recent case law. Fourth, the manner in which anthropologists and other social scientists study the issue of obviousness or non-obviousness when engaged in applied social science projects is explored. Some theoretical and methodological perspectives are shown to have potential utility in improving the success with which patent litigation arguments can be organized and presented.

Finally, it should be emphasized that this paper is an original attempt to integrate elements of two fields which have not been regarded as related. The ultimate value of the relationship, identified and discussed in the pages which follow, will emerge through a continued examination of which this paper is but the first step.

Cultural Anthropology and the Concept of Innovation

Anthropology, as one of the social sciences, is characterized by extensive overlapping with and reliance upon the humanities and biological sciences. The discipline attempts to generate knowledge regarding the nature of *Homo sapiens,* our origins and evolution as

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[2] *See* T. Field, *Intellectual and Industrial Property in a Nutshell,* 77 W. VA. L. REV. 525 (1975).

biological and social organisms, and the processes by which we affect and are affected by our biological condition and social environment. Cultural anthropology, as one of the two major branches within the discipline (the other being physical anthropology), examines the customs, or behavior, of peoples at all levels of complexity in an attempt to describe and, ultimately, to reach generalizations about the nature of human culture.[3]

In anthropology the word "culture" has acquired a number of technical meanings and usages limited, it seems, only by the number of anthropologists.[4] For the purposes of this paper, an operational definition is used. Culture may be defined as: "... those ways of behavior or techniques of solving problems which, being more frequently and more closely approximated than other ways, can be said to have a high probability of use by individual members of society."[5] This definition regards culture as a problem-solving amalgamation of techniques which allows humans to react to and manipulate their environments. The view of *Homo sapiens* which underlies this definition is that of a being which seeks to respond effectively and creatively to a physical and social environment. The definition thus recognizes the potential for innovation which exists in all cultures at all times.

Innovation as a Psychological Process[6]

It has been pointed out succinctly that if innovation is viewed entirely as a mental process, its content cannot be objects or "things," but must be "mental configurations:"

> Every innovation is essentially a recombination of two or more mental configurations. The innovator does three things to the configurations: (1) he analyzes each of them, discriminating their component elements and considering the relations among these elements; (2) he matches them, identifying certain elements of one with certain elements of another, in the context provided by the particular configurations; (3) he recombines the configurations, substituting the identified elements and recognizing changes in the mutual relations among the several elements.[7]

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[3] *See* J. HONIGMANN, THE DEVELOPMENT OF ANTHROPOLOGICAL IDEAS (1976); J. HONIGMANN, THE WORLD OF MAN (1959); F. KEESING, CULTURAL ANTHROPOLOGY: THE SCIENCE OF CUSTOM (1958).

[4] For a discussion of the extensive number of definitions of the term "culture," *see* A. KROEBER & C. KLUCKHOHN, CULTURE: A CRITICAL REVIEW OF CONCEPTS AND DEFINITIONS (1963).

[5] A. WALLACE, CULTURE AND PERSONALITY (1961) at 6. *See* KROEBER & KLUCKHOHN, *supra* note 4, at 81-8 for definitions of a descriptive sort.

[6] *See* WALLACE, *supra* note 5, at 120-163 for an excellent review of this entire area.

[7] H.G. BARNETT, INNOVATION: THE BASIS OF CULTURE CHANGE (1953).

It is important to note that people develop mental configurations not merely of physical objects (material culture) but also of social and ideological activities, such as religion, values, economic relations and so forth.

A focus on social as well as material innovation is fundamental to anthropology and researchers explore both to uncover traits, or basic elements, and determine their groupings into patterns or institutions. These, in turn, have specific forms to which specific meanings have been attached by members of a culture. As will be seen below, the perception of forms and meanings is crucial to the determination of the potential for the transmittal of patterns from one culture to another.

The Acceptance and Rejection of Innovation

Once a new configuration has been given expression, the question remains as to whether it will be accepted and utilized. This issue is of importance in discussing the interface between anthropology and patent law because the very process by which the acceptance or rejection takes place yields additional insights about the nature of the innovation process discussed above.

A new configuration, or innovation, can come to the attention of a group either from within *via* one of its own members or from without *via* an agent or another group or culture.[8] To be accepted, the innovation must pass through what amounts to a dual selection process. Under normal circumstances, this "screening,"[9] a complex psycho-social activity, tends to eliminate those innovations which are too inconsistent with the range of behavior and values considered acceptable to the culture (recall the definition of culture offered above on page 3), and those innovations which appear to contribute little to the satisfaction of fundamental needs. It should not be assumed that screening results in the same selections for all persons simultaneously. That there is a variety of responses among individuals to any innovation merely indicates that any one culture is a heterogeneous

[8] This latter phenomenon, referred to as acculturation, is another facet of the anthropological study of change. The literature is extremely extensive. *See generally,* Social Science Research Council Summer Seminar on Acculturation, *Acculturation: An Exploratory Formulation,* 56 AM. ANTHROPOLOGIST 973 (1954); A. HALLOWELL, CULTURE AND EXPERIENCE, Pt. IV at 307-58 (1955); E. Spicer, E. Dozier, & G. Barker, *Social Structure and the Acculturation Process,* 60 AM. ANTHROPOLOGIST 433-55 (1958); R. Murphy, *Social Change and Acculturation,* 26 TRANSACTIONS OF THE N.Y. ACAD. OF SCI. 845-54 (1964).

[9] *See* WALLACE, *supra* note 5, at 121. Although the topic of "screening" is very complex, Wallace's analysis is concise and helpful.

mixture of diverse individuals and interest groups which exhibit a range of mutually acceptable behavior rather than a "replication of uniformity."[10] This diversity encourages innovation because of the greater likelihood that someone will recognize and subsequently demonstrate to others the utility of innovations which otherwise would be screened.

It should be apparent that the recognition of the utility of a new configuration to one's own culture is in itself a creative act. The opportunities for such realizations are numerous when cultures come into contact. In these contact situations, the anthropological study of innovation centers mainly in the responses to the juxtaposition of *different* objects and behavioral patterns and the various ways in which this might occur. In a widely accepted scheme, H.G. Barnett

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[10] *Id.* at 26. It is important to note that diversity need not threaten the integration of a group if the diversity is kept within certain predictable and manageable boundaries. Wallace and others have been critical of those who maintain that cultures are internally unified as a result of a common thread of beliefs, goals, sentiments, character, and so forth. Maintenance of unity or organization among individuals of a social group is accomplished by a mechanism other than cognitive sharing. Wallace, somewhat cumbersomely, refers to this mechanism as "the perception of partial equivalence structures":

> By this is implied the recognition — as the result of learning — that the behavior of other people under various circumstances is predictable, irrespective of knowledge of their motivation, and thus is capable of being predictably related to one's own actions. Evidently, groups, as well as individuals, can integrate their behaviors into reliable systems by means of equivalence structures, without extensive motivational or cognitive sharing.... Thus we may say that as any set of persons establish a system of equivalent behavioral expectancies, an organized relationship comes into existence.... The relationship is not based on sharing but on a complimentarity of cognitions and motives. *Id.* at 41.

Without this type of organization of diversity, innovative behavior would be seriously retarded. The willingness to experiment publicly is, to a great extent, dependent upon the perception that while one might be regarded as eccentric, one need not be regarded as unacceptably socially deviant. In an anthology of articles on the creative process, it was written:

> Because every creative act overpasses the established order in some way and in some degree, it is likely at first to appear eccentric to most men. An inventor ordinarily must begin in isolation and draw the group to himself only as it is discovered, sometimes very slowly, that he has invented some part of what they are in need of. At the beginning of his struggle for realization his originality may achieve no more striking manifestation than an extreme dissatisfaction with established order. *See* "Introduction," in THE CREATIVE PROCESS at 13 (Ghiselin ed. 1952).

has suggested that the juxtapositions are comprised of four possibilities:[11]

1. *Different forms which, by using different principles, serve the same function.* An example is the use of a rowboat by one group and the use of a sailboat by another to catch fish or travel by water.
2. *Different forms which, by utilizing the same principle, serve different functions.* An example is the use by one group of a communal or family bath to socialize and the use by another of private personal tubs for bathing or escape.
3. *Different forms which, by utilizing the same principle, serve the same function.* An example is the pattern of ritual public gift-giving (potlach) in one culture and more informal birthday or Christmas giving in another both of which affect the status of the donor and donee.
4. *Different forms which, by utilizing different principles, serve different functions.* An example is the use by one culture of mirrors for viewing and the use by another of shells for decoration, a situation with potential for substitution in either direction (but probable substitution in the direction of mirrors being used for decorations, as is the case in numerous cultures).

Naturally, these juxtapositions result variously in the acceptance, perhaps in modified form, or rejection of innovations depending upon the operation of the highly complex screening process discussed *supra*. The following is an illuminating illustration of how the results of this process might differ from culture to culture:

> The Cheyenne Indians of the plains demonstrate how a new combination and a new synthesis may take place in a culture. Just before the arrival of the Whites, the Cheyenne had migrated from Minnesota to the plains where they practiced a primitive agriculture. All around them thundered bison, but the Cheyenne lacked the technology to substitute hunting for agriculture as the base of their economy. In the eighteenth century, though, the Cheyenne obtained Spanish horses... Once the Cheyenne began to exploit the abundance of the bison, changes swept through their culture... It may seem obvious to a modern observer that the Cheyenne would recognize instantly the superiority of the horse for use in killing bison, but that is not necessarily true. The Cheyenne culture possessed many special aspects that permitted it to accept the horse and to integrate

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[11] *See generally,* H.G. Barnett, *Invention and Cultural Change,* 44 AM. ANTHROPOLOGIST 14, 23 (1942). The examples Barnett uses differ from the ones used here. *See* H.G. BARNETT, *supra* note 7, for an expanded version of these ideas.

> it into its culture. After all, the Paiute of the Great Basin also obtained horses from the Spaniards. *But instead of using the horses for hunting, the Paiute ate them.* (Emphasis added.)[12]

The above analysis simply underscores the point that there are a limited number of ways an innovation can occur: (1) something old can be thought of or used in a new way; (2) something new can be thought of or used in an old way; (3) something new can be thought of or used in a new way. While a great deal could be written concerning the manner in which the old and the new are mentally and physically combined, these specifics are less central to this paper than is the fact that the innovations which do occur are often startling in their simplicity. In retrospect, it is often hard for anyone other than the inventor to appreciate the measure of creativity actually involved or the degree of difficulty experienced by those who, having tried earlier to solve the problem, failed. This is true whether the solution is reached "spontaneously" or as a result of methodical testing and highly rational experimentation.

Patent Law and the Concept of Innovation

Patent litigation raises from a different perspective many of the issues considered above but continues to employ the two-pronged focus: (1) the mental process involved in the creation of new forms; and, (2) the forms themselves and their degree of obviousness and utility.

Patent Law and Social Policy

There are possibly as many definitions of "law" as there are of "culture." Most people would agree, however, that law is one mechanism for social control, a primary function of which is to resolve and, to the extent possible, prevent disputes among various parties. Along with other less formal means of social control, the legal machinery ideally protects people's rights in a manner which reflects the dominant set of culturally-recognized values and goals.[13] It is precisely these "pol-

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[12] P. FARB, MAN'S RISE TO CIVILIZATION AS SHOWN BY THE INDIANS OF NORTH AMERICA FROM PRIMEVAL TIMES TO THE COMING OF THE INDUSTRIAL STATE at 10 (1968).

[13] The literature on this topic and the general nature of law as an element of culture is vast and multi-disiplinary. For examples of the anthropological approach, *see* LAW IN CULTURE AND SOCIETY (Nader ed. 1969); *The Ethnography of Law*, 67 AM. ANTHROPOLOGIST (No. 6) (Special Issue Pt. 2) (1965); M. GLUCKMAN, POLITICS, LAW AND RITUAL IN TRIBAL SOCEITY (1965); M. GLUCKMAN, THE JUDICIAL PROCESS AMONG THE BAROTSE OF NORTHERN RHODESIA (1954); E. HOEBEL, THE LAW OF PRIMITIVE MAN (1954); K. LLEWELLYN & E. HOEBEL, THE CHEYENNE WAY: CONFLICT AND CASE LAW IN PRIMITIVE JURISPRUDENCE (1941).

icy considerations" which seem to account for much of the longstanding turmoil in patent law. Judicial enforcement of legislatively-mandated policies has been repeatedly questioned as a result of perceived errors in the reasoning of the courts and their interpretations of key features of patent laws.

The authority to formulate the policies expressed in the current patent statutes is assigned to Congress by the United States Constitution: "The Congress shall have Power... to promote the Progress of... useful Arts, by securing for limited Times To Inventors the exclusive Right to their... Discoveries."[14] Patents basically are incentives which encourage the development of new ideas and the "useful Arts."

> A patent is a constitutional grant of a monopoly for a limited time after which the invention is freely available for public use and competition... The patent is constitutionally bargained for. The public reaps the benefit of new ideas and inventions, but endures the detriment of the anticompetitive harm of a monopoly.[15]

Because of the benefits and detriments involved in the granting of monopolies, it is critical that laws which seek to balance private and public interests be clear and easily applied. Nevertheless, the 1952 Patent Law appears to have generated uncertainty instead of the stabilization it sought to provide.[16] There is a disagreement over whether at the time of its passage, the statute merely codified that which existed or actually relaxed the standards of patentability.

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[14] U.S. CONST. art. I, § 8, cl. 8.

[15] Note, *Patent Law-Patent Validity: The Public is the Third Party*, 51 DEN. L.J. 95, 113 (1974); *and see* Field, *supra* note 2, at 532 distinguishing between 'legal' and 'economic' monopolies.

> [A] party successful in making an innovation acceptable under the standards of the patent laws is rewarded by the right to use, produce, or perform the subject matter of the patent *exclusively* for the duration of the patent, even though someone else may later come up with the same innovation. A patentee is thus said to have a "legal" monopoly. A legal monopoly should be distinguished from an "economic" monopoly since a great many patents are so-called 'paper' patents and are never put into commercial use.

[16] *See* P. Federico, *Commentary on the New Patent Act, 35 U.S.C. at 1.* (1952).

If the number of cases and law review articles[17] is any indication, § 103 appears to have produced the most disagreement. This section states:

> ....
>
> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[18]

The application of § 103 has resulted in much inconsistency and dispute especially regarding combination patents. These patents are granted for qualified innovations comprised of two or more forms or processes juxtaposed in a new way. The following review of a line of key cases isolates and clarifies the issues.

In 1850, in the famous *Hotchkiss* "doorknob" case[19] the Supreme Court formulated an expanded concept of "novelty" in order to avoid the granting of patents for trivial innovations. The decision held that novelty must include "invention," a confusing test at best, and made more so by Justice Douglas in the 1941 *Cuno* case.[20] The *Cuno* Court held that the combination of old or well-known devices must reveal a "flash of creative genius" and that the "flash" must be inherent in the device itself and not in the mental process which created it. Subsequent to *Cuno,* but prior to 1952, the general trend was for the lower courts to apply the Supreme Court standard. The 1950 landmark case of *Great Atlantic and Pacific Tea Co. v. Supermarket Equipment Corp.*[21] not only intensified this trend, but also intensified some of the confusion surrounding it.

The Court held in *A&P* that in a device which combines known elements, the combination must exist in some way so as to allow the

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[17] *See, e.g.,* S. Reisenfeld, *The New United States Patent Act in the Light of Comparative Law,* 102 U. PA. L. REV. 291 (1954); Note, *The Standard of Patentability – Judicial Interpretation of Section 103 of the Patent Act,* 63 COLUM. L. REV. 306 (1963); A. Sayko, *Impact of Supreme Court § 103 Cases on Standard of Patentability in the Lower Federal Courts,* 35 GEO. WASH. L. REV. 818 (1967); N.H. Shapiro, *Toward a Realistic Standard of Patentability,* 16 IDEA (2) at 3 (1974); M. Sears, *Combination Patents and 35 U.S.C.* § 103, 3 DET. COLL. L. REV. 83 (1977).

[18] 35 U.S.C. § 103 (1954).

[19] Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1850).

[20] Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941).

[21] 340 U.S. 147 (1950).

whole to exceed the sum of its parts and thereby, through this synergism, to advance science. The heightened uncertainty generated by this case revolved around three unanswered questions: (1) Was synergism required in all cases or only in combination patents? (2) To be patentable, did the device have to advance science or did it merely have to function better and in a new manner? (3) In any event, what was the precise level of the synergism, the advance or the improved function necessary to patentability?

It seems certain that the 1952 Act included § 103 ("conditions for patentability; non-obvious subject matter") in an attempt to answer these questions. Congress eliminated the "presence of invention" requirement and substituted the requirement of non-obviousness. In 1966, the Supreme Court interpreted § 103 in *Graham v. John Deer Co.*,[22] *Coleman, Inc. & Colgate Palmolive Co. v. Cook Chemical Co.*,[23] and *U.S. v. Adams*.[24] Recognizing that the test of "invention" was judicially established while the test of non-obviousness was legislatively mandated, the Court opted to apply the latter in *Graham*. It held the patent for a new plowshank invalid because the form was obvious to one with ordinary skill in the art. (A similar analysis was used in the other two cases with varying results.) The Court based its direct analysis of non-obviousness on a three-step process: (1) determination of prior art; (2) ascertainment of the differences over the prior art; and, (3) determination of the level of ordinary skill. Sub-tests were devised by the court to search for evidence of non-obviousness: (1) Did the invention meet a long-felt but unresolved need? (2) Did it meet with commercial success? (3) Did other devices fail? and, (4) Did others skilled in the art recognize its importance?

In 1969, three years after *Graham,* the Court cited § 103 in its decision in *Black Rock*[25] to hold invalid a patent which covered the addition of a radiant heater to a paving machine. The Court reasoned that both items were well known to those in the business and that the combination of the elements was too obvious to be protectable. The Court indicated that its *Graham* interpretation of § 103 governed in the *Black Rock* case. However, it stated that the combination in *Black Rock* did not meet the test of "new and different function," a test it

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[22] 383 U.S. 1 (1966).

[23] *Id.*

[24] *Id.* at 39 (1966).

[25] Anderson's Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57 (1969).

used in *Lincoln Engineering v. Stewart Warner Corp.*,[26] a 1938 case. The decision apparently left unclear whether this 1938 test was one which must be applied in addition to the *Graham* test of non-obviousness. The Court attempted to settle this uncertainty in 1971 in *Ag Pro*[27] wherein it concluded that both tests were needed to satisfy the requirement of § 103. Even though the new machinery in question produced a desired result successfully and more cheaply than previous machines, the patent was found invalid. The Court ruled that strict scrutiny was mandated for combination patents and the necessary synergistic effect must be in evidence.[28]

There is considerable feeling that the Court not only erred in some of its holdings but has continued to disregard the intent of Congress in the 1952 Act.[29] It is argued that § 103 was intended to overrule the use of separate tests. According to the analysis of one critic (reminiscent of Barnett on innovation) the two-pronged test is illogical:

"No scientific distinction exists between combinations and other developments. Because the universe consists of finite resources, all technological progress necessarily is achieved through manipulation and combination of old elements."[30] This argument further maintains that the requirement of non-obviousness when used in conjunction with novelty and utility is capable of satisfying the constitutional and practical necessities of the patent system. Novelty and utility, it is suggested, will identify developments which advance the useful arts. At the same time, developments obvious to a mechanic of ordinary skill do not need the inducements provided by the patent system's grant of a monopoly. The non-obviousness test is a practical one which generates (allegedly) simple and factual tests and is capable of meeting statutory requirements.

Considerable variation continues to be seen among jurisdictions in the interpretation and application of § 103 despite widespread criticism directed at the courts. But what all the holdings tend to exhibit is an effort to interpret and apply the policy behind the law so that rights and interests might be balanced according to an articulated set of values and goals. In this respect, problems in intellectual and in-

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[26] 303 U.S. 545 (1938).

[27] Ag Pro, Inc. v. Sakraida, 425 U.S. 282 (1971).

[28] Thus it was held that § 103 necessitated a showing of "Innovation," that *Hotchkiss* was codified in the 1952 Act, and that non-obviousness must be determined by the factual analysis used in *Graham*.

[29] *See, e.g.*, Sears, *supra* note 17 and Shapiro, *supra* note 17.

[30] Sears, *supra* note 17, at 557.

dustrial property litigation resemble those in other areas of our legal system.

Innovation and Protectability

N.H. Shapiro has offered the compelling argument that the way to balance the private and public interests (affected by the granting and protecting of patents) while determining the question of obviousness is to "consider whether the differences between the invention and the closest prior art involve changes that would be expected to flow naturally or by evolution from the endeavors of persons of ordinary skill possessing ordinary knowledge."[31] Judges could then focus their factual inquiries on a specific set of questions which are a refinement of the subtests and general analytical framework of *Graham:*

1. Was the problem solved by the invention a problem recognized by those working in the art to which the invention pertains?
2. If the problem was known to persons working in the art:
   a. How long was the problem known?
   b. Did motivation exist for a solution to the problem?
   c. What prior attempts were made to solve the problem by the inventor and others in the art?
   d. Was the inventor's solution to the problem contraindicated by the teachings of the others working in the art?
   e. Was the success of the invention in solving the problem considered surprising by persons working in the art?
3. What tributes were paid to the invention, such as:
   a. Laudatory comments of others working in the art?
   b. Commercial success due to the invention?
   c. License rights acquired from the inventor?
   d. Copying of the invention by competitors?[32]

Assuming this or a similar scheme for judicial inquiry were to be adopted widely, certain problems would still remain to affect its application. First, some of the discrepancies between the actions of the courts and the apparent intent of Congress in passing 35 U.S.C. § 100

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[31] Shapiro, *supra* note 17, at 11.

[32] *Id.* at 12.

et. seq. (1952) seem to be caused by a legitimate divergence of sentiment regarding the very important policy considerations behind the law and its interpretation. Second, and related to the above, is the belief, widely held among many patent attorneys, that many of the judges who rule on questions of validity or protectability suffer from a lack of scientific training which interferes with the proper assessment of obviousness or non-obviousness, and which is partly responsible for incorrect applications of the law.[33]

In addition to these easily identified sources of friction, another more complex factor must be examined. The allegedly straightforward, factual inquiry which the courts must perform involves, in reality, complicated and conflicting evidence which must be weighed and interpreted in light of the existing statutory and case law. A recent case, *Scully Signal Co. v. Electronics Corp. of America,*[34] so clearly identifies the problems discussed above that it should be examined at some length.

Scully involved a 1968 suit for infringement of a patented technique designed to incorporate "fail safe" features into various hazardous machinery. Defendant, Electronics Corporation of America (ECA), in turn alleged both non-infringement and invalidity of the patent. At the conclusion of the presentation of evidence, ECA sought to amend its pleadings in order to allege fraud by Scully against the Patent Office, such fraud resulting from Scully's failure to reveal allegedly anticipatory patents. The district court held that ECA in fact had infringed the patent and that Scully had not defrauded the Patent Office since the patent had not been anticipated within the meaning of 35 U.S.C. § 102. However, the Court also found that the patent was invalid for obviousness within the meaning of 35 U.S.C. § 103. Further, the Court denied ECA's motion to amend the pleadings and awarded attorney's fees to plaintiff as a result of "exceptional" conduct on the part of ECA. In this appeal, Scully challenged the finding of obviousness and ECA, in a cross appeal, sought to overturn the lower court's denial of its motion to amend. The appeals court upheld the lower court's finding of patent invalidity for obviousness as well as its denial of ECA's motion to amend its pleadings.

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[33] This appears to be a criticism which is not peculiar to patent law. A similar complaint has lead numerous scholars and practitioners of administrative law to advocate the formation of 'science courts' which would address the very technical problems encountered by those who make administrative law decisions. *See* Kantrowitz, *Controlling Technology Democratically,* 63 AM. SCIENTIST 505 (1975).

[34] Scully Signal Co. v. Electronics Corp. of America, 570 F.2d 355 (1977).

Although numerous issues were argued, of special concern to this paper is the sharp disagreement over the manner in which the finding of obviousness was reached. Scully accused the lower court of using as the true measure of obviousness of the invention its own reactions rather than the reactions of persons in the industry involved. Scully maintained that those in the industry recognized the novelty and utility of the invention and that the district court, using inappropriate hindsight, ruled by "fiat."[35] The appeals court responded that in fact the lower court was correct in holding that the patent in question displayed little novel insight beyond what was known to the art in 1957. Scully's argument regarding the patent's commercial success was given some weight by the appeals court but not enough to be determinative of validity. The court held that commercial success must be reviewed in conjunction with items such as the number of prior attempts to solve the problem and the length of time the problem and the need for its solution have existed.[36] Scully's arguments were held to be deficient in this area. A main source of the deficiency was a failure to indicate to what degree the industry had attempted to develop a similar device and whether the failure of the industry to succeed was a result of lack of technical expertise as opposed to, for example, a lack of interest. The court then cited *Ag Pro, supra,* to support its general finding of obviousness.[37]

It can be seen from this recent and not atypical case that the problems of determining obviousness or non-obviousness remain legion. It is particularly important to note that in this case the dispute arose not merely over the structure of the court's inquiry but over the efficacy of the evidence collected and the varying weight assigned to it by the Court.

The holding in *Scully* indicates that systematic schemes for judicial determination of the validity of patents cannot eliminate disagreement over the meaning of the alleged "facts" and the conclusions which may be drawn permissibly from them. Despite this, there is a particular value in adopting a comprehensive framework for the collection, presentation, and analysis of data in patent cases. If such a framework were to be widely adopted by attorneys, its use would become routinized, and all parties would at least share the expectation that they would be examining the same categories of information regardless of the variations in weight and meaning giving to them. A

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[35] *Id.* at 360.

[36] *Id.* at 361.

[37] *Id.* at 362.

perusal of the cases suggests that convincing the court to acknowledge the utility of such a framework would not be a modest task. Precedent would have to be overturned. For example, the *Scully* court, in discussing the weight to be given items of evidence, indicated that it not only relied on the *Graham* tests, it also utilized "Hand's famous compendium of 'signposts' "[38] as enumerated in *Reiner v. I. Leon Co.* (1960).[39] For all its fame, the compendium lacks detail in that it raises only four very general questions.[40] The *Graham* analysis, developed five years later, is more elaborate but is still deficient in its lack of precision. The analysis, which appeared to be straightforward and readily applicable, in practice failed to result in clarity in the holdings and consistency among the circuits. Yet the *Scully* court felt comfortable in relying on the analytical framework of *Graham* and *Reiner*.

The scheme advanced by Shapiro is a marked improvement over those used in such cases as *Graham* and *Scully*. Shapiro's critical concern appears to be in maintaining the focus of the court on the issue of obviousness as it pertains to the industry and to the state of the art. Use of the Shapiro scheme by the court should result in a more accurate appraisal of the evidence offered to support an argument and the correct assignment of weight to those items on the basis of the facts of each case considered *in toto*.

There is no doubt that the courts bear much of the responsibility for the non-existence of an articulated and widely accepted set of guidelines or framework reflective of their expectations and probable analysis of patent cases. However, the major impetus for this development must come from those litigants who stand to benefit from it. The litigants themselves must make *explicit* use of the desired guidelines. In doing so, it might be possible, in any given case, to minimize the disconcerting judicial interpretations both of congressional intent and the policy considerations of 35 U.S.C. § 100 *et. seq.* (1952).

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[38] *Id.* at 361.

[39] 285 F.2d 501, 504 (2nd Cir. 1960), *cert. denied,* 366 U.S. 929, 81 S.Ct. 1649, 6 L.Ed.2d 388 (1961).

[40] In discussing the validity of a patent for clamps used to maintain hair curls, Hand indicated that the following questions must be answered regarding this or any innovation: "how long did the need exist; how many tried to find the way; how long did the surrounding and accessory arts disclose the means; how immediately was the invention recognized as an answer by those who used the new variant?" *Id.* at 504.

How can Shapiro's model scheme be improved and utilized to achieve the above goal? Cultural anthropology will help provide an answer.

Anthropology and Patent Law: Some Useful Relationships

The fundamental purposes of anthropology and patent law are very different. However, the preceding discussion demonstrated a relationship between the two fields — a relationship based on a shared interest in the psycho-social phenomenon of the innovative process. In addition, the interface between certain methodological problems of each field can be understood through an examination of selected aspects of applied anthropology.[41]

The goal of applied anthropology is to solve specific problems for which the change agent's skills have been enlisted. One succint definition states: "... 'applied anthropology' is the phrase commonly used by anthropologists to describe their professional activities in programs that have as primary goals changes in human behavior believed to ameliorate contemporary social, economic, and technological problems, rather than the development of social and cultural theory."[42]

Applied anthropologists first attempt to identify correctly the problem to be addressed. Frequently, the locus and content of a social problem have been misunderstood. To avoid the creation of further complications, applied anthropologists must then devise a solution to the problem which is acceptable to the population.

Applied social scientists thus must become innovators whose "products" are efficiently altered social systems. Like other innovators who seek to have their creations protected and utilized by a society,

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[41] *See generally:* G. FOSTER, APPLIED ANTHROPOLOGY (1969); W. GOODENOUGH, COOPERATION IN CHANGE (1963); C. ERASMUS, MAN TAKES CONTROL: CULTURAL DEVELOPMENT AND AMERICAN AID (1961); H.G. Barnett, *Anthropology as an Applied Science,* 17 HUMAN ORGANIZATION 9-11 (1958). The separation of interests into theoretical and applied for purposes of analysis should not overshadow the importance of the interplay between the two. Applied research can be used to test various theories and thereby can result in greater conceptual clarity within the discipline. Also significant is the tendency for the problem-solving activities in applied research to integrate the theories of various sciences which otherwise might not be thought of as related. "Pure" research also has benefits for the applied focus. Theories develop general principles which can be useful in the solution of practical problems. It is also often the case that the central factors of the problems themselves are more clearly identified by pure research as are the various alternative means of solving those problems. *See* W. GOODE & P. HATT, METHODS IN SOCIAL RESEARCH at 29-40 (1952) for an expanded discussion. *See also* A. Gouldner, *Explorations in Applied Social Science,* 3 SOC. PROB. 169-181 (1956)

[42] FOSTER, *supra* note 41, at 54.

social scientists must consider carefully the degree to which their proposed solutions are useful to and capable of being integrated into the existing social fabric. Because of these demands, those whose efforts are designed to bring about social change also must be continuously cognizant of the concept of obviousness. Research designs are aimed at maximizing the ability to predict both the willingness of a group to accept an innovation and, in turn, the effects of this choice upon the group. The degree to which the innovation is screened will be determined largely by the degree to which the replacement of the old by the new is perceived to be obvious and, of course, valuable and useful. This perception is often slow in developing. Thus, one of the tasks inherent in planned social change efforts is to make the non-obvious obvious by promoting acceptance of innovations based on new perceptions of value and utility.

Social scientists are not concerned with whether their solutions to problems would pass, for example, the *Scully* tests of obviousness. In fact, attempts usually are made to build upon the existing social patterns and individual innovative efforts and tendencies in the most open and obvious manner possible.[43] Generally, the more profound or unexpected their solutions are, the greater is the likelihood of rejection, especially by socially (and technologically) conservative groups. Free of the necessity to meet the stringent tests for the granting of potentially lucrative monopolies, social scientists are not and need not be concerned primarily with the degree of novelty of their solutions to problems.

In spite of these fundamental differences, patent law and anthropology, as a prime example of social science, share the common need to determine the degree of obviousness or non-obviousness of an

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[43] *Id.* at 88. Foster writes:

> As an applied anthropologist comes to understand the ways in which the society he is studying is integrated, as he learns the premises on which behavior is based, and as he appreciates the meaning and nature of role performances, he becomes increasingly useful to the planners, administrators, and technical experts with whom he is associated. He explains what he has learned, discusses with them the feasibility of alternate approaches and analyzes the probable consequences of decisions. He helps them plan projects which do minimum violence to customary ways and which, wherever possible, build upon preexisting forms. When he is convinced that recommended new practices represent genuine improvements, and not just a planner's dream of what should be, he helps change agents to develop strategies for presenting projects so that recipient peoples will be motivated to change, so that they will perceive advantage in giving up old ways and in adopting new ones.

innovation. Some of the skills anthropologists use to accomplish this and related tasks might prove valuable to patent attorneys who must organize and present a carefully documented argument for or against the validity of a particular patent.

The earlier discussion of patent law presented Shapiro's scheme as a good example of guidelines which could be used for directing judicial inquiries into obviousness or non-obviousness. It is also apparent that these guidelines have utility for directing the formulation of a complete and persuasive legal agrument to the court. Patent attorneys must address all of the items enumerated in the scheme in order to develop a comprehensive history of the innovation and its relationship to the state of the art. Interestingly, but not surprisingly, anthropologists have a similar set of needs because of their desire to assess an innovation's potential for social acceptance. An examination of some of the anthropologists' attempts at social change and the strategies which have emerged for increasing the ability to predict success or failure should clarify this point and establish the value of the discipline to the needs of patent attorneys.

Some Applied Anthropology Problems

The anthropological literature is replete with accounts of sometimes successful but often enormously frustrating and injurious attempts to introduce an innovation into another culture. What frequently appears to be of obvious value and utility to anthropologists is often[15] rejected or utilized in unpredictable ways by the recipients of the innovation. Since a central target of planned social change efforts has been the health care field some reactions to health programs will illustrate the point.[44]

An attempt to change attitudes and behavior towards the mentally ill in a Canadian prairie town failed in spite of generous funding, a high level of staff expertise, and months of careful preparation including the use of questionnaires and interviews. The authors concluded:

> We have been unable to effect any evident change in attitudes toward the mentally ill. Attitudes toward us, on the other hand, had undergone a very evident change. The people of Prairie Town, initially friendly and cooperative, had become increasingly aloof as the months went by, despite every effort on our part to be tactful and friendly... Our well-intentioned efforts to alter attitudes had apparently produced side effects that we had

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[44] *See e.g.,* HEALTH, CULTURE AND COMMUNITY: CASE STUDIES OF PUBLIC REACTIONS TO HEALTH PROGRAMS (Paul ed. 1955) (hereinafter cited as HEALTH, CULTURE AND COMMUNITY); ESSAYS ON MEDICAL ANTHROPOLOGY, S. ANTHROPOLOGICAL SOC'Y PROCEEDINGS, No. 1 (Weaver ed. 1968).

> not bargained for....[45] [D]ata pointed to the existence of a community pattern of denial and isolation as a method for dealing with mental illness... Although malfunctional in reference to the rehabilitation of the mentally ill, this pattern appeared functional in reference to the maintenance of community solidarity. Efforts to change parts of this pattern by education produced anxiety and hostility.[46]

In another instance a research team in a Mexican village was requested unexpectedly by the village inhabitants to assist them in establishing a medical cooperative which would be served by a physician supplied by the government. The research team agreed, largely because the action appeared to respond to very clear expressions of need by the local village and government officials who sought to learn more about solving rural health problems. After an initial period of success, the clinic ultimately was abandoned:

> This case throws light upon the dynamic forces at work in a peasant community which, on the surface, appears simple and static. It shows quite clearly that the success or failure of a medical program depends on many cultural factors besides the competence of doctors and the quality of services. The major obstacles encountered in the Tepoztlán case were these: readiness to distrust innovations and a generalized lack of interest in changing local ways of doing things; inadequacy of economic resources, even the one peso fee being too high for many villagers; lack of rapport between doctors and patients resting on the doctors' ignorance of native illness concepts and an attitude of superiority; continued faith of the villagers in their local curanderos; finally, and perhaps most important, readiness of local interest groups, headed by the leading curandero, to view the medical cooperative as a threat to their power.[47]

Such examples are endless. The obstacles to successful change activities are formidable because the factors relevant to the outcome of any one effort are numerous and their interrelationships so multifaceted. It is easy to see the errors in these and other attempts when they are examined retrospectively. What is easily overlooked, however, is the extent to which social scientists have progressed in the skills they use in their change efforts. The failures are far more spectacular than the successes which themselves are often only partial. To the degree that a project achieves its goals it does so largely because care has been taken to collect systematically and continuously analyze data pertaining to the planned innovations and reactions to them.

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[45] J. Cummings & E. Cummings, *Mental Health Education in a Canadian Community,* in HEALTH, CULTURE AND COMMUNITY, *supra* note 44, at 45.

[46] *Id.* at 68.

[47] O. Lewis, *Medicine and Politics in a Mexican Village,* in HEALTH, CULTURE AND COMMUNITY, *supra* note 44, at 433.

One relatively successful applied experiment has come to be known as the Vicos project.[48] Vicos was a *hacienda* located in a Peruvian mountain valley. Prior to 1952, the *hacienda* was owned by a public welfare agency of the local political department and leased to the highest bidder. The management of the enterprise was controlled by a *mestizo* administrator who, having been hired by the welfare agency, had virtually total control over the 1700 Quechua-speaking Indians. This Indian group had been living as serfs since colonial times. A levy of three person-days per week for each family produced the necessary work force to run the *hacienda's* agricultural and grazing operations. Each family also participated in other service areas of the *hacienda* including cooking, servant duty, grooming, and so forth. *Peones* who refused to obey the commands of the administrator could be expelled from the community and left helpless and destitute since they would not be hired in other *haciendas*. Not surprisingly, the Indians had no control over their daily affairs with the exception of their traditional religious activities. As is usually the case in such circumstances, no indigenous leadership developed, involvement in public affairs was limited, the standard of living was quite depressed, and social disorganization was prevalent. Disease, malnutrition, and infant mortality were high and exacerbated by inadequate housing. One hundred percent of the children of the *hacienda* were illiterate.

In 1951, Cornell University anthropologists joined with the Peruvian National Indian Institute and formed the Cornell Peru Vicos Project which was funded by the Carnegie Institute. The project arranged to lease the *hacienda* for five years. Of extraordinary benefit to the project was a Peruvian anthropologist's thorough study of the *hacienda* prior to 1951. This study provided an excellent baseline of data and an opportunity to plan and implement changes at a relatively high rate of speed.

The goals of the *Vicos* project were concentrated in four major areas: (1) economic development (primarily agriculture); (2) education; (3) private and public socio-political institutional

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[48] *See* A. Holmberg, *The Research and Development Approach to the Study of Change,* 17 HUMAN ORGANIZATION (No. 1) at 12-16 (1958), reprinted in READINGS IN ANTHROPOLOGY 436-42 (Jennings & Hoebel eds. 1966); A. Holmberg, H. Dobyns, C. Monge, M. Vazquez & H. Lasswell, *Community and Regional Development: The Joint Cornell-Peru Experiment,* 21 HUMAN ORGANIZATION 107-24 (1962); A. Holmberg, M. Vazquez, P. Doughty, J. Alers, H. Dobyns & H. Lasswell, *The Vicos Case: Peasant Society in Transition,* 8 AM. BEHAVIORAL SCIENTIST (No. 7) at 3-33 (Special Issue) (1965); and FOSTER, *supra* note 41, at 28-34. The brief description included herein is found in FOSTER *supra* note 41, at 28.

forms; and (4) health care. By 1957 when the Cornell Peru Vicos Project lease expired, the project personnel believed the Indians had progressed sufficiently to run their own community. Following lengthy delays[49] (caused by powerful local vested interests which included landowners and conservative government officials), the *hacienda* was purchased by the Indians in 1962. By 1969, it had organized as a production cooperative for the benefit of its members.

Of the changes that occured between 1952 and 1957, seven were most striking:[50] (1) Overall political organization shifted from an exploitative *hacienda* system to a form of local control based on commonly shared interests; (2) Land ownership, impossible prior to 1957, was pressed for (and ultimately achieved); (3) A board of delegates elected from the community replaced the original administration in which the Indians had no effective secular political leaders; (4) Income was steadily produced by farming and used for the public good, thus altering the earlier *hacienda* system in which the Indians had no income of their own; (5) A modern, well-staffed and well-attended school replaced a very small, under-staffed and under-attended institution; (6) Agricultural production rose 400 to 600 per cent per *hectare;* and, (7) A modern health center with a clinic and public health program replaced existing inadequate facilities. Most of the above changes were financed by the local residents themselves.

Methodologically, the project is of great interest. To the extent possible, efforts were made to ensure that the proper data were available and analyzed so that action goals might be more easily realized. The project formalized a rather fundamental scheme for data collection and analysis which was extremely helpful. In planning every aspect of potential social change, the researchers engaged in a precise series of steps:

> In the case of Vicos, attempts were made ... to lay out about 130 specific possible lines of research and development, each matched to a specific developmental goal such as the diversification of agriculture, the development of community leadership, ... etc. Wherever possible an attempt was made to make fairly precise statements about the goals in question. To lay out the various possibilities in order to develop a strategy of research and development, each line of possible intervention was represented in a semidiagrammatic way by a column ...
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> At the top of the column is posted for some end point date the particular goal in question to be reached. At the bottom of the column are posted the counterpart institutional and ideological situations found at the base line

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[49] *See* FOSTER, *supra* note 41, at 32.

[50] *See* Holmberg, *supra* note 48, at 438.

> period before intervention. Above them are summarized any interventions so far made, and above them the present institutional and ideological situation with respect to this one line of development. The remainder of the column is given over to a proposed schedule of probes, pretests, interventions, and appraisals.
>
> By utilizing such a method, interventions are not likely to be hit or miss...[51]

The congruence of concerns faced by social scientists and patent attorneys can be seen by the degree to which Shapiro's scheme closely resembles the set of questions asked by the anthropologists in research strategy and tactics such as those used in Vicos.

Applied Anthropology and Patent Litigation —

It would be beneficial to compare the questions outlined by Shapiro with the questions raised by the anthropologists in Vicos. The parallel is striking.

Shapiro (1) *Was the problem solved by the invention a problem recognized by those working in the art to which the invention pertains?*

Vicos. As indicated above, applied social scientists must first determine that a problem does exist and must then define the configuration of that problem. While the patent attorney is concerned with the inventor's peers in the relevant industrial art, social scientists focus on the local people whose assessment of the existence of the problem is, of course, central. The decision of Cornell University and the Peruvian National Indian Institute to intervene reflected a broad perception of the existence of a major social problem.

Shapiro. (2) (a). *If the problem was known to persons working in the art how long was the problem known?*

Vicos. Part of the success of Vicos was a result of the solid baseline data collected prior to the start of the project. A fundamental datum which applied social scientists must have is the length of time a problem has existed and, consequently, the degree to which cultural responses to the problem might be routinized. Patent attorneys and social scientists are equally concerned with determining the difficulty of solving the problem, such difficulty being measured in part by the duration and persis-

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[51] *Id.* at 12-16.

tence of the problem as perceived by those in the art or in the culture as the case may be.

Shapiro. (2) (b). *Did motivation exist for a solution to the problem?*

Vicos. As in 2 (a), baseline data should reveal past and present motivation to solve the problem. This information was vital to the social scientists in Vicos who had to determine the appropriateness of particular interventions. Appropriateness must be measured largely by the degree to which those experiencing the problem with (i.e., are motivated) to solve it. Patent attorneys must establish whether a given innovation occurred in response to a problem which had hitherto remained unsolvable and which those in the art were motivated to solve.

Shapiro. (2) (c). *What prior attempts were made to solve the problem by the inventor and others in the art?*

Vicos. Again, the baseline study of Vicos (and the continuous collection of additional data) revealed prior efforts to solve the problems experienced by the community. In Vicos, very little had been attempted because of the Indians' nearly total dependence on the *hacienda* manager and owners. In general, however, social scientists must build on successful attempts to solve problems and must avoid failures which, without adequate data, might be repeated. Patent attorneys, on the other hand, focus on prior attempts as indications not only of motivation to solve a problem but also of the degree of difficulty which the problem presents to those addressing it. They endeavor to demonstrate whether the current attempt is novel relative to any past efforts while social scientists are delighted to acknowledge and encourage efforts to continue earlier useful activities.

Shapiro. (2) (d). *Was the inventor's solution to the problem contraindicated by the teachings of others working in the art?*

Vicos. Applied social scientists would wish to consider what other experiences in the profession would indicate the success of any one project might be. Vicos, for many reasons, was regarded as a very poor prospect for success: "It would be hard to imagine a less promising community in which to attempt a modernization and development program."[52]

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[52] FOSTER, *supra* note 41, at 29.

Nevertheless, the project was attempted at least partly because of the difficulty involved and the desire to demonstrate the value of the techniques which were used. Clearly, patent attorneys would wish to use the presence or absence of similar contraindications of possible success to support the non-obviousness or obviousness of the inventor's solution to a given problem.

Shapiro. (2) (c). *Was the success of the invention in solving the problem considered surprising by persons working in the art?*

Vicos. This issue was critical to the ultimate success of the project. Applied social scientists must consider the entire socio-political field in which the target community is located in determining a plan for realizing the desired social change. The surprise and consternation of local landowners and government officials in the Vicos region slowed down the final land transfers and, as has happened elsewhere, might have permanently arrested the progress of the community. Their reactions were a measure of the effectiveness of the project. Again, patent attorneys would wish to support their arguments by reference to the surprise, or lack of it, of those in the art when confronted with the inventor's solution to an existing problem.

Shapiro. (3) *What tributes were paid to the invention, such as: laudatory comments of others working in the art, commercial success due to the invention, license rights acquired from the inventor, and copying of the invention by competitors?*

Vicos. One additional measure of the success of the Vicos project was the interest it generated outside the community. While the reactions of social scientists to the project were mixed,[53] the most telling tribute was the fact that the success of Vicos had a considerable effect on communities even outside the immediate region. By 1958, the Institute of Indigenous Affairs had begun to direct five programs similar to Vicos in other areas of Peru.[54] In a similar manner, patent attorneys make use of the payment or non-payment of relevant tributes to

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[53] *Id.* at 33.

[54] *See* Holmberg, *supra* note 48, at 439.

indicate the non-obviousness or obviousness of the new solution.

The Shapiro-Vicos comparison demonstrates that the related issues of obviousness, novelty, and utility are of equal concern to patent attorneys and applied social scientists. The difference in the manner in which the professions address the subject matter is, of course, a result of their different goals and interests. But in spite of these differences, both are engaged in the assessment of particular social systems and the actual or potential significance of the introduction of innovations into those systems. It is important to emphasize that the focus on systems is as fundamental to patent attorneys as it is to applied social scientists. In order to adequately prove obviousness or non-obviousness the technological, social, and psychological components of an industry or "art" must be analyzed for their complex past and current interrelationships. The following is as applicable to the needs of patent attorneys as it is to social scientists:

> Since anthropologists believe that a culture or social system is a logical, integrated, holistic phenomenon in which the parts fit together in meaningful patterns, they assume that every bit of data in the system has meaning... Obviously this doesn't mean that all data are immediately significant to every problem... It does mean that the time and context may arrive during a major study when data previously thought to be insignificant will acquire great importance.[55]

It has been demonstrated by the Vicos project and others that Shapiro's scheme encompasses the basic questions to be answered by social scientists if their projects are to be successful. The skills with which the data are collected and analyzed are at present well developed and constantly improving. Exemplary projects such as Vicos have had a profoundly positive effect on the care with which social scientists organize their applied projects and the attention they pay to proper data collection and on-going evaluation of all phases of work. Regardless of the difference in objectives of patent law and applied anthropology it should be apparent that successful techniques from the one field should be utilized in the other because of the demonstrated overlap in the type of data to be collected and analyzed.

This issue is very important since the proper analysis of data is one of the special difficulties in patent litigation. The court is asked to look back to a temporal base line (the time of the creative act) through hindsight. This hindsight often is colored by events which occur after the creation of the innovation. Thus, what was

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[55] FOSTER, *supra* note 41, at 65.

non-obvious at the outset can become, through exposure and general social usage, familiar and obvious by the time of litigation. It should be recalled that one of Scully's main complaints was that the court incorrectly used the degree of obviousness to itself as a criterion for judging the validity of the patent in question.[56]

It is germane to point out that without the careful data collection process outlined in the Vicos project, anthropologists would be faced with the same hindsight problem. That is, without adequate baseline data pertaining to the pre-innovation social system, retrospective assessment of success or failure would necessarily involve the excessive imposition of the anthropologists' own perceptions of obviousness or non-obviousness. The earlier discussion of the Cheyenne and Paiute (page 3) should once again illustrate this point. Without the base-line knowledge about both cultures as they existed prior to contact with the Spaniards, anthropologists would be forced to impose more of their own interpretations of post-contact Indian behavior than accuracy would warrant.

Because of the inevitability of this hindsight factor (and it is more intrusive in efforts to prove non-obviousness than obviousness) the proper organization and presentation of what are essentially historical data assumes an importance which is determinant of success or failure. It must be accepted that the inquiry demanded by a Shapiro-type scheme is not straightforward, nor is it merely factual and thereby capable of simple application. In addition to numerous easily obtainable facts, the data which need to be collected and analyzed must include sophisticated measurements and impressions of complex psychological and social conditions. These conditions are often as difficult to ascertain as motivation (2.b), the *reasons* for the presence or absence of evidence of prior attempts to solve the problem by others in the art (2.c), and "surprise" (2.e.).

Every item in Shapiro's analysis is open to question by the courts, in spite of any assumption a litigant might harbor regarding the clarity and persuasiveness of the evidence. This is so because the courts do not seem willing to accept evidence of non-obviousness or obviousness without inquiring further into the general significance of that evidence in the context of the entire setting from which an innovation has emerged. For example, in *Scully* the court disagreed with plaintiff over the actual meaning of the evidence which was presented to demonstrate the long-standing nature of the unsolved technological problem, the motivation to solve it, and the failure of others to do

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[56] Scully Signal Co. v. Electronics Corp. of America, *supra* note 34.

so. Contrary to plaintiff's expectation, the court suggested that Scully's argument did not explain fully or convincingly the unsuccessful efforts in the industry to develop a similar innovation:

> Beyond indication that earlier burner monitors were less reliable, it was not brought out what sort of an effort had been mounted in the burner industry to develop a comparable system. The industry's failure earlier to develop a self-checking system could as well have been due to lack of interest or appreciation of such a system's potential or marketability, as to want of technical know-how.[57]

The court then added that there were grounds to support its suspicion.

The decision in *Scully* was based on an interpretation of each item of evidence, a weighing of the relative importance of each item, and a determination of the meaning of the inter-relationships among the items. This procedure is far from straight-forward and factual. Rather, it closely resembles the task faced by careful social scientists when engaged in the rigorous procedures used in Vicos and elsewhere.

Conclusions

For social scientists and patent attorneys alike, the key tasks are to define the boundaries of the system to be studied and then to select, out of all of the data collected, those which explain properly how that system operates. Choices must be made continuously concerning the relevance and explanatory value of all data and care must be taken to present a picture of the system being studied which is neither too broad nor too narrow.

An appreciation of the importance of the holistic approach and, through it, the ability to determine, and then express, the systematic interrelationships among an impressive quantity of data are essential to the patent attorney who wishes to affect significantly the manner in which courts reach their decisions. If the courts must struggle with the evidence and if they will make independent judgments based on that evidence, then litigants should welcome assistance in organizing arguments which might be more persuasive. The challenge of *Scully* is clear:

> While weight must be given to the presumption of validity, and this circuit is quite prepared to sustain patents which meet the statutory criteria, the time has long since gone, if it ever existed, when district courts and courts of appeal could refuse to make an independent assessment of §103 obviousness in light of all the evidence presented. To criticize a court for

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[57] *Id.* at 361.

> making an independent assessment is to criticize it for doing what the law presently requires. The process involves the ever-present risk of an overuse of hindsight, as well as the possibility of blunders by lay judges; but this court has no license, even if it wanted one, to adopt another approach.[58]

The full practical value of the relationship between anthropology and patent law remains to be determined. Future study should include a more detailed analysis of successful and unsuccessful social change projects and patent litigation. The primary goal of such an effort would be to uncover and examine more thoroughly the areas in patent litigation to which anthropology and other social sciences might be most applicable and to determine with more precision the manner in which their techniques might best be used. This paper has suggested one potentially fruitful line of inquiry and has initiated its exploration. It is apparent that the social sciences are relevant to areas of patent law (and intellectual and industrial property generally) other than litigation. A full examination of these areas should be encouraged, but is clearly beyond the scope of this discussion.

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[58] *Id.* at 362.

Post Hoc Evaluations of Obviousness: Preliminary Report of an Attempt to Identify, Empirically, the Characteristics of a Superior Evaluator*

Juanita V. Field and
Thomas G. Field, Jr.**

Over a century and a quarter have passed since the Supreme Court in *Hotchkiss v. Greenwood*[1] held that more than mere novelty is necessary to support a valid patent. Congress, after 100 years of experience with a concept which came to be called "invention," attempted to improve the situation by requiring that an invention[2] not be

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1 42 U.S. 248 (1850).

2 The word "invention" is now used to describe the advance, whether patentable or not, and should not be used to describe the quality of the advance.

"obvious" if it is to be patented.[3] It seems safe to say that in the intervening time the doctrine of non-obviousness has not developed into a foolproof yardstick for measuring the quality of cerebral or other effort necessary to make an advance over the prior art a patentable one.[4]

This is not surprising, for the relabeling of something described by Learned Hand to be "as fugitive, impalpable, wayward and vague a phantom as exists in the whole paraphernalia of legal concepts,"[5] is unlikely to change its character. Patent attorneys have advanced numerous explanations for what they regard as a uniquely difficult problem. Moreover, they have suggested a variety of strategies for overcoming it.[6]

However, one must wonder if "non-obviousness" is more difficult to define than "forseeability"[7] or "obscenity".[8] Non-obviousness has a hindsight component, as does foreseeability, and attempting to determine what should have been forseeable often involves questions of great technical complexity.[9] Try as we may to avoid problems of this sort, they are inevitable and must be addressed to the extent possible.[10]

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[3] Patent Act of 1952, 35 U.S.C. § 1 *et seq.* 35 U.S.C. § 103 deals with "obviousness" and is quoted in the section in the text entitled "The Problem".

[4] *See generally* note 16 *infra.*

[5] Harries v. Air King, 183 F.2d 158, 162 (2d Cir. 1950).

[6] *See generally* note 16, *infra. See also* Whinery, *The Role of the Court Expert in Patent Litigation* (STUDY NO. 8 FOR THE SUBCOMM. ON PATENTS, TRADEMARKS AND COPYRIGHT, COMM. ON THE JUDICIARY, 85th Cong., 1st Sess., at 8 (1958); and Conference Proceedings, *Arbitration of Patent and Other Disputes,* 18 IDEA 4 (1976).

[7] A particularly engaging discussion appears in A.P. Herbert's decision in *Fardell v. Potts.* The decision, which originally appeared in MISLEADING CASES IN THE COMMON LAW (1930), has been widely reprinted.

[8] *See, e.g.,* R. Davidow & M. O'Boyle, *Obscenity Laws in England and the States: A Comparative Analysis,* 56 NEB. L. REV. 249 (1977). *Also see* Bleistein v. Donaldson Litho., 188 U.S. 239, at 251-2 (1903), *rejecting* an attempt to establish a positive standard for the worth of illustrations subject to copyright protection. The latter is particularly related to the problem of patent obviousness and it is of some interest to note the disparity in treatment of two closely related matters.

[9] *See, e.g.,* T. Field, *The Young Consumer: A Paradigm Analysis of the Roles of Public and Private Law in Preventing and Redressing Injuries,* 29 MERCER L. REV. 523, 539 *et seq.* (1978).

[10] *See generally* R. Norvell, *Reception of Science by the Legal System,* in SCIENTISTS IN THE LEGAL SYSTEM (Thomas ed. 1974).

It has become increasingly popular within the legal community to look to the social sciences in an effort to improve the legal disposition of difficult problems.[11] The concept of non-obviousness, unlike some others with which lawyers grapple, seems to be especially susceptible to such treatment. It has a tailor-made counterpart, creativity, which has been a major subject of study in psychology.

Several years ago, as will be described in detail below, research was commenced in order to learn not about non-obviousness, per se, but rather to identify characteristics which might make some individuals more capable of hindsight evaluations of obviousness than others. It was thought that if such characteristics could be identified, they might be helpful in making policy decisions concerning the choices of fora which might be available for post-issue determinations of patent validity. Moreover, they would probably be helpful in making decisions about staffing.[12]

A number of people have been extremely cooperative with the authors.[13] Requests have been received for information about the study. While a great deal of data has been collected, progress is hampered by the lack of resources for its analysis.

Nevertheless, enough progress has been made to report on the research to date. It is hoped that this report will not only satisfy the curiosity of already-interested persons, but will also attract sufficient additional interest to enable the work to be completed.

The Problem

Section 103 of the U.S. Patent Statute[14] reads:

> A patent may not be obtained though the invention is not identically disclosed... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

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[11] *See, e.g.,* D. Cavers, *Non-Traditional Research by Law Teachers: Returns from the Questionnaire of the Council on Law Related Studies,* 24 J. Legal Ed. 534 (1972), *Compare* A. Greely, *In Soft Defense of Sociologists,* 23, N.Y.U.L. SCH. BULL. NO. 2, at 26 (1977). In a more specific context *see, e.g.,* T. Field & J. Field, "... *and Women Must Weep" v. "Anatomy of a Lie": An Empirical Assessment of Two Labor Relations Propaganda Films,* 1 PEPPERDINE L. REV. (1973); and M. Roomkin & R. Abrams, *Using Behavioral Evidence in NLRB Regulations: A Proposal,* 90 HARV. L. REV. 1441 (1977).

[12] *See* references cited in note 6, *supra,* and note 16, *infra.*

[13] Notable contributions have been made by Mssrs. Stephen Rosenman (formerly a student, now a graduate of MIT) and Bernard L. Leviner (currently a third year student at the Law Center). We are also grateful to Professor Vittek and President Rines as well as several other colleagues for their encouragement and cooperation.

[14] 35 U.S.C. § 103 (1952).

> would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains....

As noted above, it is one thing to pose these standards and quite another to apply them. The standard of "non-obviousness" is especially difficult. It seems to be widely perceived among the patent bar that (at least) unconscious application of *hindsight* results in the invalidation of patents which ought to be sustained based on the state of the art *at the time of* the invention.[15]

The prime objective of this study is to obtain more information on the parameters affecting the reliability of such evaluations. The implications of widely varying capacity to make such evaluations would seem to be clear. Thus it ought to be useful not only to determine whether such capacity does vary widely, but also whether such variation is correlated with other identifiable factors, *e.g.*, certain kinds of training, employment in the U.S. Patent and Trademark Office (USPTO), employment as a patent attorney, etc.

The basic hypothesis to be tested is that sensitivity to degrees of obviousness of useful responses to more or less useful problems does, in fact, vary.

Review of the Literature

Because the present study involves the analysis of a legal problem using social science methodology, both legal and psychological literature must be examined.

Legal Literature. There is a wealth of literature and case law concerning "obviousness." Legally, obviousness is a well defined, meaningful, and useful term. It would serve no purpose to extensively review the law here; rather, the reader is referred to two of many publications which have treated the concept extensively. The APLA (American Patent Law Association) Quarterly Journal, on the occasion of the twenty-fifth anniversary of Section 103 of the Patent Law, devoted an entire issue to obviousness: its origin, applications, and court treatment.[16] Also on ALR annotation provides a recent and extensive discussion of Section 103.[17]

Psychology Literature. It seems inappropriate to provide an extensive review of the creativity literature here because (1) good, extensive

[15] *See, e.g.*, note 16, *infra.*

[16] 4 AM. PAT. L.Q.J. 4 (1976).

[17] J. Rydstrom, *Application and Effect of 35 U.S.C. § 103 Requiring Non-obvious Subject matter in Determining Validity of Patents,* 23 A.L.R. FED. 326 (1975).

reviews[18] and bibliographies[19] are available, and (2) the psychological concept of creativity does not correspond perfectly to the legal notion of non-obviousness.

Obviousness has not been defined as a psychological variable. It was therefore necessary to attempt to arrive at such a definition in order to determine which literature required examination. As the psychological variable of "creativity" seemed closely related to the legal concept of obviousness, the literature on creativity was examined; indeed, studies of inventions and inventors, scientific productivity, etc., were found to be indexed under the heading "creativity" in the psychological literature.

The problem is that creativity is difficult to define and operational definitions from the literature tend to be in terms of "scores on a creativity test." Some studies have circumvented the issue by looking at the characteristics of the creative person and by using such measures as ratings by peers or number of publications to identify creative individuals. Theoretical discussions of creativity indicate that while the concept is difficult to define operationally, a creative product is recognizable. This is the basic assumption behind Section 103 — that non-obviousness products will be recognizable, specifically by patent examiners and the courts. Unfortunately, this "recognizable" aspect in the definition of creativity is difficult to translate into an operational definition which will allow direct study.

Despite the lack of a readily transferable definition of creativity, the psychological literature was helpful in suggesting measures or tests which could be used to measure obviousness or creativity. A large number of tests was scrutinized. Measures varied from semantic differential to polygon preference[20] to peer ratings[21] to personal value orientation,[22] etc. Specific tests examined included Sounds and

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[18] S. Galann, *Psychological Study of Creativity,* 60 PSYCH. BULL. 548-565 (1963); M. WALLACH & N. KOGAN, MODES OF THINKING IN YOUNG CHILDREN at 1-24 (1965).

[19] S. Stievator, *A Comprehensive Bibliography of Books on Creativity and Problem-Solving: Part 1,* 52 J. OF CREATIVE BEHAVIOR 140 (1971).

[20] R. Eisenman & M. Grove, *Self-ratings of Creativity, Semantic Differential Ratings, and Preferences for Polygons Varying in Complexity, Simplicity, and Symmetry,* 81 J. OF PSYCH. 63-7 (1972).

[21] B. Bergum, *Selection of Specialized Creators,* 33 PSYCH. REP. 635-9 (1973).

[22] R. Hood, *Personal Value Orientation and Judgment of Categories of Creative Behavior,* 30 PSYCH. REP. 515-20 (1972).

Images,[23] Solutions Attribute List,[24] Adjective Check list,[25] Biographical Inventory Creativity,[26] and Similies Test,[27] as well as the more standard batteries such as Torrance,[28] and Guilford.[29] Extensive lists of creativity tests were also examined.[30]

Three test sources involved subject matter or methodology appropriate to the current problem: Torrance,[31] Guilford,[32] and Murphy.[33] The Torrance test requests subjects to list ways of improving a toy monkey: this appeared to be similar to product improvements patents. Guilford's Alternate Uses test asks subjects to "Name as many uses as you can think of for: (a) a toothpick; (b) a brick; and (c) a paper clip." The Murphy test directs students to "write down all the different ways you can think of in which the object might be used." Both Guilford's and Murphy's tests requested some inventiveness on the part of the subjects. Specific use of the methodological suggestions gleaned from the literature will be discussed in the section on Procedure, *infra.*

Procedure

The First Questionnaire. Following suggestions from the creativity tests found in the literature, the authors developed a preliminary

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[23] J. Khatena, *"Sounds and Images": Further Evidence of Validity of a Test of Originality,* 32 PERCEPTUAL & MOTOR SKILLS 850 (1971).

[24] R. Sciortino, *Solutions Attribute List: I. Factor Structure for Solutions of a Task Administered Under Test-taking and Instructions,* 27 PSYCH. REP. 435-8 (1970).

[25] T. Yarnell, *Percentile Norms for the Adjective Check List (ACL) Creativity Scale,* 29 PSYCH. REP. 675-8 (1971).

[26] C. Schaefer, *Predictive Validity of the Biographical Inventor Creativity: five-year follow-up study,* 30 PSYCH. REP. 471-6 (1972).

[27] C. Schaefer, *Similies Test: A New Measure of Metaphorical Thinking,* PROCEEDINGS OF THE ANN. CONVENTION OF THE A.P.A. 169-70 (1970).

[28] E. TORRANCE, *Torrance Tests of Creative Thinking: Norms-Technical Manual* (Princeton, N.H. Personnel Press, 1966).

[29] P. CHRISTENSEN, J. GUILFORD, P. MERRIFIELD, & R. WILSON, ALTERNATE USES. (Sheridan Psychological Services, Inc.)

[30] W. Kaltsounis, *Instruments Useful in Studying Creative Behavior and Creative Talent: Part I,* 5 (2) of J. OF CREATIVE BEHAVIOR 117-126 (1977); W. Kaltsounis, *Additional Instruments Useful in Studying Creative Behavior and Creative Talent: Part III, Non-Commercially Available Instruments,* 6 (4) J. OF CREATIVE BEHAVIOR 368-74 (1972).

[31] *Id.*

[32] *Id.*

[33] R. Murphy, *Investigation of A Creativity Dimension,* (dissertation, 1972, University Microfilms International, Ann Arbor, Mich.).

questionnaire for use in establishing frequency of occurrence of responses to a creativity-new product sort of test. A number of common items were listed, drawn randomly in pairs, and used as questions in a format which requested subjects to think of as many "useful and different ways of combining the paired items" as possible. The items were (1) a paper clip and a small sheet of aluminum foil; (2) a screw-lidded jar and a wooden pencil; and (3) a clothes hanger (metal) and a spool of thread. Appendix A is a copy of the First Questionnaire.

In order to collect as many responses as possible, the questionnaire was given to students at the Franklin Pierce Law Center and at the Massachusetts Institute of Technology in the fall of 1975 and in the spring of 1976.

A total of 318 students responded to the questions; Tables 1A-D describe the sources of subjects and demographic data collected. Subjects were approached as classes, and those who did not wish to participate were allowed to leave. No data identifying individuals was collected.

TABLE 1A
SUBJECTS RESPONDING TO FIRST QUESTIONNAIRE BY SOURCE AND CLASS

SOURCE	CLASS	NUMBER
M.I.T. [a]	Freshmen	25
	Sophomores	27
	Juniors	19
	Seniors	24
	Graduates	13
	TOTAL	108
F.P.L.C. [b]	First	100
	Second	75
	Third	30
	TOTAL	205
Not Reporting		5
TOTAL		318

[a] Massachusetts Institute of Technology
[b] Franklin Pierce Law Center

TABLE 1B
SUBJECTS RESPONDING TO FIRST QUESTIONNAIRE BY SOURCE AND AGE

SOURCE	AGE			TOTAL
	UNDER 25	25-35	OVER 35	
M.I.T.	111	2	1	114
F.P.L.C.	89	108	7	204
TOTAL	200	110	8	318

TABLE 1C
SUBJECTS RESPONDING TO FIRST QUESTIONNAIRE BY SOURCE AND UNDERGRADUATE MAJOR

SOURCE	MAJOR				TOTAL
	Liberal Arts	Engineering	Social Science	Physical Science	
M.I.T.	7	69	7	31	114
F.P.L.C.	125	10	67	16	218
TOTAL	132	79	74	47	332*

*Double majors were counted separately.

TABLE 1D
SUBJECTS RESPONDING TO FIRST QUESTIONNAIRE BY SOURCE AND SEX

SOURCE	SEX		TOTAL
	Male	Female	
M.I.T.	107	7	114
F.P.L.C.	166	38	204
TOTAL	273	45	318

The Second Questionnaire. The data collected from the first questionnaire provided the authors with questions from three sources which could be analyzed for the frequency of occurrence of particular responses.

First, there were the responses to the first questionnaire which used questions involving new uses for a combination of two familiar items. A list was made of all responses to each question and frequency of duplication of responses was recorded. This allowed arrangement of responses from most frequent to least frequent.

Second, Paul Torrance graciously made available a similar response dictionary for Activity 4 in Verbal Form B of the Torrance Tests of Creative Thinking. This activity involved product improvement — ways to improve a toy monkey. For a discussion of the source of these responses, the reader is referred to the norms manual for the Torrance Tests.[34] Again, it was possible to arrange responses from most to least frequent.

Third, a list of responses to Murphy's[35] questions involving the possible uses of a tire, a shoe, and a newspaper was obtained from Dr. Murphy. This list was frequency analyzed to allow arrangement from most to least frequent responses. Again, the norms for Murphy's data may be examined in the original source.

Three judges[36] examined the frequency analyses of the questions from the three sources. Using the original stimulus as the question, the judges selected 5 multiple choice solutions which varied as evenly as possible over the spectrum from most to least frequent. Thus, the questions took this form:

What are some useful ways of using a tire?

—	A. As shoes; sandals	(f = 19)
—	B. As a doormat	(f = 2)
—	C. As a dog bed	(f = 1)
—	D. To mark paths, trails	(f = 6)
—	E. As bumpers (cars, boats, walls of race track); as a shock absorber	(f = 157)

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[34] *See* note 28, *supra.*

[35] *See* note 33, *supra.*

[36] For the benefit of readers with legal training, it should be noted that this word is used as it normally is in psychology.

"f", which indicates the frequency of occurrence of the particular response, did not appear on the questionnaire. Using this method, twenty questions were designed and arranged in two different orders to provide alternate forms of the questionnaire.

The subjects were asked to rank the multiple choice solutions from least obvious (#1) to most obvious (#5). Subjects were also asked to provide demographic data concerning age, sex, occupation, education, and patent experience. Appendix B is a copy of the Second Questionnaire. Tables 2A-F summarize the demographic data provided by the subjects.

Subjects responding to the second questionnaire were either law students, participants at an Arbitration Conference, or members of the PTC Research Foundation. The law students involved attended the Franklin Pierce Law Center and were tested in the winter of 1976-1977. The examiner entered the class about ten minutes before it was scheduled to end, explained that a questionnaire would be given (the nature of the questionnaire was not discussed) and asked students willing to participate to remain after class. Specific instructions for marking the questionnaire appear in Appendix B.

The Arbitration Conference subjects were given the questionnaire at a conference held in Boston in late November 1976.[37] Subjects took the questionnaire with them and returned it completed the next day.

Questionnaires were mailed to PTC members along with a copy of the cover letter which appears in Appendix C. Recipients were requested to respond and to return the questionnaires by mail. Some subscribers apparently reproduced the questionnaire so that their staffs and even families could respond. Such cooperation was greatly appreciated by the authors who, of course, desired as many returned responses as possible.

The three groups of subjects were expected to provide a wide range of backgrounds and patent related experience but, as will be seen in Table 2, such wide ranges were also found within the groups.

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[37] *See* note 6, *supra,* wherein the proceedings are cited.

TABLE 2A
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND SEX

SOURCE	SEX			TOTAL
	Male	Female	No Response	
F.P.L.C.[a]	88	24	29	141
A.C.[b]	29	0	3	32
P.T.C.[c]	99	24	7	130
TOTAL	216	48	39	303

[a] Franklin Pierce Law Center
[b] Arbitration Conference
[c] PTC Research Foundation

TABLE 2B
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND AGE

SOURCE	AGE							TOTAL
	15-19	20-24	25-29	30-34	35-45	Over 45	No response	
F.P.L.C.	0	42	68	24	6	1	0	141
A.C.	0	3	0	3	9	16	1	32
P.T.C.	10*	4	8	15	30	63	0	130
TOTAL	10	49	76	42	45	80	1	303

*One subject reported being age 10, the child of a patent attorney.

TABLE 2C
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND CURRENT OCCUPATION

SOURCE	CURRENT OCCUPATION						TOTAL
	STUDENT	LAW STUDENT	ATTORNEY	PATENT ATTORNEY	OTHER	NO RESPONSE	
F.P.L.C.	0	141	0	0	0	0	141
A.C.	3	0	5	15	6	3	32
P.T.C.	10	0	6	75	31	8	130
TOTAL	13	141	11	90	37	11	303

TABLE 2D
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND EDUCATION*

SOURCE	EDUCATION*											TOTAL
		UNDERGRADUATE			GRADUATE				LAW		OTHER OR NO RESPONSE	
	LIBERAL ARTS	SOCIAL SCIENCE	PHYSICAL SCIENCE	ENGINEERING	LIBERAL ARTS	SOCIAL SCIENCE	PHYSICAL SCIENCE	ENGI-NEERING	JD	LLM		
F.P.L.C.	21	79	17	3	5	8	5	0	0	0	3	141
A.C.	0	1	5	1	0	0	2	1	19	3	0	32
P.T.C.	2	4	5	1	3	0	3	3	81	0	28	130
TOTAL	23	84	27	5	8	8	10	4	100	3	31	303

*Last degree earned

TABLE 2E
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND PATENT EXPERIENCE

SOURCE	PATENT EXPERIENCE									TOTAL
	NONE	CLASS[a]	INVENTOR	CORPORATION[b] GENERAL ATTORNEY	PATENT ATTORNEY	ATTORNEY[c]	PATENT AGENT	NO RESPONSE	PARALEGAL	
F.P.L.C.	126	12	1	0	0	0	0	0	2	141
A.C.	8	3	2	4	14	1	0	0	0	32
P.T.C.	42	1	1	0	76	3	3	4	0	130
TOTAL	256	16	4	4	90	4	3	4	2	303

[a] Have taken a course in patent law — purely academic experience
[b] Corporate patent attorneys are included in the Patent Attorney Category
[c] Attorney in general practice

TABLE 2F
SUBJECTS RESPONDING TO SECOND QUESTIONNAIRE BY SOURCE AND PATENT OFFICE EXPERIENCE*

SOURCE	PATENT OFFICE EXPERIENCE					TOTAL
	NONE	1-5 YEARS	6-10 YEARS	OVER 10 YEARS	NO RESPONSE	
F.P.L.C.	141	0	0	0	0	141
A.C.	25	7	0	0	0	32
P.T.C.	98	24	3	0	5	130
TOTAL	264	31	3	0	5	303

*Employment by the U.S.P.T.O.

Results and Discussion

Analyses Performed. It must be noted that all statistical analyses which have been computed are of an exploratory rather than of a definitive nature. A superficial examination of small amounts of data was computed in order to provide rough tests of trends or results which appeared to have possible value in terms of later, more complete analysis. Lack of resources, specifically money and computer access, has made complete analysis impossible at present.

Scoring. It was necessary to establish a scoring protocol for the second questionnaire. The first responses to this questionnaire were collected at the PTC Arbitration Conference. Twenty-six papers were scored by two alternative procedures. One alternative (I) was to give one point for each "correct" response. A "correct" response was one which placed the multiple choice alternative in the same position relative to the other choices as it was in relation to the actual frequency distribution from previous study. Thus, a subject whose responses agreed with the frequency distribution received a score of 5 points for the question. Four agreements received a score of 4 points, etc.

The second scoring procedure (II) concentrated on responses at the extremes of the frequency distribution. If the least frequent alternative was marked #1 by the subject, 2 points were given; if the least frequent alternative was marked #2, 1 point was given. At the other end of the distribution, if the most frequent alternative was marked #5, 2 points were given; if the most frequent was marked #4, 1 point was given. Thus, subjects were given credit for greater accuracy.

Procedures I & II were statistically correlated. The resulting coefficient of correlation was r=.80. Procedure I had a standard deviation of 6x=6.48 and a range of 14 to 41. For Procedure II, the standard deviation was 6y=7.88 and the range was 12 to 51. Thus, the two procedures are essentially interchangeable with Procedure II having somewhat more variability. Procedure II was selected for use in additional analyses.

Table 3 provides, for the first 26 papers, means for groups of varying patent experience. Means of such small groups do not constitute conclusive evidence, but it is interesting to note that patent attorneys did not score higher than other groups, as might have been expected.

TABLE 3
MEAN SCORES ON THE SECOND QUESTIONNAIRE BY PATENT EXPERIENCE*

Experience Group	N (Number of Subjects)	Mean (Average Score)
Patent Attorney	13	41.54
Attorney [a]	4	34
No Patent Experience [b]	4	41
Patent Experienced Non-Law [c]	5	42.8

*Based on 26 papers collected at the P.T.C. Arbitration Conference.

[a] General law-no special experience with patent law.

[b] Students with no experience with patent law.

[c] Inventors, etc., with patent experience but no legal training.

Other Analyses. A preliminary item analysis has been attempted; some questions have been identified as having been missed by a large percentage of respondents. More complete item analysis will provide information about the questionnaire and may be used to make scoring reliable. Questions found to be inappropriate (non-discriminating) can be eliminated from scoring for previously collected data and from versions of the questionnaire to be used in the future.

Comparison of first half scores with second half scores for thirty questionnaires collected through the PTC showed no tendency for scores to consistently increase or decrease from first to second half. This suggests that practice and/or fatigue either had no effect or cancelled each other out.

Also, subjects, from different sources may score differently on questions from different sources. An attempt was made to determine whether gross differences might appear by selecting the 15 top scoring papers from three different groups used for the second questionnaire. Means were computed and are shown in Table 4. No attempt was made to compute significance, but it seems unlikely that significant differences would appear in the absence of a more detailed analysis.

TABLE 4
MEAN SCORES ON THE SECOND QUESTIONNAIRE BY SUBJECT GROUP AND ITEM SOURCE

SUBJECT GROUP [a]	ITEM SOURCE [b]		
	TORRANCE [c]	FPLC/MIT [d]	MURPHY [e]
F.P.L.C. (1) [f]	9	14	24
F.P.L.C. (2-3) [g]	8	14	22
P.T.C. [h]	10	15	27

[a] For each designated group, the *top* scoring 15 questionnaires were chosen. *See* "The Second Questionnaire," *Supra.*

[b] *See* "The Second Questionnaire," *Supra.*

[c] Total possible score = 16

[d] Total possible score = 28

[e] Total possible score = 36

[f] All subjects were first year law students.

[g] The subjects were mixed second and third year law students many of whom were subjects for the first questionnaire. *See* "The First Questionnaire," *supra.*

[h] Of this group, 8 subjects indicated they were patent attorneys, (mean = 10, 14 and 26, respectively); 7 questionnaires were obtained from diverse subjects (mean = 10, 16 and 27 respectively). It is interesting that the highest score obtained from *any* subject was that of the young daughter of a patent attorney whose questionnaire was in the latter group (score = 14, 18 and 28, respectively).

Proposed Analyses. There are two sets of statistical analyses which should be performed on the collected data. First, the second questionnaire should be analyzed. Essentially, this would include item analysis and reliability testing.

An item analysis would provide information about the discriminatory power of individual items; thus, items which do not differentiate high scorers from low scorers could be eliminated from further computations and the usefulness of the questionnaire would be increased. A simple split-half reliability coefficient would provide information with regard to whether the questionnaire measures the same variable at different times. For a discussion of the necessity for such testing of questionnaires, the reader is referred to any text on the theory of testing.[38] Since the dependent variable being examined here has not been tested previously, there is no immediately obvious way in which to test the validity of the questionnaire.

The second set of statistical analyses to be performed are those relating to the dependent variable itself, i.e., the ability to recognize obviousness. The proposed method of study is analysis of variance[39]

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[38] *See, e.g.,* J. NUNNALLY, PSYCHOMETRIC THEORY (1967).

[39] For a discussion of analysis of variance *see,* J. LI, STATISTICAL INFERENCE (1964).

using scores on the second questionnaire as the dependent variable and the various demographic variables (age, occupation, experience in the patent office, etc.) as independent variables. It hardly seems worthwhile to detail the specific analyses to be computed at this point, but such information will become available when resources for completion are available. Basically, the analysis of variance should indicate which of the independent variables are related to scores on the dependent variable. For example: holding other variables constant, do persons with experience in the Patent Office recognize obviousness more easily than persons without such experience? Correlation coefficients between all of the independent variables would also be helpful in suggesting which variables might be related to each other.

Summary and Conclusions

Preliminary steps are described in developing a procedure for studying skill in evaluating solutions to problems for their obviousness. It has been posited that the obviousness of a given solution is directly proportional to the frequency with which it is obtained in response to a problem. Therefore, frequency analyzed responses to problems have been obtained and used to evaluate the capacity of subjects to determine the relative frequency (or obviousness) of sets of solutions to such problems.

Problems of the sort that arise in patent practice have been used and generally fall into the categories of either improving a known article, or thinking of new and useful applications for common articles and combinations of common articles.[40] In an attempt to determine whether those with experience in patent matters might have a learned advantage over others lacking such experience, the problems were also selected so as to offer no clear advantage to those untrained in science or technology.[41]

While the data ought to be subjected to sophisticated statistical analysis before firm conclusions are drawn, a casual consideration of it suggests at least that when problems do not fall within specialized areas of science and technology, patent experience confers no special competence in ability to engage in hindsight evaluations of the creative efforts of others.[42]

It thus appears that the tools and knowledge of psychology have much to offer in this important legal area and more effort should be expended to take advantage of that potential.

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[40] *See* 34 U.S.C. § 101.

[41] *See* 35 U.S.C. § 103.

[42] *See, e.g.,* Table 4 in text.

APPENDIX A
FIRST QUESTIONNAIRE

Note:

We need your help. Your cooperation in providing some general information and in answering a few simple questions will be very much appreciated.

No attempt will be made to identify individuals. Please do not put your name on this.

Information:

Please check the appropriate spaces.

I. Class: 1st ___ 2d ___ 3d ___

II. Age: under 25 ___ 25 to 35 ___ Over 35 ___

III. Undergraduate education: Liberal arts ___ Engineering ___ Social sci. ___ Physical sci. ___

IV. Sex: F ___ M ___

Questions:

Below 3 pairs of common, household items are listed. How many useful and different ways of combining the paired items can you think of? Please describe the ways of combining them in the space provided. If you do not have enough room, use the back of this sheet, being sure to indicate the number of the question. Also, please try to divide your time equally.

I. A paper clip and a small sheet of aluminum foil:

II. A screw-lidded jar and a wooden pencil:

III. A clothes hanger (metal) and a spool of thread:

THANKS FOR YOUR HELP! (If you're interested, we will be pleased to keep you informed of the progress of our research.)

APPENDIX B
SECOND QUESTIONNAIRE
PERSONAL DATA FORM

Although the personal identity or individual characteristics of any particular person are of little consequence, it is vital that as much information as possible be obtained about the group of respondents in this study. Thus, carefully answering these questions is as important as completing the attached questionnaire.

Age:	15-19 ___	30-34 ___	Sex:	M ___
	20-24 ___	35-45 ___		F ___
	25-29 ___	over 45 ___		

Occupation: _____

Have you had any experience with the patent law? If so, please briefly indicate its nature and duration. Experience *in* the Patent Office, if any, should be separately indicated.

Education: please list degrees and majors.

QUESTIONNAIRE

Each of the following questions present a simple problem and five solutions to the problem — which were chosen from a substantial number of solutions provided by people with a variety of backgrounds and experience. Using the average person of your acquaintance as the standard, please try to rank the solutions from the least obvious (or predictable) to the most obvious, using the numbers 1 through 5, respectively.

1	*2*	*3*	*4*	*5*
Very Unobvious	Unobvious	.....	Obvious	Very Obvious

1. How can a metal clothes hanger and a spool of thread be usefully combined?

___ A. Wrap the hanger to prevent rusting.
___ B. As a fishing pole.
___ C. Place spool on hook of hanger to move hanger more easily.
___ D. As a strainer, sieve.
___ E. Insert hanger through spool to make pulley or thread dispenser.

2. What are some useful ways of using a tire?

___ A. As shoes; sandals.
___ B. As a doormat.
___ C. As a dog bed.
___ D. To mark paths, trails.
___ E. As bumpers (cars, boats, walls of race track); as a shock absorber.

3. What are some useful ways of using a shoe?

___ A. As a container.
___ B. As a cage for small animals.
___ C. To stamp out fires.
___ D. As a doorstop.
___ E. As a chew toy for a dog.

4. How can a stuffed, toy monkey be improved?

___ A. Make it so it can sit.
___ B. Make it so it can eat.
___ C. Make it so it can drink.
___ D. Put it on wheels.
___ E. Make its eyes move.

5. What are some useful ways of using a tire?

___ A. Use the tube for a sling shot.
___ B. As bicycle brake pads.
___ C. Use the tube for a rubber band.
___ D. To hang up for a swing.
___ E. To cut into belts for machinery.

6. What are some useful ways of using a shoe?
___ A. As bookends.
___ B. To hide money in them.
___ C. To protect feet from hazards as in stamping out fires.
___ D. Use for target practice.
___ E. To train a dog to retrieve.

7. How can a screw-lidded, glass jar and a pencil be usefully combined?
___ A. As a drum.
___ B. As a rattle.
___ C. To make a shaker (dispenser).
___ D. As a planter.
___ E. As a container; labeled jar.

8. How can a stuffed, toy monkey be improved:
___ A. Give it clothes.
___ B. Make it into a bank.
___ C. Make it walk on its hind legs.
___ D. Make it walk on its hands.
___ E. Make it climb.

9. What are some useful ways of using a newspaper?
___ A. Use for wrapping (fish).
___ B. As a mask.
___ C. As a weapon.
___ D. As a blanket.
___ E. As a seat cover or cushion.

10. How can a paperclip and a small square of aluminum foil be usefully combined?
___ A. As a weather vane (wind).
___ B. As a scarecrow.
___ C. As a candle snuffer.
___ D. As an airplane, glider or kite.
___ E. Make an open container: eating or cooking utensil.

11. How can a screw-lidded, glass jar and a pencil be usefully combined?
___ A. As a pencil holder.
___ B. Punch holes in lid: keep fish, insects, small animals.
___ C. As a spin toy (top).
___ D. As a wheel and axle.
___ E. As a shipwreck message container.

12. What are some useful ways of using a shoe?
___ A. Use shoelace to tie objects.
___ B. Bronze them for ornaments.
___ C. Throw as a weapon; at animals.
___ D. Use laces for molotov cocktail fuses.
___ E. Use it as a hammer; gavel.

13. How can a metal clothes hanger and a spool of thread be usefully combined?
___ A. As a dispenser for thread: mount spool on hanger.
___ B. As a net (fish).
___ C. As a bow.
___ D. To make ornaments, art work: mobiles.
___ E. As a musical instrument.

14. What are some useful ways of using a newspaper?
___ A. To make paper airplanes.
___ B. To stuff in shoes.
___ C. To protect floors: from paint, muddy feet.
___ D. As a window shade.
___ E. For personal hygiene (toilet paper, napkin, tissue).

15. How can a stuffed, toy monkey be improved?
___ A. Make it into a music box.
___ B. Make it talk.
___ C. Make it hiccup.
___ D. Make it stand on its head.
___ E. Make the tail move.

16. How can a paperclip and a small square of aluminum foil be usefully combined?
___ A. As a dart.
___ B. As a fan.
___ C. As a pinwheel.
___ D. In art, as a mobile, decorations, ornaments.
___ E. As reflector: on clothing, mirror, solar.

17. What are some useful ways of using a newspaper?
___ A. To clean glass: windows, glasses, mirrors.
___ B. As a splint or brace.
___ C. To hide magazines.
___ D. To burn for fuel.
___ E. To keep the rain off.

18. How can a paperclip and a small square of aluminum foil be usefully combined?
___ A. To make ornaments: mobiles, etc.
___ B. To make a cup or container.
___ C. To make an antenna.
___ D. As a plate for engraving (images).
___ E. To make a funnel.

19. How can a stuffed, toy monkey be improved?
___ A. Give it a hat.
___ B. Make its nose move.
___ C. Give it a moustache.
___ D. Make it bigger.
___ E. Give it a tongue.

20. What are some useful ways of using a tire?
___ A. As a target for throwing balls.
___ B. Use the tube for flotation.
___ C. As a basketball hoop.
___ D. As a basis for a chandelier.
___ E. As a flower planter.

APPENDIX C
COVER LETTER SENT TO PTC MEMBERSHIP WITH SECOND QUESTIONNAIRE

February 11, 1977

Dear PTC Members and IDEA Subscribers:

As part of our expanded PTC research activities, we would like to recruit your help.

Enclosed is a questionnaire which has been developed by Dr. Juanita V. Field, Research Associate to the PTC and Thomas G. Field, Jr., Associate Professor at the Law Center. It would be appreciated if you could take 15-20 minutes to complete it and return it to the PTC.

The Fields' research is an attempt to determine whether some individuals are better than others in sorting out obvious and non-obvious responses to problems. This questionnaire is the second part of the project. In the first part, people were asked how they could combine common items in useful ways. This questionnaire is based on actual returns which are, in some instances, unique in 1000 responses. They have also been backed up by other studies.

The potential significance of such research will be apparent to those of you who are perplexed by judicial "Monday-morning quarterbacking" in patent validity litigation. We are not limiting our research by asking only patent attorneys to complete these — so, even if you couldn't care less about patent validity, we would appreciate it if you could complete the questionnaire and return it.

Also, we realize that many of our members have large staffs of attorneys and others, and we encourage you to duplicate the questionnaire accordingly — or write to us for more copies. At this point, we are trying to get as much data as possible — from as many different people as possible. Anything you can do to help us will be very much appreciated.

Sincerely,

Joseph F. Vittek, Jr.
Director

JFV/ml

enc.

Patent Invalidity Studies: A Survey**

Carole Kitti*

This paper[1] surveys the literature on court determinations of patent invalidity and will show the percentages of patents judged valid and the factors behind these decisions. This survey has uncovered an important problem in the use of validity rates: the unexplained variation in the basic data on patent validity decisions.

The interest in court determinations of patent validity flows from several sources. Because the possibility of a court invalidity judgment

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**The views, opinions, facts and interpretations expressed in this paper are solely those of the author and do not necessarily reflect any policy, position, or view of the National Science Foundation.

[1] The author would like to note the important contribution made to the field of invalidity studies by G. Koenig in PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS (1st revised ed. 1976), which was, unfortunately, unavailable to the author at the time this paper was written. Chapters 3 and 4 of Koenig's book relate to this article. Chapter 3 discusses prior studies of adjudicated patents by Federico, Dann, Dearborn and Boal, Gausewitz and the Senate Subcommittee on Patents, Trademarks and Copyrights whereas this paper focuses on studies by Federico, Dann, Dearborn and Boal, Gorn, Baum, Tegtmeyer and the U.S. Patent Office. The tables used by Koenig present data from individual prior studies; the tables in the present paper combine data from various sources to provide a more facile comparison of different invalidity studies. Koenig's emphasis is on case law and the effects of particular decisions on validity and invalidity rates. Chapter 4 is Koenig's own study of invalidity for the years 1953 through 1974.

can make a newly issued patent a "lottery ticket"[2] or an invitation to expensive litigation,[3] the perceived value of a patent to the patentee is almost certainly affected. The ability of a patent to provide an incentive to innovation is therefore influenced, although the direction of the effect has not been empirically established. The influence may be demonstrated by the use of three illustrations: (1) a patentee could be gaining patent protection for an unpatentable invention thereby increasing the invention's value; (2) a patentee may allow a valid patent to be infringed rather than engage in litigation thereby decreasing the patent's value; or (3) an inventor may keep his invention secret thereby hoping that the invention's economic life will be longer than its patent life.

Judgments of invalidity have also caused concern because the courts and the Patent Office have developed different standards of invention. Patentability under United States patent law requires novelty and non-obvious subject matter. That is, an invention must not be previously known, used, or patented and it must demonstrate a quality of originality and insight such that the invention would not be obvious to one with ordinary skill in the art.

Patent Office examiners review the prior art to determine an invention's novelty and the degree of advancement in the art represented by the invention (the level of inventive activity). The level of inventive activity appears to be the predominant ground in court decisions of invalidity.[4] Thus there is substantial interest in whether court decisions on invalidity reflect a different standard of invention than that employed by the Patent Office or the use and availability of different information. For example, the amount of prior art reviewed by the patent examiner is important even if the invention did not previously exist (thereby meeting the novelty criterion) because the state of the art affects the judgment of non-obviousness or level of inventive activity.

Policymakers who want to reduce invalidity rates and patentees who want to reduce the uncertainty about the value of their patents are interested in determining the reasons for invalidity judgments because the appropriate remedy depends on the cause. Suggested remedies range from limiting patent litigation by restricting the grounds for such litigation — to providing more resources for patent examination and

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[2] M. Polanvyi, *Patent Reforms,* 11 REV. OF ECON. STUD. 69 (1943).

[3] V. Bush, *Some Proposals for Improving the Patent System,* 39 J. PAT. OFF. SOC'Y 29 (1957).

[4] R. Tegtmeyer, *For Greater Patent Validity,* 19 AM. L. REV. 19 at 21 (1969).

introducing adversarial hearings before the granting of a patent in order to get more information at the examination stage.

Calculation of Validity Rates

Studies of court determinations of patent invalidity generally discuss rates or percentages of patents judged invalid as well as absolute numbers of patents. Confusion may exist because of the casual and imprecise use of certain terms. For example, the *Patent, Trademark and Copyright Journal,* in reporting on a recent Patent Office study, stated: "The results of the study, covering the years 1968-1972, show that 50 percent of the patents litigated were held valid and 65 percent were infringed. This figure is in sharp contrast with previous studies from other sources disclosing invalidity rates as high as 72 percent."[5]

However, an examination of the methodology and definitions used by the Patent Office reveals that the 50 percent validity rate is misstated. The Patent Office looked specifically at cases in which a final judgment of validity, invalidity, or infringement was made by a court (the patents were adjudicated) and then formed a ratio between patents judged invalid and the total of valid plus invalid patents. The ratio of valid patents to litigated patents (patents involved in a suit)[6] based on data from the Patent Office study, is 18.2 percent and not the 50 percent of the quotation above, while the ratio of invalid patents to all litigated patents is 17.6 percent.

The point of this example is not to criticize one particular use of terms but to illustrate the subtleties inherent in the calculation of patent validity rates. The rates discussed and compared below are all expressed as percentages of adjudicated patents (patents involved in court decisions) rather than as percentages of litigated patents. This is a more useful method because some litigations are terminated by a consent judgment or dismissal, some are dismissed for want of prosecution, some result in a default judgment, and some are transferred or remanded to another court. Table 1 shows the disposition of patent suits in district courts (the level at which a patent suit is first brought). It shows the number of suits terminated and the number of that group which are terminated after contest, i.e., the adjudicated suits. Federico notes that for 1949 through 1954 only 21.4 percent of the suits terminated involved

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[5] *Patent Office Study Shows Half of Litigated Patents are Valid,* 144 PAT. T.M. & COPYRIGHT J. A-5 (1973).

[6] In many instances, patent litigation ends with an out-of-court settlement rather than with an adjudication of patent validity.

an actual adjudication by the court. This rate is similar to the rates for other civil suits.[7]

Although the validity rates discussed below have comparable denominators, the choice of the appropriate numerator is subject to debate. The court may decide that a contested patent is (1) valid and infringed; (2) valid but not infringed; (3) not infringed but no judgment is made as to validity; or (4) invalid. When several claims of a patent are contested, these choices are available for each claim. Thus, some claims may be valid and others may be invalid.

A patentee in any infringement suit will regard only a decision of valid and infringed as a successful outcome because a judgment of not infringed and invalid allows competitors to remain. Others concerned with court and Patent Office standards may only be interested in decisions specifically declaring a patent invalid. To the extent possible, the tables in this paper provide rates for patents judged invalid (or, conversely, for the patents not judged invalid: 100 minus the percent invalid) and rates for the patents judged valid and infringed. Because some writers classify patents as valid or invalid with no indication of infringement, the figure for patents declared valid and infringed as a percentage of all patents adjudicated is not always available.

Data Sources

One of the major problems in studying patent validity rates is obtaining the results of court decisions. All federal court decisions are published in the *Federal Reporter* and the *Federal Supplement.* Because the task of isolating the decisions involving patents is unwieldy, most writers use the *United States Patent Quarterly* (USPQ) and the *Official Gazette* of the Patent Office. Although federal court clerks are required by 35 U.S.C. § 290 to file with the Patent Office notices of patent suits and their disposition, the Patent Office has found certain defects in these notices. Notices are not filed in every case or are not filed promptly and the information in the notices is sometimes incomplete and inaccurate.[8] The *Official Gazette,* in which these notices are published, would therefore not appear to be reliable.

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[7] P. Federico, *Adjudicated Patents, 1948-54,* 38 J. PAT. OFF. SOC'Y. 233, 238 (1956).

[8] *Patent Office Study of Court Determinations of Validity/Invalidity, 1968-1972,* 144 PAT., T.M. & COPYRIGHT J. F-2 (1973) [hereinafter cited as Patent Office Study].

TABLE 1
DISPOSITION OF PATENT SUITS BY DISTRICT COURTS

Fiscal Year	Number of Suits Terminated	Suits Terminated After Contest		Decisions Published
		Number	% of Total	
1938[9]	1338	226	16.9	
1939[9]	1293	208	16.1	
1940[9]	1140	263	23.1	
1941[9]	1104	265	24.0	
1942[9]				
1943[9]				
1944[9]				
1945[9]	279	81	29.0	
1946[9]	252	72	28.6	
1947[9]	333	83	24.9	
1948[9]	346	72	20.8	
1949[9, 10, 11]	374	121	32.4	71
1950[9, 10, 11]	519	101	19.5	70
1951[9, 10, 11]	549	105	19.1	75
1952[9, 10, 11]	608	125	20.6	77
1953[9, 10, 11]	529	105	19.8	82
1954[9, 10, 11]	532	110	20.7	67
1955[10]	544	109	20.0	
1956[10]	680	110	16.2	
1957[10]	609	123	20.2	
1958[10]	610	110	18.0	

The major source of information on adjudicated patents is the USPQ. Although most judgments of courts of appeals are published in the USPQ, this is not true for decisions of district courts. Table 1 presents the numbers of suits terminated by contest in the district courts and the number of decisions published. For the 1949-1954 period, only about two-thirds of the decisions of district courts are published. In addition to the incomplete reporting of district court decisions, the Patent Office study suggests a bias in the nature of the cases published. In comparing 35 U.S.C. § 290 notices of patent suits filed with the Patent Office with published decisions, the Patent Office study found that "Of the 368 patents held valid, about 131 (approximately 50%) were the subject of unreported district court decisions. Similarly, of the 357 patents held invalid, 28 (approximately 8%) were the subject of unreported district

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[9] Federico, *supra* note 7, at 243.

[10] E. Gorn, *Economic Value of Patents,* THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT at 223 (1964).

[11] Federico, *supra* note 7, at 238.

court decisions."[12] Thus, the published district court decisions may over-represent the proportion of cases dealing with patent invalidity.

Validity at the District Court Level

Tables 2 and 3 present the rates of patent invalidity judgments from published district court decisions for groups of years from 1921 through 1972 (Table 2) and for individual years for 1948-1954 (Table 3). Table 2 also indicates another problem — that of definitions or categories: the patent classifications of utility, plant, design, and reissue patents. Because some authors prefer to exclude one or more of these groups, the comparability of different validity studies is hampered unless the exclusions have been specified. However, the Patent Office study indicates that of 989 adjudicated patents, 58 were design patents (5.9 percent); 38 were reissue patents (3.8 percent); and 1 was a plant patent (.1 percent).[13] Therefore, the error from an unknown inclusion or exclusion of plant, design, or reissue patent is relatively small.

TABLE 2
PUBLISHED DECISIONS OF DISTRICT COURTS
(BY GROUPS OF YEARS)

Years	Total Patents Adjudicated	Invalid Patents	
		Number	% of Total
1921-25[14]	274	99	36.1
1926-30[14]	350	136	38.9
1931-35[14]	427	177	41.4
1936-40[14]	518	293	56.6
1941-45[14]	384	249	64.8
1946-50[14]	203	105	51.2
1951-55[14]	299	210	70.2
1956-60[14]	296	192	64.9
1961-65[14]	366	219	59.8
1966-73[14]	549	338	61.6
1968-72[15]	681	158	23.2
1068-72[16]	630	149	23.6

[12] *Id.* at F-2.

[13] *Id.* at F-1.

[14] L. Baum, *The Federal Courts and Patent Validity: An Analysis of the Record,* 56 J. PAT. OFF. SOC'Y. 758 at 761 (1974).

[15] *Patent Office Study, supra* note 8, at F-1. The figures show total patents.

[16] *Id.* Total patents excluding plant and design patents.

TABLE 3
PUBLISHED DECISIONS OF DISTRICT COURTS[17]
(YEARLY)

Years	Total Patents Adjudicated	Invalid % of Total	Valid & Infringed % of Total	Not Infringed % of Total
1948	99	36.4	41.4	22.2
1949	112	52.7	29.5	17.8
1950	100	33.0	43.0	24.0
1951	105	61.9	26.7	11.4
1952	112	62.5	27.7	9.8
1953	87	65.5	17.3	17.2
1954	78	55.1	32.1	12.8
Total	693	52.4	31.2	16.4

In Table 2, the 1968-1972 period in the Patent Office study is a subset of Baum's 1966-1973 period and so provides a basis for comparison. There is a significant difference in the percentages of patents held invalid. Baum found 23.6 percent invalid, a difference of 38 percentage points. Although the Patent Office period is a subset of Baum's interval, the Patent Office study reports more patents adjudicated. These differences may be attributed to the difference in data sources. Baum used the USPQ while the Patent Office relied on the § 290 notices. This difference in invalidity rates supports the suspected bias mentioned above: that there is a greater tendency to publish decisions of invalid patents than decisions of patent validity.

Validity at the Court of Appeals Level

The general emphasis in patent validity studies has been on decisions at the court of appeals level. This emphasis is due in part to the incomplete reporting of district court decisions and in part to the possibility that the court of appeals may reverse or overrule a lower court's decision. Tables 4, 5, 6 and 7 present the decisions for patents adjudicated at both the district court and court of appeals levels using data from the Federico and Tegtmeyer studies. Tables 4 and 5 show the rates of validity and invalidity for the same patents at each level for the period 1948-1955 (Table 4) and for 1953-1962 by circuit (Table 5). The courts of appeals appear to have a somewhat higher validity rate during the later period than during the earlier one, although the categories of court holdings are not strictly comparable. Table 6 presents the holdings of the courts of appeals broken down by type of decision at the

[17] Federico, *supra* note 7, at 237.

district court level. The higher courts appear much more likely to uphold decisions of patents being invalid (94 percent) or not infringed (91 percent) than to uphold district court decisions of valid and infringed (48 percent). Similarly, Table 7, in examining the total reversals of district court decisions by courts of appeals, shows in general that more decisions of validity were overturned than were decisions of invalidity.

TABLE 4
CONSISTENCY OF DISTRICT COURTS AND COURTS OF APPEALS PATENT DECISIONS (1948-1955)[18]

	Number of Patents	Valid and Infringed		Invalid		Not Infringed	
		No.	%	No.	%	No.	%
District Courts	428	145	33.9	219	51.1	64	15.0
Courts of Appeals	428	76	17.8	268	62.6	84	19.6

TABLE 5
CONSISTENCY OF DECISIONS (1953-1962 BY CIRCUIT)[19]

Circuit	Holdings in District Court					Holdings in Courts of Appeals			
	Total Patents[20]	Valid		Invalid		Valid		Invalid	
		No.	%	No.	%	No.	%	No.	%
1	26	8	30.8	18	69.2	6	23.1	20	76.9
2	59	21	35.6	38	64.4	10	16.9	49	83.1
3	45	9	20.0	36	80.0	8	17.8	37	82.2
4	36	20	55.6	16	44.4	19	52.8	17	47.2
5	46	26	56.5	20	43.5	24	52.2	22	47.8
6	68	25	36.8	43	63.2	23	33.8	45	66.2
7	76	31	40.8	45	59.2	34	44.7	42	55.3
8	21	3	14.3	18	85.7	2	9.5	19	90.5
9	67	27	40.3	40	59.7	23	34.3	44	65.7
10	19	14	73.7	5	26.3	12	63.2	7	36.8
DC	3	1	33.3	2	66.7	2	66.7	1	33.3
Total	466	185	39.7	281	60.3	163	35.0	303	65.0

[18] Federico, *supra* note 7, at 242. This table gives the patents adjudicated by the district court during 1948-54 which have been appealed. The decisions by the courts of appeals on these same patents include some decisions rendered in 1955.

[19] P. Tegtmeyer, *For Greater Patent Validity*, 19 AM. U. L. REV. 23 (1969).

[20] Excluding mixed reversal decisions.

TABLE 6
COURT OF APPEALS REVERSALS OF DISTRICT COURT DECISIONS[21] (1948-1955)

Holdings in District Court		Holdings in Courts of Appeals					
		Valid & Infringed		Invalid		Not Infringed	
Holding	Number of Patents	No.	%	No.	%	No.	%
Valid & Infringed	145	70	48.3	57	39.3	18	12.4
Invalid	219	5	2.3	206	94.1	8	3.6
Not Infringed	64	1	1.6	5	7.8	58	90.6
Total	428	76		268		84	

[21] Federico, *supra* note 7, at 242.

TABLE 7
COURT OF APPEALS REVERSALS OF DISTRICT COURT DECISIONS (1953-1962, BY CIRCUIT)[22]

Circuit	Total Number of Patents Involved	Total Consistent District & Appellate Decisions	Court of Appeals Reversals of the District Courts					
			Total Reversals	Mixed	District Court Valid		District Court Invalid	
					Number	% of Total Reversals	Number	% of Total Reversals
1	26	24	2	—	2	100.00	—	0.0
2	61	44	17	2	13	76.5	2	11.8
3	45	40	5	—	3	60.0	2	40.0
4	36	25	11	—	6	54.5	5	45.5
5	46	34	12	—	7	58.3	5	41.7
6	68	62	6	—	4	66.7	2	33.3
7	77	67	10	1	3	30.0	6	60.0
8	21	20	1	—	1	100.0	—	0.0
9	67	57	10	—	7	70.0	3	30.0
10	19	15	4	—	3	75.0	1	25.0
DC	3	2	1	—	—	0.0	1	100.0
Total	469	390	79	3	49	62.0	27	34.2

[22] Tegtmeyer, *supra* note 4, at 23.

Tables 8 and 9 present rates of patent invalidity judgments for circuit courts of appeals for groups of years from 1921-1972 (Table 8) and yearly for 1925-1968 (Table 9). The data for Table 8 were derived from three studies. Those by Baum and Federico are of particular interest because of their long period of overlap (1925-1954) and the large discrepancy in reporting the numbers of patents adjudicated and invalidity rates. For 1926-1955 Baum reported 2,126 patents adjudicated, while for 1925-1954 Federico found 3,371 patent decisions. Baum's percentages of patents held invalid average 16 points higher than Federico's for the same period. Even when differences in the methodologies of the two studies are taken into account, these large differences cannot be explained satisfactorily.

TABLE 8
DECISIONS OF CIRCUIT COURTS OF APPEALS (GROUPS OF YEARS)

Years	Total Patents Adjudicated	Invalid Patents	
		Number	% of Total
1921-25 [23]	338	199	58.9
1925-29 [24]	649	218	33.6
1926-30 [23, 24]	437, 717	219, 236	50.1, 32.9
1930-34 [24]	719	274	38.1
1931-35 [23, 24]	412, 683	256, 289	62.1, 42.3
1935-39 [24]	803	409	50.9
1936-40 [23, 24]	539, 831	368, 432	68.3, 60.0
1940-44 [24]	602	364	60.5
1941-45 [23, 24]	338, 511	259, 317	76.6, 62.0
1945-49 [24]	262	169	64.5
1946-50 [23, 24]	190, 272	140, 161	73.7, 59.2
1950-54 [24]	336	204	60.7
1951-55 [23]	210	156	74.3
1956-60 [23]	228	158	69.3
1961-65 [23]	287	170	59.2
1966-73 [23]	403	277	68.7
1968-72 [25]	282	190	67.4
1968-72 [26]	274	182	66.4

[23] Baum, *supra* note 14, at 760; excludes plant and design patents.

[24] Federico, *supra* note 7, at 244.

[25] *Patent Office Study, supra* note 8.

[26] *Id.* Total patents excluding plant and design patents.

TABLE 9
DECISIONS OF CIRCUIT COURTS OF APPEALS
(YEARLY)

Year	Total Patents Adjudicated	Invalid Patents % of Total	Valid & Infringed Patents % of Total
1925 [27]	99	37.4	31.3
1926 [27]	120	38.3	36.7
1927 [27]	142	30.3	39.4
1928 [27]	170	34.7	42.9
1929 [27]	118	38.1	34.8
1930 [27]	167	35.3	36.5
1931 [27]	133	40.6	37.6
1932 [27]	137	43.8	29.9
1933 [27]	140	45.0	16.4
1934 [27]	142	36.6	33.8
1935 [27]	131	55.3	29.0
1936 [27]	105	51.4	26.7
1937 [27]	165	40.6	32.1
1938 [27]	209	55.0	19.1
1939 [27]	193	57.5	20.8
1940 [27]	159	59.2	18.4
1941 [27]	141	63.1	15.6
1942 [27]	138	68.2	10.1
1943 [27]	77	67.5	20.7
1944 [27]	87	47.1	16.1
1945 [27]	68	67.6	11.8
1946 [27]	43	65.1	23.3
1947 [27]	38	71.1	26.3
1948 [27]	51	60.8	25.5
1949 [27]	62	64.5	19.4
1950 [27]	78	48.7	29.5
1951 [27]	69	58.0	14.5
1952 [27]	58	69.0	6.9
1953 [27, 28, 29]	77, 13, 66	63.6, 69.2, 62.2	22.1, 23.1, 24.2
1954 [27, 28, 29]	54, 46, 61	68.5, 76.2, 75.5	13.0, 13.0, 14.7
1955 [28, 29]	40, 44	72.2, 63.6	20.0, 18.2
1956 [28, 29]	52, 80	69.1, 51.3	23.1, 32.5
1957 [28, 29]	63, 74	69.6, 64.9	22.2, 29.7
1958 [28, 29]	56, 60	62.5, 66.7	25.0, 26.6
1959 [28, 29]	50, 70	68.0, 57.1	26.0, 25.7
1960 [28, 29]	48, 62	60.2, 51.6	33.3, 30.7
1961 [28, 29]	55, 59	51 , 42.4	38.2, 45.8
1962 [28, 29]	46, 62	54.3, 48.3	28.3, 40.3
1963 [28, 29]	66, 96	66.6, 53.2	24.2, 28.1
1964 [28]	73	76.3	15.1
1965 [28]	65	53.9	36.9
1966 [28]	62	77.2	16.1
1967 [28]	59	62.5	18.6
1968 [28]	75	69	22.7

[27] Federico, *supra* note 7, at 244.

[28] Tegtmeyer, *supra* note 4, at 21.

[29] R. Dearborn & R. Boal, *Adjudications by Circuits and Arts Involved,* THE ENCYCLOPEDIA OF PAT. PRAC. AND INVENTION MANAGEMENT at 20 (1964).

Different data sources were used by the two authors. Baum used the Patent Office's *Official Gazette* for the period being discussed, while Federico used the USPQ for at least some of the data. Federico's sources for the pre-1948 period are unspecified. However, because almost all courts of appeals decisions are published in the USPQ, the differences in sources used do not suggest an obvious bias. For a later period (1967-1973), Baum did use data from the USPQ. He compared USPQ data with that of the *Official Gazette* and found that the *Official Gazette* showed a higher proportion of patent validity than did the USPQ but that the differences averaged less than 2 percent and no difference was greater than 3.3 percent.[30] If the *Official Gazette* has a bias toward higher validity rates, then the higher invalidity rates found by Baum (compared with Federico's rates) are even more significant.

Another methodological difference between the two studies is that Baum excluded the District of Columbia Court of Appeals from his data base while Federico included it. However, this court makes very few patent decisions. For 1948-1954 Federico reports one decision of the District of Columbia Court of Appeals and 443 patents adjudicated by the other circuits.[31] Still another difference is that Federico apparently dated patent cases by the year in which the decision was made while Baum classified cases by the year in which the decision was published. However, the lag of one year between Baum's figures and Federico's (see Table 8) should largely account for this dating effect. The large differences in the numbers of patents adjudicated and in invalidity rates remain.

Another possible explanation is the difference in classification of patents as valid and invalid. Federico classifies patents as having been judged valid, invalid, or not infringed (with no judgment as to validity). Baum, on the other hand, classifies patents as having been adjudicated valid or invalid. If Baum has excluded patents judged as not infringed from his total patents adjudicated, the difference between Federico and Baum in numbers of patents adjudicated, (excluding non-infringed judgments from Federico's totals) becomes smaller, less than 80 patents per five-year period.[32] However, Baum does not state that he has made

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[30] Baum, *supra* note 14, at 786.

[31] Federico, *supra* note 7, at 236.

[32] *Compare* Baum, *supra* note 14, at 760 (Total Patents) with Federico, *supra* note 7, at 244. (Number of patents minus Not Infringed Patents.)

this exclusion.[33] Thus, from the information provided by the authors, the known data differences do not appear to adequately explain the large discrepancies between the Baum and Federico studies with respect to numbers of patents adjudicated.

The yearly invalidity rates presented in Table 9 are combined from three separate sources with an overlap of at least two studies for the years 1953-1963. Again, there are discrepancies. The figures from Tegtmeyer on total patents adjudicated are consistently smaller than those from Dearborn and Boal. Tegtmeyer's rates of invalidity are generally higher. Dearborn and Boal do not identify the source of their data nor do they indicate whether the cases are dated by the year of the decision or the year of publication of the decision. Therefore, the source of their difference with Tegtmeyer is unknown. The discrepancy between the figures in the Federico and Tegtmeyer studies for total patents adjudicated for 1953 and 1954 is also difficult to explain because the data source (USPQ) and the year of classification are the same. The only reported difference is that Federico excludes reissue patents while Tegtmeyer includes them but excludes design patents.

Validity Rates Among Different Circuits

Table 10 lists by circuit of courts of appeals the patent validity rates as percentages of all patents adjudicated. As mentioned earlier, the classification of patent decisions varies from study to study. In addition, the validity rate of greatest interest varies. For the patent holder only a decision of valid and infringed is considered a success (because competition can be arrested) while for those concerned with the difference between court and Patent Office standards, decisions of invalidity may be of prime importance. For these reasons two different validity rates have been reported in Table 10 — valid and infringed patents as a percentage of all adjudicated patents and the percentage of patents not judged invalid (100 minus the number of invalid patents as a percent of all adjudicated patents). The differences between these two rates represent the patents that were not infringed or whose validity was not determined.

The comparison of the period 1948-1954 with that of 1953-1963 shows the percentages of judgments of valid and infringed increased from 2 to

[33] At Table 4, Baum explicitly states that not infringed judgements were classed as "anti-patentee," so these patents are included in the patent total of Table 4, Baum, *supra* note 14, at 780. However, Table 4 does not appear to have been drawn from Baum's earlier Tables on patent validity in the courts of appeals and the district courts (Tables 1 and 2) so the patents included in the total patents adjudicated base may not be the same.

35 points depending on circuit. The most favorable circuits in the earlier period (arranged by decreasing percentages) are the 4th, 5th, 9th, and 10th, and in the later period are the 10th, 5th, and 4th circuits (also arranged by decreasing percentages). The least favorable circuits in the earlier period (arranged by decreasing percentages) are the 2nd, 3rd, and 8th and in the later period are the 8th, 2nd, and 3rd (also arranged by decreasing percentages). With respect to the patents not judged invalid, the change in percentages in the two periods ranged from a decline of 7 points to an increase of 16 points and, over all, 7 circuits showed an increase in the percentage of patents not declared invalid.

It is not clear whether the data for the periods 1953-1968 and 1961-1973 can be satisfactorily compared with the earlier periods. Baum and Tegtmeyer, who did the later studies, classified patents as either valid or invalid without taking into account any information on infringement. Because only two categories were used, a patent judged not invalid is valid, and the rates from the two studies can be directly compared. The two studies are in accord in stating that the most favorable circuits for patent validity decisions are the 8th, 2nd, and 3rd. The question of the validity of comparisons between the earlier and later studies arises in light of Tegtmeyer's study of the period 1953-1968 which significantly overlaps the 1953-1963 period studied by Dearborn and Boal. Tegtmeyer's percentage rates of not invalid patents are closer to Dearborn and Boal's rates for valid and infringed patents than to their rates for not invalid patents. This situation suggests either the presence of definitional problems or a large drop in rates of not invalid patents (a rise in invalidity rates) after 1963. Examination of Tables 8 and 9 does not suggest any sharp rise in invalidity rates over all circuit courts of appeals. The differences in the validity rates in Table 10 are based on the same unknown factors causing the differences in the invalidity over all circuits calculated by Tegtmeyer and by Dearborn and Boal.

TABLE 10
PATENT VALIDITY RATES FOR COURTS OF APPEALS BY CIRCUITS (PERCENT OF TOTAL PATENTS ADJUDICATED)

Circuit	1948-54[34]		1948-57[35]		1953-63[36]		1953-68[37]	1961-73[38]
	Valid & Infringed	Not Invalid	Valid & Infringed	Not Invalid	Valid & Infringed	Not Invalid	Not Invalid	Valid
1	11.5	26.9	20.6	32.4	20.4	42.9	25.0	26
2	2.6	25.7	4.8	20.6	14.4	26.6	18.6	18
3	7.5	15.0	16.7	25.8	16.9	22.5	19.4	20
4	37.0	50.0	37.2	51.6	43.6	54.9	33.8	26
5	36.7	50.0	42.9	55.1	43.8	59.7	46.6	46
6	15.4	36.9	19.6	41.4	26.9	39.8	32.3	42
7	19.0	33.7	21.1	39.1	35.3	52.1	49.7	49
8	8.4	29.2	6.7	30.0	10.0	23.3	9.3	11
9	24.5	48.9	21.4	40.0	29.5	42.0	26.7	26
10	21.9	65.6	20.6	61.8	57.2	61.9	68.8	70
D.C.	0	0			0	40.0	25.0	

[34] Federico, *supra* note 7, at 236.

[35] C. Dann, *Floor Discussion of Mr. Cooch's Paper,* DYNAMICS OF THE PAT. SYS. at 57 (1960).

[36] Dearborn & Boal, *supra* note 29, at 23.

[37] Tegtmeyer, *supra* note 4, at 22. Valid plus invalid = total.

[38] Baum, *supra* note 14, at 762. Table only gives figures for valid patents, no indication of infringements. Other tables have had valid and invalid = total patents.

The pattern of courts of appeals invalidity rates over time has also been described by C. Marshall Dann.[39] Dann uses a three year moving average of the number of patents held valid and infringed as a percent of total adjudicated patents for the periods 1925 through 1962. He found a variable pattern with a high of 40 percent found valid (around 1927) to a low of 15 percent found valid (around 1941 and 1953). He speculates that the decline through the 1930s was due to the depression and the antimonopoly feelings of the New Deal and the TNEC hearings. The *Cuno* case,[40] in which the Supreme Court announced the "flash of genius" doctrine, and the *A&P*[41] and *Crest*[42] cases, in which the Court set strict standards of inventiveness, account for the low validity rates in these years. The increasing validity rates since 1953 are attributed to the 1952 Patent Act[43] in which Congress stated, "Patentability shall not be negatived by the manner in which the invention was made".[44] This language was intended to eliminate the "flash of genius" doctrine. Dann's accounts of the pattern over time of courts of appeals invalidity rates, suggest that the courts were responding to changing standards set by the Supreme Court and Congress regarding the level of inventive activity required.

Validity and Subject Matter

The great unexplained variation in validity and invalidity rates among various studies has been discussed and the apparent causes therefore noted. The last few tables show the subject matter of adjudicated patents and the predominant grounds for invalidity judgments. Because Tegtmeyer and Dearborn and Boal are the major sources of data for these tables, the difference in numbers and percentages are still left unexplained.

Table 11 shows the subject matter of patents adjudicated by the courts of appeals and the percentage of patents judged valid and infringed. Mechanical patents, particularly mechanical apparatus patents, are adjudicated most often. Chemical product and process patents, however,

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[39] C. Dann, *Adjudication of Patents Under the 1952 Act,* THE ENCYCLOPEDIA OF PAT. PRAC. & INVENTION MANAGEMENT at 20 (1964). *See also,* Dann, *supra* note 35, at 54.

[40] Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941), *amended* 314 U.S. 587 (1942).

[41] Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147 (1950), *reh. den.* 340 U.S. 918 (1951).

[42] Crest Specialty v. Trager, *mem.,* 340 U.S. 147 (1950), *ref'd per curiam* 341 U.S. 912 (1951), *reh. den.* 341 U.S. 934 (1951).

[43] 35 U.S.C. § 1 *et. seq.* (1952).

[44] 35 U.S.C. § 103 (1952).

TABLE 11
PATENTS ADJUDICATED BY COURTS OF APPEALS BY SUBJECT MATTER

Subject Matter of Patents	1956-57[45]		1953-63[46]		% Not Invalid
	Number of Patents	% Valid & Infringed	Number of Patents	% Valid & Infringed	
Chemical	40	42.5	98	32.7	48.0
Mechanical	77	23.4	482	23.8	30.9
Electrical	5	20.0	108	30.6	49.2
Design			42	28.6	41.1
Plant			4	0	25.0
Process Patents	32	37.5			
Apparatus Patents	70	31.4			
Products Patents	33	27.3			
Chemical Product	15	53.3			
Chemical Process	22	45.5			
Chemical Apparatus	12	33.3			
Mechanical Product	17	5.9			
Mechanical Process	10	20.0			
Mechanical Apparatus	54	31.5			
Electrical Product	1	0			
Electrical Process	0	-			
Electrical Apparatus	4	25.0			

[45] Dann, *supra* note 35, at 63.

[46] Dearborn & Boal, *supra* note 29, at 23.

are most likely to be judged valid and infringed. Note that the totals of the chemical product, process, and apparatus cases do not equal the number of chemical and mechanical cases at the top of the table. This discrepancy was not explained by Dann.

Grounds for Invalidity Decisions

Tables 12 and 13 illustrate the grounds used for invalidity decisions in the circuit courts of appeals. Section 103 of the Patent Act specifies the level of invention required for the grant of a patent.

TABLE 12
GROUNDS OF INVALIDITY IN COURTS OF APPEALS

Year	Total Patents Adjudicated	Invalid Patents % of Total	Invalid for Lack of Invention	
			% of Total	% of Those Invalid
1953 [47, 48]	13, 66	69.2, 62.2	61.5, 53.1	88.9, 85.4
1954 [47, 48]	46, 61	76.2, 75.5	67.4, 60.7	88.6, 80.4
1955 [47, 48]	40, 44	72.2, 63.6	60.0, 50.0	82.8, 78.6
1956 [47, 48]	52, 80	69.1, 51.3	69.2, 42.5	100.0, 82.8
1957 [47, 48]	63, 74	69.6, 64.9	60.3, 50.0	86.4, 77.1
1958 [47, 48]	56, 60	62.5, 66.7	58.9, 55.0	94.3, 82.5
1959 [47, 48]	50, 70	68.0, 57.1	58.0, 50.0	85.3, 87.5
1960 [47, 48]	48, 62	60.2, 51.6	43.8, 32.3	72.4, 62.4
1961 [47, 48]	55, 59	51.0, 42.4	38.2, 25.4	75.0, 60.0
1962 [47, 48]	46, 62	54.3, 48.3	45.6, 41.8	84.0, 86.6
1963 [47, 48]	66, 96	66.6, 53.2	53.0, 35.5	79.5, 66.7
1964 [47]	73	76.3	68.5	90.9
1965 [47]	65	53.9	46.2	85.7
1966 [47]	62	77.2	62.9	81.2
1967 [47]	59	62.5	49.2	78.4
1968 [47]	75	69	62.7	90.4

That this is the ground most often used in patent litigation is shown by the ratios of patents invalid for lack of invention to those patents judged invalid. In courts of appeals decisions for 1953-1963, Dearborn and Boal report that 57.4 percent of adjudicated patents were invalid and that 77.7 percent of those deemed invalid were judged invalid for lack of invention.[49] Dearborn and Boal state, "(T)he reason for the

[47] Tegtmeyer, *supra* note 4, at 21.

[48] Dearborn & Boal, *supra* note 29, at 24.

[49] 35 U.S.C. § 103 (1952).

prevalence of this ground is probably the fact that this is the most subjective of the various usual patent defenses."[50] Tegtmeyer's study of invalidity in courts of appeals found that in 85.6 percent of the cases where there was a determination of an invalid patent, the decision was based on § 103. However, this does not mean that claiming lack of invention will most likely lead to a judgment of invalidity since 85 percent of all patent cases involved § 103 and 85.6 percent of the valid and infringed patent judgments also used § 103.[51]

To determine whether circuits with high rates of invalidity judgments used the ground of lack of invention significantly more than other circuits, the author did a simple rank correlation between percent of patents invalid by circuit (from Table 13) and patents invalid for lack of invention as a percent of those invalid, also by circuit. This test showed little correlation (about 11 percent) between high invalidity rates and high use of § 103.

TABLE 13
GROUNDS OF INVALIDITY BY CIRCUIT, 1953-63[52]

Circuit	Total Patents Adjudicated	Invalid Patents % of Total	Invalid for Lack of Invention	
			% of Total	% of Those Invalid
1	49	57.1	34.7	60.6
2	90	73.4	65.6	89.4
3	71	77.5	57.8	74.5
4	62	45.1	35.5	78.5
5	82	40.3	26.9	66.7
6	93	60.2	53.8	89.3
7	119	47.9	37.0	77.2
8	30	76.7	56.7	73.8
9	112	58.0	42.0	72.3
10	21	38.1	33.3	87.5
D.C.	5	60.0	40.0	66.7

Federico conducted a study of 50 specific patents found invalid by courts of appeals in 1954 and 1955.[53] He found that the ground of lack of invention or anticipation was used for 43 of the 50 patents (86 percent). A possibly important reason behind these invalidity findings might be the use by the courts of prior art references that differ

[50] Dearborn & Boal, *supra* note 29, at 25.

[51] Tegtmeyer, *supra* note 4, at 21.

[52] Dearborn & Boal, *supra* note 29, at 24.

[53] Federico, *supra* note 7, at 245, 249.

from those used by the patent examiner. Federico found that for the 40 cases in which the references used in the decision were mentioned, 34 cases had new references cited. In 17 of these 34 cases, the decision was a direct result of the new references, while in the remaining cases the holding of the invalidity may or may not have been caused by the new references.

Federico's results suggest that court judgments of invalidity of issued (and examined) patents are not only due to different standards of invention even though 103 is often cited. Invalidity judgments are also a result of incomplete examination of applications by the Patent Office.

Conclusions

One reason that has been suggested for invalidity judgments is the difference in the information on the state of the art available to the Patent Office examiners and to the courts. However, strong arguments have been made that courts set higher standards of invention than does the Patent Office in part because of disapproval of secret *ex parte* Patent Office examination procedures and in part because of a distrust of the monopoly powers granted by a patent.[54] The reasons for the variance in patent validity rates among circuit courts may lie in the different philosophies of the judges and the disapproval and distrust mentioned above. However, the literature reviewed here has not attempted to explain the variance.

The studies surveyed show that the rate of patent validity or invalidity judgments is not well established. There are large, unexplained differences among the studies cited in the absolute numbers of patents adjudicated and in the percentages of valid patents. The question remains, of course, whether accuracy in validity rates is important. A value of validity rates is that they indicate differences in patent standards between the courts and the Patent Office. It is not clear whether it is important to explain completely the variations among patent validity studies that show, for example, 50 percent held invalid and 75 percent held invalid. For policy purposes, patent invalidity rates in the 50-75 percent range may indicate the same degree of concern over patent quality. However, if one study were to show a 10 percent invalidity rate and another a 90 percent rate, the source of this discrepancy would be much more important to the es-

[54] *See* Baum, *supra* note 14.

tablishment of the policy implications of the invalidity rate. The value of general validity rates to the patentee or to the potential infringer is also unknown and so far appears to be unstudied. While the ability of a patent to provide an incentive to innovation is influenced by validity rates, it is impossible to determine what the effects will be.

Description of the Invention*

Paul T. Meiklejohn**

The first paragraph of 35 U.S.C. § 112 requires, *inter alia,* that every specification contain a written description of the invention.[1] The Court of Customs and Patent Appeals (hereinafter CCPA) has recently construed the written description section of that statute in various factual settings. One opinion questions the very existence of a separate description requirement.[2] Many other opinions by the court appear to presage the emergence of a more relaxed approach to the requirement.[3]

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[1] The first paragraph of 35 U.S.C. § 112 reads as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

For a discussion and analysis of pre-1972 description cases, *see* Gholz, *Recent Developments in the C.C.P.A. Relating to the First Paragraph of 35 U.S.C. 112,* 54 J. PAT. OFF. SOC'Y 768 (1972).

[2] In re Barker, 559 F.2d 588, 194 U.S.P.Q. 470 (C.C.P.A. 1977).

[3] The court has expressly disavowed the existence of any "rules" in this area. Cases are decided on their own particular facts on a case by case basis. *See* In re Edwards, C.C.P.A. Appeal No. 77-532, at 7, decided January 12, 1978; In re Driscoll, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977); and In re Wertheim 541 F. 2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976).

For example, many recent cases have departed even further than *In re Lukach*[4] from the rather strict and frequently formalistic *in haec verbis* standard. Even the requirements of the "necessary and only reasonable construction" test of inherency appear to have been relaxed somewhat.[5] The burden has been placed on the Patent and Trademark Office (hereinafter PTO) to show lack of description.[6] This has been done in the past in cases dealing with enablement[7] and utility[8] issues.

The description issue has frequently arisen in the context of 35 U.S.C. §§ 119 and 120[9] whereby the applicant must obtain the benefit of a prior foreign or United States application in order to antedate a reference which would otherwise anticipate his claims.[10] Frequently,

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[4] 442 F.2d 967, U.S.P.Q. 795 (C.C.P.A. 1971). *See also,* In re Edwards, *supra* note 3; In re Hogan, 559 F.2d 595, 608, 194 U.S.P.Q. 527, 539 (C.C.P.A. 1977); In re Voss, 557 F.2d 812, 817, 194 U.S.P.Q. 267, 271 (C.C.P.A. 1977); and In re Wertheim, *supra* note 3, at 265, 191 U.S.P.Q. at 98.

[5] *See* In re Hogan, *supra* note 4, at 608, 194 U.S.P.Q. at 539, where the court concluded that " 'polymers of 4-methyl-1-pentene' describes homopolymers ... of 4-methyl-1-pentene because that is the necessary and only reasonable construction' to be given this statement [citations omitted]. If copolymers were being described, the sentence would refer to 4-methyl-1-pentene *and some other monomer.*" [Emphasis in original]

[6] *See* In re Edwards, *supra* note 3, at 13-14; In re Salem, 553 F.2d 676, 682, 193 U.S.P.Q. 513, 518 (C.C.P.A. 1977); and In re Wertheim; *supra* note 3, at 263, 191 U.S.P.Q. at 97.

[7] *See* In re Armbruster, 512 F. 2d 676, 677, 185 U.S.P.Q. 152, 153 (C.C.P.A. 1975).

[8] *See* In re Langer, 503 F. 2d 1380, 1391-92, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

[9] *See* notes 53 & 54 *infra.* The description issue may also arise in a reissue context. *See* In re Salem, *supra* note 6.

[10] § 120 expressly requires that a prior U.S. application comply with the first paragraph of § 112 if the benefit of its filing dates is desired. The filing date of a prior U.S. application under 35 U.S.C. § 120 was needed to antedate the reference in In re Edwards, *supra* note 3; In re Sichert, 556 F.2d 1154, 196 U.S.P.Q. 209 (C.C.P.A. 1977); In re Driscoll, *supra* note 3; In re Johnson, 558 F.2d 1008, 194, U.S.P.Q. 187 (C.C.P.A. 1977); In re Voss, *supra* note 4; and In re Blaser, 556 F.2d 534, 194 U.S.P.Q. 122 (C.C.P.A. 1977). § 119 does not expressly require that a prior foreign application comply with the first paragraph of § 112 if the benefit of its filing date is desired, but it has been so construed. *See* In re Wertheim, *supra* note 3; and Kawai v. Metlesics, 480 F.2d 880, 887-88, 178 U.S.P.Q. 158, 164 (C.C.P.A. 1973).

this prior art is applicant's own foreign-filed application and contains exactly the same disclosure as the ancestral United States case.[11]

Existence of a Separate Description Requirement

The very existence of a written description requirement separate from the enablement requirement was at issue in *In re Barker*.[12]

Facts and Opinion of the CCPA. The appellant in *Barker* argued "that the 'enablement' requirement of the first paragraph of 35 U.S.C. § 112 cannot be read separately from the 'description' requirement therein."[13] The majority did not agree.

Judge Miller, writing for himself and Judge Lane, first noted that the CCPA had in the past recognized the separate description requirement[14] as well as instances where a specification could be enabling without complying with the description requirement.[15] The

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[11] *See* In re Edwards, *supra* note 3; In re Sichert, *supra* note 10; In re Driscoll, *supra* note 3; In re Johnson, *supra* note 10; In re Voss, *supra* note 10; and In re Blaser, *supra* note 10. The fate of some of the claims in some of these applications illustrates the dangers in filing continuation-in-part applications when a foreign counterpart of a prior U.S. application has issued. In this connection, *see The Continuation-In-Part Practice – Should It Be Abolished?*, 55 J.P.O.S. 542 (1973).

[12] 559 F. 2d 588, 194 U.S.P.Q. 470 (C.C.P.A. 1977).

[13] *Id.* at 591, 194 U.S.P.Q. at 472.

[14] The opinion cites In re Bowen, 492 F.2d 859, 864, 181 U.S.P.Q. 48, 52 (C.C.P.A. 1974); In re Smith, 481 F.2d 910, 914-15, 178 U.S.P.Q. 620, 623-25 (C.C.P.A. 1973); and In re Moore, 439 F.2d 1232, 1235, 169 U.S.P.Q. 236, 238-39 (C.C.P.A. 1971).

[15] The opinion cites Fields v. Conover, 443 F.2d 1386, 1391, 170 U.S.P.Q. 276, 280 (C.C.P.A. 1971); and In re Ruschig, 379 F.2d 990, 995-96, 154 U.S.P.Q. 118, 123 (C.C.P.A. 1967). A specification could be *enabling* with respect to the method of preparation of ployesters, for example, if it disclosed how to make various species of these polyesters. This same specification, although describing individual polyester species, might not be found to *describe* polyesters generally because of the lack of a teaching in the specification as filed that the method applies to all polyesters. For cases where it was recognized that a specification could be enabling, yet not contain a description of the invention, *see* In re Mott, 539 F.2d 1291, 190 U.S.P.Q. 536 (C.C.P.A. 1976); and In re DiLeone, 436 F.2d 1404, 168 U.S.P.Q. 592 (C.C.P.A. 1971). The converse could also be true, i.e., a specification could contain a description of the invention as broadly as claimed yet fail to be enabling. For example, the specification as filed might contain a description of the claimed process which is as broad as the claim, yet fail to be enabling because the examiner has produced evidence that one or more polyesters within the claimed class cannot be prepared by that process. For a case in which it was recognized that the specification could describe the invention, yet not satisfy the enablement requirement, *see* In re Angstadt, 537 F.2d 498, 190 U.S.P.Q. 214 (C.C.P.A 1976).

Court then engaged in a language analysis of paragraph one of the present § 112[16] and its predecessors and concluded that such a separate description requirement has always existed.

The purpose of such a description requirement is to ensure that the inventor possessed the claimed subject matter as of the filing date of the application upon which he relied.[17] The court determined that such a separate description requirement existed and then looked to the particular facts in *Barker* to see if it was satisfied. The claimed invention related to a "method of making prefabricated panels of wooden shingles."[18] Claim 18, the sole claim on appeal, read as follows:

> The method of making substantially uniform, regular modular prefabricated shingle panels which comprises selecting individual wooden shingles of at least three different predetermined widths, each shingle having a tip portion and a butt portion and being tapered in thickness away from the butt portion toward the tip portion, selecting elongated backing boards all of substantially the same predetermined length and width, each backing board having a length at least as great as the aggregate width of *at least six shingles* and of a width less than one-half the length of a shingle, laying the selected shingles of different predetermined widths in only a single course in each of at least two repetitive identical series, each series including at least three different selected, predetermined widths along the length of each backing board, with their tip portions overlying the backing board and with their butt portions overhanging one edge of the backing board in free cantilever fashion without any underlayer for a distance at least as great as the width of the backing board and thereby forming substantially identical shingle arrangements in all panels with respect to such widths of the shingles, and securing the shingles to the backing boards in such arrangements only by their tip portions. [Emphasis supplied by court.][19]

At issue was whether the phrase "at least six shingles," which was added to the claim by amendment, was adequately supported in the specification. The court found that the specification and drawings

> indicate that appellants' contemplated backing boards of four and eight foot lengths having a repetitive series of eight or sixteen shingles thereon.

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[16] The dissent also engaged in statutory analysis and arrived at the opposite conclusion. 559 F.2d at 594-95, 194 U.S.P.Q. at 475.

[17] *See* In re Hogan, *supra* note 4, at 592, 194 U.S.P.Q. at 473. The C.C.P.A. has consistently stated that the function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him. *See, e.g.,* In re Edwards, *supra* note 3, at 7; In re Blaser, *supra* note 10, at 537, 194 U.S.P.Q. at 124-25; In re Wertheim. *supra* note 3, at 262, 191 U.S.P.Q. at 96; and In re Smith and Hubin, *supra* note 14, at 914, 178 U.S.P.Q. at 624.

[18] In re Barker, *supra* note, 2 at 589, 194 U.S.P.Q. at 471.

[19] *Id.* at 590, 194 U.S.P.Q. at 472.

> Thus, the limitation 'at least six shingles' in the claim is not supported by the description of the invention in the specification or drawings and also constitutes new matter.[20]

Judge Rich concurred, thinking there was much ado about nothing.[21] He believed the issue was simply "new matter" and that the claim should be rejected on that ground. He further noted that the particular wording of paragraph one of § 112 requires "case-by-case treatment of issues of the sufficiency of description and enablement which, I agree, are distinct though commingled requirements."[22]

Judge Baldwin dissented without opinion. Chief Judge Markey, who dissented with an opinion, engaged in an analysis, as did the majority, of the particular wording of the first paragraph of present § 112, but came to the opposite conclusion. He characterized the majority opinion as a mistaken attempt to

> create historical and current statutory support for a 'separate description' requirement, which was solely a judicial (and unnecessary) response to chemical cases in which appellants were arguing that those skilled in the art 'might' make and use a claimed invention.[23]

In Judge Markey's opinion, a description requirement separate from the enablement requirement is superfluous because "the board's use of the same alleged defect as the foundation for *three* rejections."[24] [Emphasis in original.]

Since Judge Markey believed that the separate description requirement was developed in complex chemical cases, he felt it should not be applied to this "simplest of mechanical inventions."[25] Furthermore, he did not see how the enablement requirement could be satisfied without necessarily describing the invention.[26] Judge Markey concluded, "I can't escape the view that eight includes 'at least 6'."[27]

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[20] *Id.* at 593, 194 U.S.P.Q. at 474.

[21] "[F]or a relatively uncomplicated case, the opinion unduly complicates matters." *Id.* at 594, 194 U.S.P.Q. at 475.

[22] *Id.* at 594, 194 U.S.P.Q. at 475.

[23] *Id.*

[24] *Id.* at 595, 194 U.S.P.Q. at 475.

[25] *Id.*

[26] For an example of how the enablement requirement can be satisfied without describing the invention, *see* note 15, *supra.*

[27] In re Barker, *supra* note 2, at 595, 194 U.S.P.Q. at 476, Judge Markey probably intended to say "eight is included in 'at least 6'."

Analysis. In addition to the historical and current statutory analysis relied upon by Judge Miller to justify his finding of a separate description requirement, he also looked at the so-called "essential goal" of the description requirement. "The specification as originally filed must convey clearly to those skilled in the art the information that the applicant has invented the specific subject matter later claimed."[28]

This goal appears to be very similar to the one outlined by the Supreme Court in *Evans v. Eaton*[29] wherein the Court discussed the analogous statutory section. In *Evans,* the Court found that the purpose of this section of the statute is to

> put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known... and... for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects...[30]

Such a description requirement might have been necessary in 1822, since the 1793 Patent Act did not require claims.[31] Thus, some means was needed to put the public on notice as to what the inventor believed his invention to be. The same justification for a description requirement separate from the enablement requirement does not exist in 1978, however, since the 1952 Patent Act requires the inclusion of "one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[32]

Although the "essential goal" of the description requirement as envisioned by the majority does not appear to be justified in view of the 1952 Patent Act, the existence of a description requirement separate from an enablement requirement is not "superfluous" as suggested by the dissent. There may be imagined many factual situations, especially those involving chemical cases, wherein the specification fulfills the enablement requirement but fails to describe the invention.[33]

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[28] *See* In re Smith and Hubin, *supra* note 14, at 914, 178 U.S.P.Q. at 624; and In re Ruschig, *supra* note 15, at 996, 154 U.S.P.Q. at 123.

[29] 20 U.S. (7 Wheat.) 356 (1822).

[30] *Id.* at 434.

[31] *See* In re Barker *supra* note 2, at 592, 194 U.S.P.Q. at 473.

[32] 35 U.S.C. § 112, second paragraph.

[33] *See* note 15 *supra.*

Thus, although a specification may be enabling without describing the invention, in many cases a description requirement is not necessary because such a specification might also be objected to for the introduction of "new matter."[34] The new matter prohibition is set forth in 35 U.S.C. § 132 which states, in pertinent part: "No amendment shall introduce new matter into the disclosure of the invention."

This section only applies when new matter is introduced by *amendment.* Admittedly, this covers a large number of the situations in which a rejection for failure to describe the invention could be made. However, the new matter prohibition does not cover the situation where a continuation-in-part (hereinafter CIP) application is filed and the applicant attempts to rely on a prior United States or foreign priority application.[35] The prior United States or foreign application could be enabling with respect to the invention claimed in the CIP application yet not describe the invention so claimed.[36]

Without the existence of a separate description requirement there would be no statutory basis[37] for denying an applicant the right to the filing date of the prior filed application even though it was clear that the applicant did not appreciate that the broad class of subject matter claimed would be useful in his invention at the time he filed the filing prior application. Even the new matter prohibition would not be violated since the new matter was added in a CIP application, rather than by amendment as 35 U.S.C. § 132 requires.

An example might be helpful. In *In re Wertheim,*[38] discussed below,[39] a prior United States and a prior Swiss application were alleged by the Board of Appeals (hereinafter Board) not to contain a written description of the range "at least 35%" solids content which was claimed in the CIP application. There was no question of

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[34] Indeed, the C.C.P.A. has stated that a "new matter rejection under 35 U.S.C. 132, predicated on claim language, is tantamount to a rejection for lack of a written description of the claimed invention under 35 U.S.C. 112, first paragraph." In re Hogan, *supra* note 4, at 608, 194 U.S.P.Q. at 539. *See also* in re Salem, *supra* note 6, at 682, 193 U.S.P.Q. at 517-18; and In re Wertheim, *supra* note 3, at 265, 191 U.S.P.Q. at 99.

[35] *See* note 10 *supra.*

[36] *See* notes 10 & 15 *supra.*

[37] There is some authority for a non-statutory basis for denying an applicant the right to the benefit of a prior filed application or even the benefit of his filing date in the same application. For a discussion of the so-called "late claiming" doctrine, *see Is There a Viable Doctrine of Non-Statutory Late Claiming as a Defense in Patent Litigation,* 50 J. PAT. OFF. SOCY. 676 (1968).

[38] In re Wertheim, *supra* note 3.

[39] *See* text accompanying notes 56-69 *infra.*

enablement involved. The parent United States and Swiss applications both stated that coffee extract should be concentrated "... until a concentration of 25 to 60% solid matter is reached. Examples in each [application] disclose specific embodiments having solids contents of 36% and 50%."[40]

The CCPA held that the claimed range "at least 35%" was not described in the parent United States or Swiss applications and thus the applicants were not entitled to rely on the filing dates of those applications. Since the technology involved was unpredictable, the disclosure of the prior filed applications would not necessarily have put the invention in the possession of the public. However, without the existence of a separate description requirement, there would have been no way to prevent applicants from relying upon the earlier filing dates since (a) the enablement requirement was satisfied, and (b) new matter concepts were irrelevant because no amendment had been made.

Thus, the dissent's assertion that it is superfluous to have a description requirement separate from the enablement requirement appears to be incorrect.[41] Furthermore, the dissent's conclusion that there is no separate description requirement appears to be inconsistent with the court's position in other cases, such as *Wertheim,* where "description of the invention" was clearly the issue.[42]

It is interesting to note that the CCPA did not even have to address the issue of a separate description requirement in *Barker* since the only claim on appeal was also rejected for lack of enablement and the

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[40] In re Wertheim, *supra* note 3, at 262, 191 U.S.P.Q. at 96.

[41] *See* text accompanying notes 34-36 *supra.*

[42] Chief Judge Markey authored the opinion for the majority in In re Johnson, *supra* note 10, at 1009, wherein he characterized the rejection as involving "a written description issue under 35 U.S.C. § 112, first paragraph." Other decisions in which Judge Markey participated but in which he did not question the separate description requirement issue include In re Sichert, *supra* note 10; In re Hogan, *supra* note 4; In re Voss, *supra* note 3; In re Driscoll, *supra* note 3; In re Farrow, 554 F.2d 468, 193 U.S.P.Q. 689 (C.C.P.A. 1977); In re Salem, *supra* note 6; In re Hughes, 550 F.2 1273, 193 U.S.P.Q. 141 (1977), In re Wertheim *supra* note 3; In re Mott, 557 F.2d 266, 190 U.S.P.Q. 536 (C.C.P.A. 1976); and In re Winkhaus, 527 F.2d 637, 188 U.S.P.Q. 129 (C.C.P.A. 1975). *See* In re Blaser, *supra* note 10, at 538, 194 U.S.P.Q. at 125 where it is specifically stated that enablement is not at issue.

addition of new matter.[43] The issue of a separate description requirement should have been challenged in a case where no other rejection could have been made.[44]

The conclusion of the majority in *Barker* (that there was no description of "at least six shingles" by a specification that disclosed a "series of eight or sixteen" shingles) is discussed *infra* and compared with the decisions in chemical cases where description was in issue. Suffice it to say for now that the appellants in *Barker* have filed a petition for writ of certiorari in the United States Supreme Court. The basis asserted for the petition is that 35 U.S.C. § 112 is a fundamental federal patent statute and the CCPA is clearly divided as to its interpretation. As of this writing, the petition has been neither granted nor denied.

Demise of the In Haec Verbis Standard

Given the existence of a separate description requirement, several recent CCPA cases have interpreted it quite liberally, particularly in two kinds of factual settings. In the first situation,[45] the claimed invention was generally of the chemical type[46] and involved numerical ranges which defined properties,[47] composition ranges,[48] process variables,[49] and the like.[50] At issue in each was whether a particular numerical range was described by a different range either in the same application or in a prior United States or foreign counterpart

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[43] *See* text accompanying notes 34-36 *supra*. It should be noted that 35 U.S.C. § 132 states that no new matter may be introduced into the "disclosure" of the invention. At least in their Petition for Writ of Certiorari in the Supreme Court, the appellants in *Barker* argue that "disclosure" may not include the claim and, apparently, the introduction of new subject matter into a *claim* but not into the *disclosure* does not constitute new matter. The board's opinion in *Barker, supra* note 2, makes clear that "disclosure" includes the claim. Although the C.C.P.A. did not specifically address this point, the majority at least impliedly agreed with the board's definition.

[44] *See* text accompanying notes 34-36 *supra*. Such a case would be In re Wertheim, *supra* note 3, wherein the limitation "at least 35%" in a CIP application was found not to be described in prior filed applications. A new matter rejection was not appropriate since the claimed limitation was not introduced by amendment.

[45] In re Sichert, *supra* note 10; In re Barker, *supra* note 2; In re Voss, *supra* note 4; In re Blaser, *supra* note 10; and In re Wertheim, *supra* note 3.

[46] *See* note 45, *supra*. However, *Barker* involved a mechanical invention.

[47] In re Voss, *supra* note 4 (percent crystallinity).

[48] In re Sichert, *supra* note 10; In re Blaser, *supra* note 10; and In re Wertheim, *supra* note 3.

[49] In re Blaser, *supra* note 10 (temperature range).

[50] In re Barker, *supra* note 2 (number of shingles).

application that was being relied upon for the benefit of its filing date.

The second kind of factual situation also involved chemical inventions wherein the issue was whether a particular subgenus was described by a particular genus in an ancestral United States application.[51]

In all but one *(Barker, supra)*[52] of these cases, the description issue arose in the context of 35 U.S.C. §§ 119[53] and 120[54] wherein the applicant attempted to obtain the benefit of a prior filed United States or foreign application in order to antedate a prior art reference. It is interesting to note that in all of these cases except *Barker* the existence of a separate description requirement was essential to the rejection of the claims although that existence was not challenged. In *Barker,* however, the existence of the description requirement was not essential to the rejection[55] yet the existence of a separate description requirement was challenged.

Herein follows a summary and analysis of each of the cases within these two general categories.

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[51] In re Driscoll, *supra* note 3; and In re Johnson, *supra* note 10.

[52] *See* text accompanying notes 12-44 *supra.*

[53] Section 119 reads, in pertinent part, as follows:

Benefit of earlier filing date in foreign country; right of priority.

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed....

[54] Section 120 reads as follows:

Benefit of earlier filing date in the United States.

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

[55] A new matter rejection under 35 U.S.C. § 132 was also affirmed by both the board and the CCPA. *See* text accompanying note 34 *supra.*

—"Numerical Range" Cases

A. In re Wertheim. An apparent relaxation of what some might consider to have been the description "rules," first occurred in *In re Wertheim* although the majority opinion makes clear that there are no "rules" in this area.[56] The appellants in *Wertheim* had to rely on both a United States parent and a prior Swiss application in order to antedate a prior art reference. At issue was whether certain of the claimed numerical ranges were described in these applications. Also, with respect to claim 6, an additional issue was whether the claimed limitation "that the frozen foam be ground 'to a particle size of at least 0.25mm' before it is dried, was added to the instant application in violation of 35 U.S.C. § 132."[57]

The limitations at issue with respect to the description requirement were " 'at least 35% [solids content]' in claim 1, 'between 35% and 60% soluble solids' in claims 2 and 4, and 'pressure of less than 500 microns' and 'final temperature of less than 110°F.' in claim 4."[58]

There was no question that the above limitations were all described in the subject application. Furthermore, since the disclosures of the parent United States and the prior foreign applications were "virtually identical," the court considered only the disclosure of the Swiss application.[59]

The Swiss application disclosed that "the coffee extract initially produced by percolation of water through ground roasted coffee is concentrated prior to foaming by suitable means 'until a concentration of 25 to 60% solid matter is reached.' Examples in each disclose specific embodiments having solids contents of 36% and 50%."[60] The burden was placed on the PTO to present "evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."[61] That burden was satisfied for the claim limitation "at least 35%" solids content by the

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[56] In re Wertheim, *supra* note 3, at 263, 191 U.S.P.Q. at 97.

[57] *Id.* at 265, 191 U.S.P.Q. at 99. Issues concerning "obviousness" under 35 U.S.C. § 103 were also discussed in *Wertheim.* These issues will not be treated here since they do not relate to the description question.

[58] *Id.* at 264, 191 U.S.P.Q. at 94-95.

[59] *Id.* at 262, 191 U.S.P.Q. at 96.

[60] *Id.*

[61] *Id.* This requirement is new. Although the burden was on the P.T.O. initially whenever enablement and utility were at issue, *see* notes 8 & 9, *supra,* it had never been held (until *Wertheim*) that the P.T.O. had the initial burden in description cases.

PTO[62] "pointing to the fact that claim 1 reads on embodiments outside the scope of the description."[63] The burden then shifted to appellants to prove that the upper limit (60%) is inherently disclosed "in 'at least 35%,' as that limitation appears in claim 1."[64] That burden was not satisfied by appellants.

The limitations "pressure of less than 500 microns" and "final product temperatures of less than 110°F." in claim 4 were also found not to be described in the Swiss application. However, the limitation "between 25% and 60% presented a different question."[65] The court found that the PTO did not present sufficient evidence to doubt that the broader (25% to 60%) described range also described the narrower (35% to 60%) claimed range. In arriving at this conclusion, the court stated,

> We note that there is no evidence, and the PTO does not contend otherwise, that there is in fact any distinction, in terms of the operability of appellants' process or of the achieving of any desired result, between the claimed lower limit of solids content and that disclosed in the Swiss application.... Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. *In re Baird,* 52 CCPA 1747, 348 F.2d 974, 146 U.S.P.Q. 579 (1965); *In re Draeger,* 32 C.C.P.A. 1217, 150 F.2d 572, 66 U.S.P.Q. 247 (1945).[66]

The court was careful to distinguish between numerical range cases such as *Wertheim* and

> broad generic *chemical compound* inventions, for example, as in *In re Ruschig, supra,* in which each compound within the genus is a separate embodiment of the invention... What those skilled in the art would expect from using 34% solids content in the concentrated extract prior to foaming instead of 35% is a different matter from what those skilled in the art would expect from the next adjacent homologue of a compound whose properties are disclosed in the specification.[67] [Emphasis by the court]

The "new matter" rejection was also reversed. In arriving at this conclusion, the court stated:

> We conclude that the originally filed specification clearly conveys to those of ordinary skill in the art that appellants invented processes in which the

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[62] *Id.* at 263, 191 U.S.P.Q. at 97.

[63] *Id.*

[64] *Id.* at 264, 191 U.S.P.Q. at 97.

[65] *Id.* at 264, 191 U.S.P.Q. at 98.

[66] *Id.* at 264-65, 191 U.S.P.Q. at 98.

[67] *Id.* at 264, 191 U.S.P.Q. at 98. For a discussion of cases involving generic chemical compound inventions, *see* text at "Numerical Range" Cases.

frozen foam is ground to a particle size of 'at least 0.25 mm,' and not, as the PTO asserts, only processes in which the particle sizes are no larger than 2 mm. *See In re Smythe, supra.*

The specification states, *inter alia* (emphasis ours):

> At the end of the [cooling] belt the extract is removed as a continuous rigid sheet which *may* then be broken up into fragments suitable for grinding. These fragments *may, for example,* be ground to a particle size which is *preferably* within the range 0.25 to 2.0 mm.
>
> ....
>
> In a modification of the process, the frozen extract may be freeze-dried in the form of *plates or lumps* which are *subsequently* ground to the desired particle size.

The examples speak of drying frozen ground particles of sizes between 0.1 and 2 mm. While the specification indicates that the 0.25 to 2.0 mm range is preferred, we think it clearly indicates that, as an alternative embodiment of appellants' invention, the foam may be dried in lumps or plates of undisclosed size which are reduced to the obviously smaller preferred particle size by grinding only *after* being dried. The solicitor argues that the claimed 'range' has no upper limit, wherefore it is not disclosed. The clear implication of this disclosed modification is that appellants' specification does describe as their invention processes in which particle size is 'at least 0.25 mm,' without upper limit, as delineated by the rejected claims.[68]

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[68] *Id.* at 265-66, 191 U.S.P.Q. at 99.

Judge Miller dissented with respect to claim 1 although he did not state whether he disagreed with the majority's view on the description issue.[69]

B. In re Blaser. In *Blaser,* Judge Kashiwa of the United States Court of Claims, sitting with the CCPA by designation,[70] affirmed in part and reversed in part a decision of the Board on a description issue similar to that involved in *Wertheim.* Two kinds of rejections were involved in *Blaser* although the legal issue underlying each rejection was the same.[71]

For ease of reference, claims 1, 7 and 12 are presented with the disputed limitations underscored as follows:

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[69] Judge Miller believed that all the appellants had to do to overcome the prior art reference was to "establish a reduction to practice of sufficient subject matter to render the claimed invention obvious to one of ordinary skill in the art." *Id.* at 273, 191 U.S.P.Q. at 105. His opinion concerning that issue reads, in part, as follows:

> I dissent on claim 1. The error of the majority in affirming the rejection stems from a misstatement of the issue. It is not necessary when antedating a reference under 35 U.S.C. 102 (a) or (e) to establish a prior reduction to practice, constructive or actual, of *all* the subject matter falling within the claims. It is necessary only to establish a reduction to practice of suffiecient subject matter to render the claimed invention obvious to one of ordinary skill in the art. In re Spiller, 500 F. 2d 1170, 182 U.S.P.Q. 614 (C.C.P.A. 1974). The majority errs, therefore, in seeking a description in appellants' parent and foreign priority applications to support the entire claimed subject matter as though these were the applications in which the claims appear. *See* In re Ziegler, 347 F.2d 642, 146 U.S.P.Q. 76, 52 (C.C.P.A. 1965). Appellants have clearly shown possession of enough of the invention to antedate Pfluger 1966 by establishing a prior constructive reduction to practice in their parent and foreign applications of specific embodiments disclosing concentrating to 50% and 36% total solids and be a broader disclosure of "25 to 60%." Although the rejection of claim 1 arises in the context of an attempt to initiate an interference, the rejection is clearly under 35 U.S.C. §102 (a) or (e) and not under Rule 204 (c), 37 C.F.R. §1.204 (c). Even if the rejection were under that rule, the substance of the rule's requirement for evidence sufficient to establish a prima facie case for a judgment of priority against Pfluger 1966 would be satisfied by the prior constructive reduction to practice of embodiments within claim 1 in appellants' parent and foreign applications. *Id.* at 273-74, 191 U.S.P.Q. at 105.

[70] 28 U.S.C. § 293 (a).

[71] The rejections were for "lack of description" and "new matter." A new matter rejection has been said by the C.C.P.A. to be tantamount to a rejection for lack of written description under 35 U.S.C. § 112. *See* note 34, *supra.*

1. A process for the manufacture of acylation products of a phosphorous acid having at least two phosphorous [sic] atoms in their molecules, which consists essentially of the steps of mixing one mol of phosphorus trichloride with from 2.5 to 3 mols of a mixture of carboxylic acid plus water, said acid being selected from the group consisting of an aliphatic monocarboxylic acid having 2 to 12 carbon atoms and benzoic acid; *the share of said water in said mixture being from 1.2 to 1.5 mols;* at a temperature up to 80°C; heating the reaction blend thus obtained, after completing of said mixing to 100°C to 160°C and recovering said acylation products.

7. A process for the manufacture of acylation products of a phosphorous acid having at least two phosphorus atoms in their molecules, which consists essentially of the steps of mixing one mol of phosphorus trichloride with from 2.5 to 3 mols of a mixture of carboxylic acid plus water, said acid being selected from the group consisting of an aliphatic monocarboxylic acid having 2 to 12 carbon atoms and benzoic acid; *the share of said water in said mixture being from 0.6 to 1.6 mols;* at a temperature up to 80°C; *heating the reaction blend thus obtained,* after completing of said mixing *to 80°C to 200°C* and recovering said acylation products.

12. The process of Claim 7, *wherein said share of said water in said mixture is from 1.2 to 1.6 mols.*[72]

Claims 1, 2, 4, 5 and 6 were rejected as allegedly containing "new matter."[73] The sole disputed limitation in these claims was "the share of said water in said mixture [or carboxylic acid and water] being from 1.2 to 1.5 mols."[74] The Board agreed with the applicants that the applicants' ancestral United States application (which contained six working examples) supported a range of from 1.2 to 1.5 mols. However, in the present application, appellants added two new examples (examples 1 and 2) which covered a range of 0.6 to 1.6 mols water. Examples 3-8 were virtually identical to the six examples of the ancestral United States application. The Board believed that in considering all of the relevant examples, there was no basis for "carving out specific examples 3-8 for the purpose of supporting the range of 1.2 to 1.5."[75]

The CCPA reversed, pointing out the Board's inconsistency in finding that the applicants had possession of the invention as of the filing date of the prior United States application but, in effect, lost possession of that subject matter in the present application which disclosed the original six examples plus two new ones.

Claims 7-12 were rejected over a foreign-filed counterpart of applicants' ancestral United States application. However, if the applicants were entitled to the filing date of their prior United States applica-

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[72] In re Blaser, *supra* note 10, at 535-36, 194 U.S.P.Q. at 123.

[73] *Id.* at 537, 194, U.S.P.Q. at 124.

[74] *Id.*

[75] *Id.*

tion, the foreign-filed counterpart would not be available as prior art. The Board felt that applicants were not entitled to the prior United States filing date because there was no description therein of the subject matter of claims 7-12.

The CCPA reversed claim 12 only. Claim 12 contains two disputed limitations: (a) "said share of said water in said mixture is from 1.2 to 1.6 mols,"[76] and (b) "heating the reaction blend... *to 80°C to 200°C.*"[77] The first limitation was held to be described in the applicants' earlier application since "the upper limit of 1.6 mols was expressly disclosed and examples 1-6 therein encompassed the range of 1.2 to 1.5 mols."[78] Although the temperature range of from 80°C to 200°C does not appear in the applicants' prior application *in haec verbis,* "60°C to 200°C" does so appear. Applying the rationale of *In re Wertheim* that a broad range describes a wholly subsumed narrower range in the absence of criticality,[79] the court concluded that "60°C to 200°C "describes "80°C to 200°C." The majority affirmed the rejection of claims 7-11 which, in addition to the "heating... to 80°C to 200°C" limitation, required that the share of the water in the mixture be "from 0.6 to 1.6 mols."[80]

The majority conceded that the upper limit of 1.6 mols was disclosed in the applicants' prior application but found that the lower limit was not. Concerning the latter point, they stated:

> After the filing date of SN 159, 159, appellants themselves disclosed a series of experiments which demonstrate that reduction of the amount of water below 0.6 mols renders their process unusable in practice due to greatly prolonged reaction times. It follows that appellants are not entitled to the benefit of this filing date for claims 7-11 on appeal, which recite 0.6 mols as the lower limit of water used. See *In re Wertheim, supra* at 264-65, 191 U.S.P.Q. at 98.[81]

Chief Judge Markey and Judge Baldwin dissented, believing that the "majority's treatment of these claims is... in direct conflict with its treatment of the others."[82] The theory of the dissent was that the prior application discloses that "some" water must be used and

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[76] *Id.* at 538, 194 U.S.P.Q. at 126.

[77] *Id.* at 538, 194 U.S.P.Q. at 125.

[78] *Id.* at 538, 194 U.S.P.Q. at 126.

[79] *See* text accompanying notes 56-69 *supra.*

[80] *Id.*

[81] 556 F.2d at 538, 194 U.S.P.Q. at 125.

[82] *Id.* at 539, 194 U.S.P.Q. at 126.

"some" describes 0.6 mols. Thus appellants "are merely claiming less than they would have had a right to claim"[83] in their prior United States application.

C. In re Voss. The description issue again arose in a § 120[84] context in *Voss*. A French patent which was based on the parent United States application of the subject United States application was asserted by the examiner to be an anticipation of all claims under § 102 (b). The applicant argued that he was entitled to the benefit of the filing date of his parent United States application. The examiner did not agree because the claim limitation "at least 50%" crystal content was, in his opinion, not described in the parent United States application. The appellant argued that the "50% limitation merely quantifies the percentage crystal content inherent in use of the term 'glass-ceramic material.' "[85]

The court looked to the particular technology involved to see if it, in fact, was inherently disclosed, and found that a patent which the prior United States application incorporated by reference[86] was in litigation.[87] In that litigation the following findings of fact were made by the District Court:

> (1) the change in properties in a glass ceramic begins at approximately 40% crystallinity and in most cases is complete at 60% crystallinity, (2) the 50% crystallinity limitation found in all claims of the Stookey '971 patent must be read in light of the patent's overall purpose to convert preformed glass articles to predominantly crystalline bodies with substantially crystalline properties, and (3) at the time the Stookey inven-

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[83] *Id.*

[84] *See* note 54 *supra.*

[85] In re Voss, *supra* note 4, at 818, 194 U.S.P.Q. at 271.

[86] *Id.* at 816, 194 U.S.P.Q. at 269. The following language was concluded to be sufficient to incorporate by reference in *Voss:*

> Reference is made to United States Patent No. 2,920,970, granted to S.D. Stookey, for a general discussion of glass-ceramic materials and their production." *See* also In re Hughes, 550 F.2d 1273, 1275, 193 USPQ 141, 143, where similar language was also found sufficient to incorporate by reference. In *Hughes,* a patent application was incorporated into a reference which was used to reject claims under 35 U.S.C. § 103. The incorporated language was such that when the reference and the incorporated language were read as a whole, it taught away from the claimed invention. Accordingly, the rejection under § 103 was reversed.

[87] Corning Glass Works v. Anchor Hocking Glass Corp., 253 F.Supp. 461, 149 U.S.P.Q. 99 (D. Del. 1966), *modified* 374 F.2d 473, 153 U.S.P.Q. 1 (3d Cir. 1967).

> tion was made it was possible to only roughly determine the percent crystallinity of a glass-ceramic material.[88]

The PTO cited another patent "to show that glass-ceramic materials can have as low as a 20% crystal content."[89] In a footnote to this statement, the court said:

> Even if we were to assume that the term 'glass-ceramic material' encompassed materials with a crystal content as low as 20% by weight, description of the range 20-100% (100% being the theoretical upward limit of crystallinity) would necessarily describe the range 50-100% crystal content now claimed unless the broad range pertained to a different invention from that involving the narrower range. *In re Wertheim, supra,* at 264-65, 191 USPQ at 98. The portions of appellant's parent application, quoted *supra,* indicate no criticality in the percentage crystallinity utilized in the practice of the invention, merely stating that the glass-ceramic material have physical properties 'more nearly characteristic of a conventional crystalline ceramic material,' citing Stookey '971.[90]

The court concluded that the " 'at least 50%' limitation in appellant's claims merely quantifies the percentage crystallinity one of ordinary skill in the art *at that time* would have attributed to the term 'glass-ceramic material.' "[91] [Emphasis added by the court]

This claimed limitation was thus found to be inherently described in the parent application.

D. In re Sichert. In *Sichert,* a claim was rejected for anticipation over appellant's prior filed German patent. To avoid this anticipation, the applicant needed to obtain the benefit of the filing date of his United States parent application. The rejected claim recited "between about 3 and about 35% of potassium arsenite"[92] which the examiner alleged was not described in the applicant's parent case. The applicant's parent application and the German patent both contained the same disclosure with respect to this quoted phrase. Both contained an example which disclosed that 7.5 grams of potassium arsenite were added to 30 grams of the composition. This recitation fell within the 3-35% range. In addition, both the parent application and the German patent disclosed:

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[88] In re Voss, *supra* note 4, at 818, 194 U.S.P.Q. at 271-72.

[89] *Id.* at 818, 194 U.S.P.Q. at 272.

[90] *Id.*

[91] *Id.* at 819, 194 U.S.P.Q. at 272.

[92] In re Sichert, *supra* note 10, at 1164, 196 U.S.P.Q. at 217.

> According to a particular embodiment of the invention, the composition also contains arsenicum or compounds of arsenicum. By this means an additional very important enhancement of the activity is achieved. Examples of arsenicum or compounds of arsenicum, respectively, which may be contained in the compositions according to the invention are colloidal arsenicum, arsenious acid and potassium arsenite.[93]

The board affirmed the examiner's finding that the claim limitation was not described in the parent application. The CCPA found that this disclosure, in addition to the disclosure of the single species within the claimed range, was not sufficient to describe the claimed range. As a result, the Board's decision was affirmed.

E. In re Barker.[94]

Analysis

An analysis of the above-discussed cases enables one to predict with some degree of accuracy the kinds of factual situations where the CCPA is likely to find that the description requirement has been satisfied, the kinds of factual situations where the CCPA is likely to find it not satisfied, and the kinds of factual situations where a decision cannot be accurately predicted because of the court's divisiveness.

It is clear, for example, that when a narrow range is subsumed within a broad described range and there is no distinction in terms of operability or of the achieving of any desired result between the broad range and the narrow range, then the broad range describes the narrow range.[95] Of course, if "it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range."[96]

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[93] *Id.* at 1164, 196 U.S.P.Q. at 218.

[94] For a discussion of the facts of this case, *see* the text accompanying notes 12-44 *supra.*

[95] *See* In re Voss, *supra* note 4; In re Blaser, *supra* note 10; and In re Wertheim, *supra* note 3.

[96] In re Wertheim, *supra* note 3, at 265, 191 U.S.P.Q. at 98, citing In re Baird, 348 F.2d 974, 146 U.S.P.Q. 579 (C.C.P.A. 1965); and In re Draeger, 150 F.2d 572, 66 U.S.P.Q. 247 (C.C.P.A. 1945).

Thus, in *Wertheim,* the court concluded that "25 to 60%" describes "35 to 60%" since there was no "distinction, in terms of operability of appellants' process or of the achieving of any desired result, between the claimed lower limit of solids content and that disclosed in the Swiss application."[97] Yet in *In re Baird*[98], the CCPA found that the temperature range "32° to 176°F." did not describe the range "from about 40°F. to at least as low as about 60°F.", because there it was clear that the 40°F. minimum was a "practical" limit and also that at temperatures above 60°F., an undesirable product result was obtained.[99]

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[97] In re Wertheim, *supra* note 3, at 264, 191 U.S.P.Q. at 98. Although this result has been criticized by others (*see* Patent Law Perspectives, § A.5[1] [a] at 99 & 103 of the 1977 Developments), the author believes this decision to be correct.

If there is no criticality or invention associated with a narrower range which is subsumed within a broader range, the applicant should be able to claim that narrower range, since then he is merely claiming less than what he has described. *See* In re Johnson, *supra* note 10; and In re Wertheim, *supra* note 3.

Of course, if the narrower range is presented in view of some post-filing experiments which the applicant conducted and as a result of which he discovered that the narrower range is in some way critical, the presentation of that range should rightly be objected to either as the introduction of new matter or, if a prior filed application is involved, as not being described.

It might be argued that the above analysis requires the examiner (Board or C.C.P.A.) to determine exactly *why* an applicant is presenting a narrower and subsumed range and, from the reason given, conclude whether the range presented either constitutes new matter or is not described. This determination appears to be justified, however, particularly in view of the court's reiteration that description issues should be decided on the facts of each case. The alternative is to resort to some kind of inflexible rule which frequently exalts form over substance and could lead to the loss of patent rights in certain situations. Furthermore, if the *in haec verbis* approach is the law, applicants would have open to them two courses of action as described by Judge Learned Hand in another context:

> They must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the branch than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. It is impossible to imagine any public purpose which it could serve. Eng'r. Dev. Laboratories v. Radio Corp. of America, 153 F.2d 523, 526-27, 68 U.S.P.Q. 238, 241-42 (2d Cir. 1946).

[98] 348 F.2d 974, 146 U.S.P.Q. 579 (C.C.P.A. 1965).

[99] *Id.* at 982, 146 U.S.P.Q. at 585.

These "rules" were developed in the context of technologies generally considered to be unpredictable.[100] As will be seen below,[101] they should not apply to predictable technologies.

Although all members of the court appear to agree that a broad range describes a narrow range which is subsumed within it in the absence of "different invention" or of a difference in operability, etc.[102], the court was divided in *Blaser* with respect to the degree of difference in operability required before the narrow subsumed range is no longer described by the broad range. In particular, the majority, including Judges Rich and Miller, believed that the lower limit of the range "0.6 to 1.6" was not described in the parent application on the theory that this lower limit was "discovered" after filing the parent application. "Appellants have discovered that 'reduction of the amount of water used [below 0.6 mols] renders the process unusable in practice owing to the greatly prolonged reaction times'."[103]

Judges Markey and Baldwin disagreed, noting that the parent application disclosed "a range, extending from *some* water (say 0.1 mols) to 1.6 mols."[104] Since this range included the lower limit of 0.6 mols they argued that the narrow and subsumed range (0.6 to 1.6) was described by the broad (0.1 to 1.6) range.

Thus, the majority in *Blaser* appears to attach some kind of criticality to the lower claimed limit whereas the dissent does not.

At least in unpredictable technologies, it appears that none of the present members of the CCPA will consider in an application the assertion that a composition can "contain" a particular compound (*e.g.*, potassium arsenite) coupled with a single example illustrating the inclusion of a certain percentage of that compound in the composition (*e.g.*, 7.5 grams of potassium arsenite is added to 30 grams of the composition) as a description of a range (e.g., 3 to 35%) which includes that particular percentage but where that range is

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[100] In re Blaser, *supra* note 10; In re Voss, *supra* note 4; In re Wertheim, *supra* note 3; and in re Baird, *supra* note 98. Technologies involving "chemical reactions and physiological activity" have been considered to be unpredictable in the past by the C.C.P.A. *See* In re Fisher, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970).

[101] *See* text accompanying notes 107-114 *infra*.

[102] *See* In re Voss, *supra* note 4; In re Blaser, *supra* note 10; and In re Wertheim *supra* note 3.

[103] In re Blaser, *supra* note 10, at 538, 194 U.S.P.Q. at 125.

[104] *Id.* at 539, 194 U.S.P.Q. at 126.

otherwise not mentioned in the specification.[105] Thus the applicant in *Sichert* appeared to simply create the "3 to 35%" range in his CIP application without regard for the fact that it was not disclosed in his parent application. The inclusion of this range was rightly objected to as not being described in the parent. Had the applicant attempted, by amendment, to include the same range in the parent, it should have been objected to as "new matter."

This is consistent with decisions in cases which involve unpredictable technologies wherein a claimed range which reads literally on embodiments outside of the range described in a prior United States or foreign application will not be described by that prior application. For example, in *Wertheim,* the court found that "a solids content range of 'at least 35%', which reads literally on embodiments employing solids contents outside the 25-60% range described in the Swiss application"[106] was not described in that Swiss application.

Although all members of the court have joined in decisions to depart further from the *in haec verbis* test,[107] they are divided as to the extent of such departure. This division is apparent in the *Barker* case. The majority in *Barker* apparently wished to apply to predictable technologies the rule that "a claimed range which reads literally on embodiments outside of the range described in the application (or prior United States or foreign application) will not be described in that application." Judges Markey and Baldwin disagreed, possibly because they may believe that a separate description requirement does not even exist.[108]

Barker involved a technology described by Judge Markey as the "simplest of mechanical inventions."[109] The claimed invention was directed to a method of making prefabricated panels of wooden shingles. The limitation "at least six" shingles was put into the original claim by amendment. (From an inspection of the file history, it ap-

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[105] *See* In re Sichert, *supra* note 10. The same rule seems to apply for predictable technologies, but there is a division within the C.C.P.A. *See* text accompanying notes 109-115 *infra.*

[106] In re Wertheim, *supra* note 3, at 263, 101 U.S.P.Q. at 97.

[107] In re Voss, *supra* note 4; In re Blaser, *supra* note 10; and In re Wertheim, *supra* note 3.

[108] Chief Judge Markey stated in his dissent that he did not believe that a separate description requirement exists. Since Judge Baldwin also dissented, it may be inferred that he either (1) believed that a separate description requirement does not exist, or (2) believed that a separate description requirement existed but that it was satisfied under the facts of this case.

[109] In re Barker, *supra* note 2, at 595, 194 U.S.P.Q. at 475.

pears that this amendment was added in order to distinguish over the prior art.) This limitation was not expressly recited in the original disclosure. However, the specification did disclose embodiments wherein eight and sixteen shingles were employed and an original claim, which was part of the disclosure, called for a "course of shingles" which would mean "at least two."

The majority opinion seemed to indicate that there exists a single description standard regardless of the predictability or unpredictability of the technology involved.[110] Judge Markey seemed to think that even if a separate description requirement exists it should be more easily satisfied when predictable technologies are involved. Although Judge Rich concurred with the majority, he seemed to disagree with the majority view that a "single standard" exists regardless of the technology involved. "While the majority opinion states, in footnote 6, that, in applying the statute, we have but a single standard for simple and complex cases, the fact is that different fact situations demand different treatment. *In re Nelson,* 280 F.2d 172, 184, 126 U.S.P.Q. 242, 253, 47 C.C.P.A. 1031, 1048 (1960)."[111] Nevertheless, he agreed with the majority view that a description requirement exists which is "distinct though commingled" with the enablement requirement.

> Attention must be paid to the key words 'such' and 'as to' in the phrase 'such full, clear, concise and exact terms as to enable,' which compel case-by-case treatment of issues of the sufficiency of description and enablement which, I agree, are distinct though commingled requirements.[112]

The majority view in *Barker* appears to be incorrect although it is consistent with those description cases which involve unpredictable technology.[113] The standard should be different depending upon the technology involved.[114] If the policy underlying the description requirement is the desire to keep post-filing discoveries out of the originally filed application, then it can be appreciated that courts will not look favorably upon post-filing additions to an application when those additions have no basis whatsoever in the originally filed

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[110] *Id.* at 593, 194 U.S.P.Q. at 474, n. 6.

[111] *Id.* at 594, 194 U.S.P.Q. at 475.

[112] *Id.*

[113] *See* note 107 *supra.*

[114] Even if the "single standard" majority view were correct, the disclosure in *Barker* of "a course of shingles" (which means "at least two") in addition to the disclosure of eight and sixteen shingles should constitute a sufficient description of "at least six" shingles in the absence of criticality.

application. For example, in *Blaser,* where the claimed limitation ("0.6 to 1.6 mols") was not expressly disclosed in the prior application, the majority found that the questioned limitation was not described, presumably because of the fear of allowing an applicant to insert post-filing discoveries into an application.

That same fear should not exist when very predictable technologies are involved. In *Barker,* almost anyone reading the specification could tell that the number of shingles is in no way critical. Whether the court will follow the majority "single standard" view or adopt the view espoused by Judge Markey remains to be seen.

—"Genus/Subgenus" Cases

A. In re Johnson. In *Johnson,* the applicants needed to obtain the benefit of the filing date (1963) of a parent United States application in order to avoid the admitted anticipation of the subject matter of the claims before the examiner by a Netherlands patent, which was a counterpart to their parent United States application. Because the applicants had lost an interference count involving a particular species which was within the genus of the claims of the prior application, the applicants presented to the examiner in a subsequent (1972) CIP application a subgenus which excluded from the claims the subject matter of the lost count. This subject matter was excluded by means of two provisos.

Claim 1 is illustrative of the group of claims which were on appeal, and reads as follows (with the two provisos italicized):

> 1. A substantially linear thermoplastic polyarylene polyether composed of recurring units having the general formula:
>
> (O-E-O-E′)
>
> where E is the residuum of a dihydric phenol and E′ is the residuum of a benzenoid compound having an inert electron withdrawing group in one or more of the positions ortho and para to the valence bonds having a sigma* value above about +0.7, and where both of said residuum [sic, residua] are valently bonded to the ether oxygens through aromatic carbon atoms *with the provisos that E and E′ may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei.*[115]

The examiner and the Board each relied on *In re Welstead,*[116] *In re Lukach,*[117] and *In re Smith*[118] in concluding that the applicants were

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[115] In re Johnson, *supra* note 10.

[116] 463 F.2d 1110, 174 U.S.P.Q. 449 (C.C.P.A. 1972).

[117] 442 F.2d 967, 169 U.S.P.Q. 795 (C.C.P.A. 1971).

[118] 458 F.2d 1389, 173 U.S.P.Q. 679 (C.C.P.A. 1972).

not entitled to the 1963 filing date because the presently claimed subject matter was not "described" in the 1963 application. The Board found that an "artificial subgenus"[119] was created by the insertion into the claims of a proviso which excluded the subject matter of the lost interference count. The Board also believed that, "[t]he reason why appellants now limit their claims to exclude those species eliminated by the provisos, *i.e.*, loss in an interference, is manifestly immaterial."[120]

Chief Judge Markey, writing for the majority, reversed. He concluded that there was "more than ample basis for claims of such scope"[121] in the prior application. The court first pointed out some of the disclosure in the prior application which pertained to the subject matter of the claims before the court.

> Fifty specific choices are mentioned for the E precursor compound, a broad *class* is identified as embracing suitable *choices* for the E' precursor compound, and twenty-six 'examples' are disclosed which detail fifteen species of polyarylene polyethers. Only fourteen of those species and twenty-three of the 'examples' are within the scope of the claims now on appeal. Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is *claiming less* than the full scope of his disclosure.[122] [Emphasis supplied by the court].

The court then carefully distinguished each of the cases relied upon by the Board. It noted that the court in *Lukach* indicated that the prior application did not disclose "any defined genus of which the presently claimed copolymers are a subgenus."[123] That was not the case in *Johnson*. With respect to *Smith,* the court stated that

> the applicant sought the benefit of his prior application for a broadened generic claim, replacing the claim limitation 'at least 12 carbon atoms . . .' with a new limitation calling specifically for 8 to 36 carbon atoms, when there was no disclosure of either the range itself or of a sufficient number of species to establish entitlement to the claimed range.[124]

Unlike the situation in *Smith,* the applicants in *Johnson* were "narrowing their claims, and the full scope of the limited genus now

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[119] In re Johnson *supra* note 10, at 1014, 194 U.S.P.Q. at 192.

[120] *Id.* at 1014, 194 U.S.P.Q. at 193.

[121] *Id.* at 1018, 194 U.S.P.Q. at 195.

[122] *Id.*

[123] *See supra* note 117, at 969, 169 U.S.P.Q. at 797.

[124] In re Smith, *supra* note 10, at 1018, 194 U.S.P.Q. at 196.

claimed is supported in appellants' earlier application, generically and by specific examples."[125]

Seemingly, the most difficult case for the court to distinguish was *Welstead.* In *Welstead,* the applicant limited his claims by adding a proviso. Because the proviso was somewhat ambiguous, there was some confusion as to which of four classes of chemical compounds was excluded by the proviso. Both the applicant and the Board interpreted the amended claim as excluding the third of four possible classes. On appeal the CCPA found that the applicant had changed his position and argued that the proviso excluded compounds of the second type.

The CCPA decided to adopt the interpretation used by the Board, *i.e.,* that the proviso excluded compounds of the third type but did not exclude compounds of the second type. The applicant conceded that his "disclosure contains no examples or recitations of inventiveness with respect to compounds . . . [of the second type]."[126] The court thus held that there was no description of the limited genus "nor description of the species thereof amounting, in the aggregate, to the same thing."[127]

The court found that *Johnson* was clearly distinguishable from *Welstead* since in *Johnson* the prior filed application "contains a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed."[128]

The court even believed that *Welstead* might have been cited by the Board in support of a decision *contrary* to that reached since in *Welstead* the CCPA stated that the description requirement could be fulfilled by "descriptions of species amounting in the aggregate to the same thing."[129]

After distinguishing the cases relied upon by the Board, the court then embarked on a discussion which would be more appropriate in an enablement context, rather than in a description context:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of

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125 *Id.*

126 *See supra* note 116, at 1113, 174 U.S.P.Q. at 451.

127 *Id.* at 1114, 174 U.S.P.Q. at 451.

128 See *supra* note 124.

129 *See supra* note 116.

> the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.[130]

The court also made it clear that it disagreed with the Board's conclusion that the reason appellants amended their claims "is manifestly immaterial."

> Though it is true that insufficiency under §112 could not be cured by citing the causes for such insufficiency, it is not true that the factual context out of which the question under § 112 arises is immaterial. Quite the contrary. Here as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter."[131]

Judge Lane, dissenting in part, stated:

> I would affirm the rejection of claims 64 and 68-70 under § 112 paragraphs 1 and 2 because the specification indicates that a minimum sigma value of +0.7 is an *essential requisite.* These claims fail to recite this requisite, thus fail to define appellants' invention and are broader than the disclosure. I concur in reversing the rejection of claims 1-9.[132]

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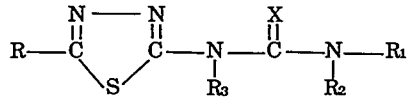
130 In re Smith, *supra* note 10, at 1019, 194 U.S.P.Q. at 196. By using this particular language, the court seems to mix in some "enablement" language in its discussion of a "description" deficiency. Perhaps this reflects the beginnings of a division within the court as to the very existence of a separate description requirement. The existence of a separate description requirement was not expressly at issue in *Johnson* as it was in *Barker. See* text accompanying notes 12-44 *supra.*

131 In re Johnson, *supra* note 10, at 1019, 194 U.S.P.Q. at 196. The author has recently experienced a situation wherein an examiner has looked to this quoted language of the court and interpreted it to mean that a genus could only be limited by the use of provisos (as in *Johnson*) when the claim was limited as the result of a lost interference count. The examiner would not apply the rationale of *Johnson* to the case where a genus was being limited as the result of prior art which was not known to the applicant at the time of filing but which was used by the examiner to reject the genus claims.

The examiner believed that the court in *Johnson* was attempting to distinguish the *Johnson* situation (wherein the applicant *could not have known* of the existence of the prior art) and a non-interference situation (where the claim was limited because of prior art which *could have been discovered* by the applicant). The present author pointed out that this distinction would, in effect, require an applicant to (1) conduct a search, and (2) locate the most pertinent art. The former has never been a prerequisite to the filing of a patent application. The latter is impractical and frequently impossible, particularly if the most pertinent art is a foreign literature reference not readily available to those who ordinarily conduct patent searches.

132 *Id.*

B. In re Driscoll. In *Driscoll,* an applicant again needed to obtain the benefit of an earlier filing date (1968) under 35 U.S.C. § 120 in order to avoid the admitted anticipation of the subject matter of the claims before the examiner by a Belgian patent (effective reference date of 1970) which is a counterpart to his parent United States application. The single claim on appeal reads as follows:

> 13. A Compound of the Formula
>
> 
>
> wherein R is alkylsulfonyl (C_1-C_6);
> R_1 is selected from the group consisting of H, alkyl (C_1-C_4), and cycloalkyl (C_3-C_6); R_2 is from the group consisting of H, alkyl (C_1-C_4), haloalkyl (C_1-C_4); alkoxy (C_1-C_4), alkenyl (C_2-C_4), alkynyl (C_2-C_4), aryl, and haloaryl, and wherein R_1 and R_2 are alkylene which, together with N, form a ring of at least 3, but not more than 6 members; R_3 is H or alkyl (C_1-$_6$); and X is selected from the group consisting of oxygen and sulfur.[133]

The disclosure of the 1968 application with respect to these compounds is the same as that of claim 13 except that R is defined as being

> selected from the group consisting of H, alkyl (C_1-C_6), haloalkyl (C_1-C_6), cycloalkyl (C_3-C_6), halocycloalkyl (C_3-C_6), alkoxy, alkoxyalkyl, alkoxyalkylthio, aryl, substituted aryl, alkenyl (C_2-C_6), alkylthio (C_1-C_6), alkylsulfoxide (C_1-C_6), and alkylsulfonyl (C_1-C_6).[134]

The examiner denied the applicant the benefit of the filing date of the 1968 application because, in his view, one reading the 1968 application "would simply *not* conceive of, without more, the new genus reflected in instant claim 13." [Emphasis in original][135] The Board sustained the examiner, stating

> In view of the relatively large number of possible values for R, and in the absence of anything in the disclosure to direct one specifically to the subgenus where R is alkylsulfonyl, we cannot agree with appellant's position .... To hold otherwise would be to find within appellant's generic description also a description of each subgenus wherein R_1 was selected from a single member of the group disclosed, while retaining the generic description of the remaining variable symbols, and each subgenus obtained by carrying out a similar operation with R_2 and R_3 and X. We think it clear that the single generic description relied on, in the absence

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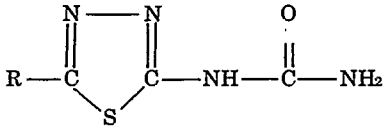
[133] In re Driscoll, *supra* note 3, at 1246, 195 U.S.P.Q. at 435.

[134] *Id.* at 1247, 195 U.S.P.Q. at 435.

[135] *Id.* at 1247, 195 U.S.P.Q. at 436.

> of any additional subgeneric disclosure, is incapable of constituting a written description of so many different genera or subgenera of chemical compounds in the manner required by the statute.[136]

Judge Almond, writing for a unanimous court, reversed the Board. He used an example to illustrate that a Markush group, such as that defining R in the instant case, actually describes each and every member within that group. In the example, the compound



was used to represent a class of herbicides. R was defined in the example compound the same way as it was in the 1968 application. The court stated that

> one skilled in the art would view the above formula as a description of fourteen distinct classes of 5-substituted thiadiazole ureas, each possessing herbicidal activity, just as if the application had listed a first structural formula wherein R was hydrogen, a second wherein R was alkyl (C_1-C_6), a third wherein R was haloalkyl (C_1-C_6), and so on."[137]

Although the above compound was used for purposes of illustration, the court noted that "in reality, the exemplified structural formula constitutes the essence of appellant's invention and that one skilled in the art would recognize it as such from the earlier filed application."[138]

The 1968 application pointed to appellant's contribution as follows: "Particularly effective [herbicides] are [thiadiazole ureas] which contain an organic substituent in the 5-position of the thiadiazole portion."[139] The court believed that: "the focus is unquestioningly on the substituents at the 5-position of the thiadiazole moiety, and not on the substituents of the urea moiety,"[140] and found that: "one skilled in the art would regard the structural formula of [the prior filed application] as signifying that no matter which member of the R group is present on the thiadiazole moiety, the urea moiety may be substituted or unsubstituted."[141] Thus, it concluded

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[136] *Id.* at 1248, 195 U.S.P.Q. at 436.

[137] *Id.* at 1249, 195 U.S.P.Q. at 437.

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Id.*

> that a skilled artisan would recognize from the disclosure of [the prior filed application] fourteen distinct classes of compounds, each class having a single member of the R group at the 5-position of the thiadiazole moiety and variable substituent groups on the urea moiety. This being the case, it follows that [the prior filed application] describes the subject matter of claim 13 inasmuch as one of the fourteen classes of compounds is the 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas defined therein.[142]

The solicitor asserted that *In re Ruschig*[143] "may be considered controlling in the present appeal."[144] The issue in *Ruschig* was whether or not a specification contained a description of the single claimed compound: N-(p-chlorobenzenesulfonyl) -N^1-propylurea. The specification disclosed a general structural formula of a compound which contained two varying groups, R and R_2. R was defined as "a member selected from the group consisting of chlorine and bromine,"[145] and R_2 was defined as "a member selected from the group of alkyl-, alkenyl-, cycloalkyl- and cycloalkylalkyl radicals containing 2 to 7 carbon atoms."[146]

The CCPA in *Ruschig* agreed with the Board which had concluded: cluded:

> Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.[147]

Driscoll was distinguished from *Ruschig* as follows:

> Any seeming similarity between *Ruschig* and the present case is illusory, however, because the structural formula there relied on could have described, at best, only a subgenus including the specific compound claimed, and not the compound itself. In this respect, *Ruschig* is readily distinguishable from the present case where the exact subgenus claimed is clearly discernible in the generalized formula of the thiadiazole urea set forth in the earlier filed application.[148]

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[142] *Id.* at 1249, 195 U.S.P.Q. at 437-38.

[143] In re Ruschig, *supra* note 15.

[144] *Id.* at 1250, 195 U.S.P.Q. at 438.

[145] *Id.* at 990, 994, 154 U.S.P.Q. 118, 121.

[146] *Id.*

[147] *Id.* at 995, 154 U.S.P.Q. at 123.

[148] 562 F.2d at 1250, 195 U.S.P.Q. at 438.

Analysis

In both *Johnson* and *Driscoll* the court characterized the description rejection as a "hypertechnical application"[149] of the § 112 requirements. Furthermore, in both cases, the court found that a genus described a subgenus or a limited genus which was wholly subsumed within that genus. Thus the CCPA appears to be taking more of a "rule of reason" approach to genus/subgenus description issues.

In *Johnson,* Markush groups were not involved. Rather, the generic claim was limited in the CIP application by the addition of two provisos which excluded two species which were the subject of the lost interference count. The court held that since these two species were "specifically disclosed in the [prior filed] 1963 application,"[150] and since the original genus was also described in that application, then the remaining "limited genus" was also described in that application.

It should be noted that *Johnson* is a somewhat special fact situation in that the limited genus was not rejected as obvious over the subject matter of the lost count.[151] Although such rejections may be somewhat difficult to overcome when the subject matter of the lost count is from the same genus as that being claimed, there do arise situations in which the limited genus is not obvious in view of the excluded species. For example, in *Johnson,* the excluded species could be made by the *Johnson* process as well as by the processes disclosed by the party who won the interference. However, the non-excluded species

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[149] In re Johnson, *supra* note 10 at 1019, 194 U.S.P.Q. at 196; In re Driscoll, *supra* note 3, at 1249, 195 U.S.P.Q. at 438.

[150] In re Johnson, *id.* at 1012, 194 U.S.P.Q. at 191.

[151] The claims must patentably distinguished over the lost interference count. As the C.C.P.A. stated in In re Cole, 82 F.2d 405, 409, 29 U.S.P.Q. 137, 141 (C.C.P.A. 1936):

> We therefore hold, in harmony with our decisions hereinbefore cited, that in order to warrant the allowance of the claims before us the claims must be inventively different from said interference counts; or, in other words, the specific details or limitations in the claims before us not found in said interference counts must, when combined with the structure embraced in said counts, involve [patentable] invention over said counts.

could not be prepared by the processes disclosed by the party who won the interference.[152]

Aside from the fact that the *Johnson* decision may have somewhat limited applicability, there is also a question as to how far the court will go in applying *Johnson*. For example, it is not clear whether the same conclusion would result if the *Johnson* issue arose in a non-interference context. The court's statement that "it is not true that the factual context out of which the question under § 112 arises is immaterial"[153] clearly rejects the Board's conclusion on the same point.[154] However, the court does not indicate *why* the fact that the issue arose in an interference context is important, although it can be easily inferred that a lost count is prior art in the same sense as a prior art reference. Furthermore, the court provides no hint or suggestion as to what the outcome might be if the same issue arose in a non-interference context.

A *Johnson* type issue might arise in a non-interference context if the examiner rejects a generic claim over prior art which discloses one or more of the species within that genus.[155] If the applicant either amends his claim or files a CIP application with claims directed to a limited genus which excludes the species which are in the prior art, the issue is whether that limited genus is descibed by the original disclosure.

The argument against applying the *Johnson* rationale in a non-interference context might be presented as follows. The applicant had the opportunity to find the prior art by conducting a search. Theoretically, he should have located the pertinent prior art and drafted his claims accordingly. Since he did not find this pertinent

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[152] Another way in which a limited genus might be found to be patentable over an excluded species could arise in a non-interference context. Suppose the examiner rejected the genus claim over a reference which generally taught away from the claimed invention but that contained a single example which disclosed a species within that genus and thus constituted an anticipation of the generic claim. The generic claim could be amended to exclude that species and also eliminate the anticipation problem. Any obviousness rejection might be rebutted by arguing that the

> relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention. In re Mercier, 515 F.2d 1161, 1166, 185 U.S.P.Q. 774, 778 (C.C.P.A. 1975).

[153] In re Johnson, *supra* note 10, at 1019, 194 U.S.P.Q. at 196.

[154] *Id.* at 1014, 194 U.S.P.Q. at 193.

[155] *See* note 152 *supra*.

prior art (and/or did not conduct a search), he should not be heard to complain about the description rejection.

The author believes that the outcome of the description question should be the same regardless of whether the issue arises in an interference context. First, it is generally agreed that the applicant is under no obligation to conduct a search.[156] Second, even if such an obligation were to exist, it is simply unrealistic to think that the most pertinent art would be uncovered in every case.[157] This is especially true with respect to art which is not readily available to those who ordinarily conduct patent searches.[158]

Accordingly, if a court were faced with a situation similar to *Johnson,* but certain species had to be excluded from a genus because of the existence of prior art other than the lost interference count, it is predicted that the court would arrive at the same result as they did in *Johnson.*

Given that the court would extend *Johnson* to a non-interference context, a second issue is whether *Johnson* would be applied to the situation where the excluded species are not specifically described. It should be remembered that in *Johnson* the excluded species were each specifically described.[159] The appellants in *Johnson* in effect made an algebraic argument in their Brief on Appeal before the CCPA.

> Appellants submit that they have adequately *described* their original broad genus in their grandparent application and that they have specifically and generically *described* the two classes of polymeric materials excluded by the provisos. Logically, one must conclude that what remains, that is to say what is claimed within appealed claims 1-9, 64 and 68-70, is also *described* in Appellants original parent application.[160] [Appellants' Emphasis]

It is not certain what the court would do if the species which are excluded from the limited genus were not specifically described in the prior application whereas the original genus was so described. On the

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[156] Even the new rules, which emphasize a duty of disclosure, do not require that patent applicants conduct a search. One way to comply with this duty of disclosure, 37 C.F.R. 1.56, is to file a prior art statement 37 C.F.R. 1.97. In pertinent part, this rule states that "the statement shall not be construed as a representation that a search has been made or that no better art exists."

[157] *See supra* note 156.

[158] Such art includes foreign literature references which might be sufficiently accessible under 35 U.S.C. § 102 but, in practice, be unavailable in the course of a regular search.

[159] *See supra* note 150.

[160] *See* Appellants' Brief on Appeal at 21, In re Johnson, *supra* note 10.

one hand, the applicant would merely be "*claiming less* than the full scope of his disclosure"[161] and the court might find that if the applicant described the whole genus, he also described the limited genus which is wholly subsumed therein. On the other hand, the court could hold *Johnson* to its particular facts and conclude that a "limited genus" is described only when the original genus and excluded species are all described. Based on the court's recent more relaxed approach to description issues and their desire to avoid "hypertechnical applications" of § 112, the author predicts that the court would find such a limited genus to be described even if the excluded species were not specifically described.[162]

The court has also indicated that it wishes to avoid "hypertechnical applications" of the description requirement of § 112 when considering whether a subgenus is described by a genus which wholly encompasses that subgenus. In *Driscoll,* the Court decided that the disclosure of a genus in a prior filed United States application described a subgenus that was claimed in the application at issue.

The genus described in that prior United States application was of a structural formula which contained five variable substituents. The court simplified a potentially complex problem by focusing on a single variable substituent (R). The court justified this simplication by noting that when that particular variable substituent was present at that particular position in the molecule, the claimed herbicides were particularly effective.

Since this variable substituent was described as being selected from a group which contained fourteen members, each of which defined a subgenus, the court believed that the original genus contained fourteen subgenera. In the application under consideration, the applicant eliminated all but one of those fourteen members from the Markush group. The court stated that a Markush group describes each individual member of that Markush group so that each of these fourteen subgenera were specifically described. Therefore, the single subgenus presented in the application under consideration was described in the

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[161] In re Johnson, *supra* note 10, at 1018, 194 U.S.P.Q. at 195.

[162] At least the broad language of *Johnson* does not attach much importance to the fact that the excluded species were specifically described. For example, the court states that "appellants are merely excising the invention of another, to which they are not entitled, and are not creating an 'artificial subgenus' or claiming 'new matter'." *Id.* at 1019, 194 U.S.P.Q. at 196. It should be noted that the quoted language refers to "excising the invention of *another.*" It is interesting to query whether the *Johnson* holding might be extended to the situation where an applicant is excising *his own* invention under, for example, 35 U.S.C. § 102 (b).

ancestral application. *Driscoll* then holds that a subgenus which is wholly subsumed within a genus is described by that genus under the circumstances discussed above.

It is not totally clear how broadly this doctrine will be applied by the court. The following discussion is intended to illustrate factual situations in which *Driscoll* clearly applies, those where it clearly does not apply, and those where it is uncertain whether or not *Driscoll* applies.

The following are believed by the author to be examples of factual situations wherein the *Driscoll* rationale should apply.

(a) A disclosure of a genus by a structural formula which contains a single variable substituent R, where R is defined as a Markush group of various members, would constitute a description of each subgenus within that genus. For example, if R could be either alkyl, alkenyl, or aryl, the claim would encompass three subgenera, each of which would be described by that genus.

This factual situation is very similar to that in *Driscoll.* The only difference is that the genus of *Driscoll* contained five variable substituents (which would include hundreds of subgenera) and the court ignored all but one of those substituents. Accordingly, the *Driscoll* holding would clearly apply to this first hypothetical example.

(b) A genus is diclosed by a structural formula which contains multriple variable substituents (R, R′, R″, etc.) but the compounds are useful only when a particular substituent (e.g., R) is present at a particular position in the molecule. The presence or absence of the other variable substituents is optional. This particular R substituent is defined as a Markush group of various members. Under these facts, which are essentially the same as those in *Driscoll,* that genus would constitute a description of each subgenus within that genus.

(c) Consider a factual situation which is the same as that in (a) above but where the claim limitation in the application before the Examiner recites that R may be alkyl or alkenyl (but not aryl). This is somewhat different from *Driscoll* in that in this fact setting the claim before the Examiner contains *two* subgnera whereas in *Driscoll* the court looked upon the claim as including only a single genus. The court in *Driscoll* concluded that a Markush group containing fourteen members would be regarded by those skilled in the art as describing "fourteen distinct classes" of those compounds "just as if the application had listed a first structural formula wherein R was hydrogen, a second wherein R was alkyl (C_1-C_6), a third wherein R was haloalkyl (C_1-C_6), and so on."[163]

[163] In re Driscoll, *supra* note 3, at 1249, 195 U.S.P.Q. at 437.

Since the genus describes each subgenus within the Markush group, it would be inconsistent to conclude that the genus does not describe *two* subgenera which are formed by removing only one of the three members of the Markush group.

(d) Consider a situation where a genus is disclosed by its structural formula which contains a single variable substituent, R, which is defined as "an alkyl group having from 1 to 10 carbon atoms." The issue is whether this genus describes the subgenus formed when R is defined as "an alkyl group having from 2 to 5 carbon atoms." The answer should be that the subgenus is described by the genus in view of *Wertheim, supra* and *Driscoll, supra.* In *Wertheim* it was concluded that a broad numerical range describes a wholly subsumed narrower range in the absence of criticality. Even if "1 to 10" and "2 to 5" are concluded *not* to be numerical ranges because they describe a group of chemical compounds, the broader group should be held to describe the narrower group since it was determined in *Driscoll* that a genus describes a subgenus which is wholly subsumed within that genus. The fact that *Driscoll* involved Markush language and the hypothetical does not is of no significance.

The following are believed by the author to be examples of factual situations wherein the *Driscoll* rationale would *not* apply.

(e) A structural formula is disclosed which contains a single variable substituent R which is defined as either alkyl or alkoxy. This would *not* constitute a description of the same structural formula wherein R is defined as "alkyl, alkoxy or *aryl.*"

Furthermore, the disclosure of a structural formula which contains a single variable substituent R which is defined as "alkyl containing from 5 to 10 carbon atoms," would not describe the same structural formula wherein R is defined as "alkyl containing from 1 to 20 carbon atoms." The rule seems to be that although a genus may describe a wholly subsumed subgenus under certain circumstances, a subgenus cannot generally constitute a description of the genus.

In re Ahlbrecht[164] and *In re Smith*[165] each involved the issue of whether a subgenus could descibe a genus. The answer in each was no. In *Ahlbrecht,* the applicant's parent application disclosed a structural formula for monomeric esters. These esters contained an alkylene group in which "m" represented the number of carbon atoms in the alkylene chain. The symbol "m" was defined as an integer from "3 to 12". In the application before the CCPA, the applicant attempt-

[164] 435 F.2d 908, 168 U.S.P.Q. 293 (C.C.P.A. 1971).

[165] 458 F.2d 1389, 173 U.S.P.Q. 679 (C.C.P.A. 1972).

ed to claim esters where "m" was from "2 to 12". The court held that "2 to 12" carbon atoms was not described by "3 to 12."

In *Smith,* a prior application disclosed that an organic material (which may be used to coat a pigment) contains "at least 12 carbon atoms." In a subsequent application, the applicant claimed the same organic material containing "at least 8 carbon atoms." The CCPA denied the applicant the benefit of the earlier application on the ground that "at least 12 carbon atoms" does not describe "at least 8 carbon atoms."

(f) A structural formula is disclosed which contains two variable substituents, R and R'. R is defined as "alkyl or aryl" and R' is defined as "chloro or bromo". This disclosure would *not* constitute a description of a *species* within that genus under *Driscoll.* It would not, for example, describe the specific compound in which R is ethyl and R' is chloro. The above facts are similar to those involved in *In re Ruschig*[166] which the court distinguished from the facts in *Driscoll*[167]. Whether the court will extend the *Driscoll* doctrine to conclude that a genus constitutes a description of each *species* (rather than each *subgenus*) within that genus is not clear.

(g) Another setting in which the *Driscoll* doctrine would probably not apply is where an applicant claims a subgenus in a subsequent application and attempts to rely on the disclosure of a genus in a parent case when there is some degree of "criticality" or "invention" associated with that subgenus. For example, suppose the parent application discloses a structural formula containing a single variable substituent R which is defined as alkyl or aryl and the subsequent application claims the subgenus where R is alkyl alone. Alkyl alone is claimed in the subsequent application because it has been determined that these compounds have non-obvious properties not disclosed in the parent. The parent disclosure would probably not describe the claimed limitation because "criticality" or "invention" is associated with that subgenus.

In *Wertheim,* the court carefully distinguished the facts therein from those in a case like *In re Baird*[168] where it was clear that "the broad described range pertains to a different invention than the narrower (and subsumed) claimed range."[169] Although similar language

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[166] 379 F.2d 990, 154 U.S.P.Q. 118 (C.C.P.A. 1967).

[167] *See* text accompanying notes 144-148 *supra.*

[168] 348 F.2d 974, 146 U.S.P.O. 579 (C.C.P.A. 1965). *See* text accompanying notes 98-100 *supra.*

[169] *See* text accompanying note 66 *supra.*

does not appear in the *Driscoll* opinion, the record indicates that the claimed subgenus did not represent a "different invention" over the described genus.

Although the above-discussed hypothetical examples represent factual situations in which the *Driscoll* rationale either clearly applies (a, b, c, and d) or clearly does not apply (e, f, and g), there are several instances in which it is not clear whether the *Driscoll* holding would be extended. The following hypothetical examples represent some of those situations.

(h) A structural formula is disclosed with multiple variable substituents and the non-obvious properties of the compound are not associated with any one particular variable substituent at any particular position on the molecule. Thus, the genus may include literally hundreds of subgenera. It is not clear whether that disclosure would describe a single claimed subgenus within that genus. These facts differ from those in *Driscoll* since in *Driscoll* the herbicidal properties were associated with a particular substituent at a particular molecular position. Thus, in *Driscoll,* only fourteen subgenera were subsumed within the genus. If hundreds of subgenera would be included within the genus, the court may conclude that it is too difficult to locate a particular tree in such a large forest. On the other hand, there is nothing in the *Driscoll* opinion to indicate that there would be a different result if more, even many more, than fourteen subgenera were involved.

(i) *Driscoll* does not seem to require that the ancestral application contain a description of both the genus *and* a species within the subgenus claimed in the subsequent application in order to constitute a description of that subgenus. However, an analysis of the record reveals that the ancestral application did describe such a species.

The facts in *Driscoll* were similar to those in *In re Risse*[170] where a claimed subgenus was held to be described by a disclosure of 1) a genus which encompassed that subgenus, and 2) a species within that subgenus. This so-called "rule" of *Risse* was overruled in *In re Smith*[171] "to the extent that it provides the aforementioned requirement of the first paragraph of § 112.[172]

Smith, however, was clearly distinguishable from *Risse* in that there was no well-defined genus in *Smith* whereas in *Risse* there was.

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[170] 378 F.2d 948, 154 U.S.P.Q. 1 (C.C.P.A. 1967).

[171] 458 F.2d 1389, 173 U.S.P.Q. 679 (C.C.P.A. 1972).

[172] *Id.* at 1395, 173 U.S.P.Q. at 683.

There was no need to overrule *Risse* in *Smith* and some suggest that it was never overruled.[173]

In *Driscoll,* the court may be resurrecting the *Risse* "rule". Indeed, the broad language of *Driscoll* indicates that a genus describes a wholly subsumed subgenus without reference to the disclosure of a species within that subgenus.

Thus, it is not clear whether, under the *Driscoll* doctrine a claimed subgenus would be found to be described by the disclosure of a genus which wholly encompasses that subgenus, *absent* the disclosure of a species within that subgenus. In view of the court's recent more relaxed approach to the description requirement, however, the author predicts the court would conclude that the subgenus is described by such a disclosure in the absence of criticality.

Conclusions

The existence of a separate description requirement has been confirmed by a majority of the CCPA. Although the majority opinion in *Barker* indicated that a "single standard" for description existed whether the technology was upredicable or not, the better view is that the standard should be different depending upon the predictability of the technology.

There has recently been a significant departure from the *in haec verbis* standard particularly in chemical cases where the description issue arose in "numerical range" or "genus/subgenus" contexts. The author predicts that the court will continue to apply the *Wertheim* rationale to conclude that a numerical range which is wholly subsumed within a broader numerical range is described by that broader numerical range in the absence of criticality. The author further predicts that the court will extend *Driscoll* to other factual situations by concluding that a claimed subgenus wholly subsumed within a genus is described by that genus in the absence of criticality. The court most likely will continue to conclude that a broad numerical range is not described by a narrower one and that a genus is not described by a subgenus.

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[173] *See* Gholz, *supra* note 1.

Book Reviews

PATENT INTELLIGENCE AND TECHNOLOGY REPORT 1977

Compiled and published by IFI/Plenum Data Co.
Copyright 1978
Arlington, Virginia

Reviewed by Harry M. Saragovitz

This report is a compilation of information on ownership and subject matter distribution of United States patents. It is a very useful statistical tool for managers, engineers, licensing executives, and others who are involved in technology management and transfer. The data is arranged in the following manner: (1) an alphabetical list of companies which indicates the total number of United States patents granted in 1977, the rank number and a patent activity profile; (2) a list of companies in descending order of patents granted; (3) the distribution of United States patents by company within the United States; and (4) a five-year patent activity profile for each company. pany.

These statistics paint a sobering picture of how new technology (expressed in the form of United States patents) is being produced throughout the industrialized world. The list of patent-distribution by company gives a startling picture of the displacement by foreign companies of United States companies in the number of United States patents obtained in fields such as chemistry, power plant, optics, gas separation and internal combustion engines.

This report is valuable to all persons who would like to see the United States regain its former stature as the world leader in the development of technology.

THE VISUAL ARTIST'S GUIDE TO THE NEW COPYRIGHT LAW

by Tad Crawford
Published by the Graphic Artists Guild
New York, N.Y., 1978

Reviewed by Harry M. Saragovitz

The author, a lecturer and writer on legal matters of importance to artists, has written a legal guide for visual artists and writers. Mr. Crawford knows his subject well as he describes the new Copyright Law and the "Fair Use" doctrine in a manner the lay artist can easily understand. The author's warnings about the hazards and pitfalls awaiting the unsuspecting artist who sells his/her work to magazines and collective works and the threatening aspects of producing "work for hire," make this publication valuable to the visual artist, whether or not the artist is engaged in art full time. In addition to an index, the pamphlet contains an appendix of the forms used in applying for a copyright registration from the Copyright Office.

The booklet should be valuable not only to the visual artist but also to attorneys who desire a general view of the new copyright law as it affects visual artists.

Law Center Report

Supplementing the Law Center's cooperative academic efforts with Carnegie-Mellon's Center for Entrepreneurial Development and Dartmouth's Innovation Center (wherein Law Center students and faculty are aiding in the development of patent protection and planning for innovative concepts maturing from these programs) is a developing cooperation for similar purposes between the Law Center and the Biomedical Engineering Center for Clinical Instrumentation of the Harvard-Massachusetts Institute of Technology Division of Health Sciences and Technology. Initial assistance is being rendered in the development of technology packages stemming from research in micro-processor-based clinical instrumentation for presentation to potential industrial users.

In collaboration with our PTC research programs, several monographs are being prepared on the following topics:

- Potential FDA regulation of medical devices;
- Proposed changes of FDA trade secret;
- Computer software protection; and
- Modern trends in court attitudes towards the presumption of patent validity.

Studies continue on the barriers and incentives to technology transfer between the federal government and private American industry in connection with two projects: (1) modification in food thermal sterilization processing by means of the flexible retort pouch and, (2) preservation of food by ionizing radiation.

The experiences of our recent second annual institute on trading in the European Economic Community, conducted by an international and interdisciplinary faculty, are under review with the Academy of Applied Science and others, to meet the objective of tailoring continued activities in these areas to the actual up-dating needs of the industrial and academic communities.

A program has been launched to elicit expanded private and public financial support for the above activities, which are necessarily limited in the light of the Law Center's resources. Comments and expressions of interest from PTC members and subscribers and others would be most appreciated.

Robert H. Rines
President of Franklin
Pierce Law Center

Citation of Canceled Matter in United States Patent Files as Prior Art

JOSEPH SCAFETTA JR.*

There is a lack of clarity over the issue of when canceled matter in United States patent files may be cited as proof either that a litigated patent is invalid or that an examined patent application is not allowable because the invention under study was already "known or used by others in this country, or patented or described in a printed publication in this or a foreign country."[1] The controversy centers around the date on which the canceled subject matter constitutes knowledge, use, or a description in a printed publication in the United States.

A clear distinction must be made between the filing date of an application and the issuing date of the patent that arises from the application. This distinction must be maintained when considering the subject matter in the specification of the issued patent and any subject matter canceled from the filed application of the issued patent as a "prior art reference" in a study of the validity of a later issued patent or in an examination of the patentability of a later filed application.

With respect to the filing date of the application that eventually matures into a patent, it is now clear, without any dispute or split opinions, that canceled subject matter appearing only in the file

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[1] 35 U.S.C. § 102(a) (1970) provides in full: "A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or discribed in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent...."

wrapper of the patent and not in the patent itself, cannot be used as a prior art reference as of the filing date against a later issued patent or a later filed application because it was not "known or used by others in this country, or patented or described in a printed publication in this or a foreign country" as of the filing date.[2] Section 102(a) of the Patent Code requires the knowledge, use, or description in a printed publication to be public even though the word "public" does not appear in the statute. There are numerous court decisions[3] since the effective date of the present Patent Code in 1953 which emphasize that the prior knowledge, use, or description in a printed publication must be public as of the date that the prior art is to be used against a later issued patent or a later filed application.

The second date that must be distinguished is the issuing date of the patent that arises from the application. The specification as it then stands on the issuing date is part of the patent. Thus, the subject matter in the specification, which appears on the face of the issued patent, is universally recognized as a proper prior art reference against any later issued patent or any later filed application as of the issuing date of the patent to be cited as prior art. Also, anything disclosed in the specification of the patent is available as prior art as of the filing date of the application against any later issued patent or any later filed application under section 102(e)[4] of the Patent Code.

However, on the same issuing date of the patent, any subject matter canceled from the specification of the filed application of the issued patent also becomes available to the public in the "file wrapper."

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[2] There are two exceptions to this generally accepted rule. In *Hommel Mfg. Co. v. East Side Mfg. Co.*, 16 F.2d 1008 (N.D. Cal. 1926), the district judge clearly misconstrued the Supreme Court ruling in the *Milburn* case, *infra,* note 13, which was handed down only five months beforehand. The second exception is *Ruskin v. Watson,* Civil Action No. 621-54 (D.D.C. 1956), which has been roundly criticized by other courts as bad law. For example, *see* Stalego, *infra* note 28, at 53; *Ex parte* Osmond, 191 U.S.P.Q. 334, 337n, 1 (Pat. & Tr. Bd. App. 1973). The decision has also not been followed by the same court that handed down the *Ruskin* ruling. *See* Rem-Cru Titanium v. Watson, 152 F.Supp. 282 (D.D.C. 1957).

[3] For example, *see* Minneapolis-Honeywell Regulator Co. v. Midwestern Instruments, Inc., 298 F.2d 36, 38 (7th Cir. 1961); Application of Hilmer, 359 F.2d 859, 878, 53 C.C.P.A. 1288, 1311 (C.C.P.A. 1966); Soundscriber Corp. v. United States, 360 F.2d 954, 960, 175 Ct.Cl. 644, 650 (Ct.Cl. 1966); Hughes Aircraft Co. v. General Instrument Corp., 275 F.Supp. 961, 972 (D.R.I. 1967), *aff'd. in part, rev'd in part on other grounds,* 399 F.2d 373 (1st Cir. 1968); Rem-Cru Titanium, Inc. v. Watson, *supra* note 2, at 285.

[4] *See* note 14, *infra.* For a good discussion of the relationship of § 102(e) and the *Milburn* case to § 102(a), *see In re* Lund, 376 F.2d 982, 153 U.S.P.Q. 625 (C.C.P.A. 1967).

This file wrapper, that is, the file telling the history and containing all the papers generated during the prosecution of the patent through the Patent Office from the time the application for a patent was filed until the time the patent was issued, is physically available from only one location — the Public Search Room of the U.S. Patent and Trademark Office (USPTO) in Arlington, Virginia, across the Potomac River from Washington, D.C.

Here, there is now no difference of opinion that the filing date of canceled subject matter cannot be used as the date of a prior art reference, but there are some differences of opinion as to whether or not canceled subject matter may be used as a proper prior art reference against a later issued patent or a later filed application as of the issuing date of the patent from which application the subject matter was canceled before issue. However, the differences of opinion do not arise because there is only one physical copy of the file wrapper containing the canceled subject matter available to the public but rather because there is no reference to the canceled subject matter on the face of the issued patent to be used as prior art so that such reference would render the canceled subject matter part of a "printed publication."

In order to have a clearer understanding of why the citation of canceled subject matter in U.S. patent files as prior art is important, it is necessary first to understand how pertinent canceled subject matter is located during the course of a patent validity study or during the examination of an application for a patent.

Locating the Canceled Matter

Let us suppose that you are a small business person and that you have been accused of infringing a larger competitor's patent that just issued. You contact your local patent attorney and tell him your plight. He makes a long distance telephone call to a professional searcher in Washington, D.C. and requests a validity search on the patent which you are accused of infringing. Your patent attorney hangs up and tells you that he will call you in about a month to let you know the results of the search. You shake his hand and leave his office a bit relieved with the hope that all will soon be well.

Our scenario shifts to the Public Search Room of the USPTO. The professional searcher, who may also be a patent attorney or an engineer or scientist registered to practice as a patent agent, first orders the file wrapper in order to send a copy of it to the patent attorney requesting the validity search. If the patent being investigated was recently issued, the file wrapper is kept on the premises of the Patent Office and not in storage at some remote location. Thus, the file

wrapper can be available to any member of the public for inspection and for photocopying within an hour rather than within three to five days, as is the case of file wrappers kept in storage. After the file wrapper is delivered to the searcher and sent to the patent attorney, the searcher reviews the recently issued patent and the earlier issued patents, that is, the prior art cited by the examiner during the course of the prosecution of the application. By determining the differences of the recently issued patent from the prior art, the professional searcher is usually able to ascertain what subject matter the examiner considered to be patentable in the application. The file wrapper often aids in this determination if the patentable differences are not clear from a study of only the recently issued patent and the prior art.

Also, from the face of the patent, the professional searcher is able to review the "field of search" of the examiner, that is, those areas of technical classification of subject matter that the examiner considered most highly pertinent to the invention disclosed in the application. Thereafter, the professional searcher would set up his own field of search to ascertain the validity of the patent being investigated. For example, if the patented invention related to clothing, he would be sure to look into the various subject matter breakdowns or "subclasses" in utility class 2 and design class 2, both appropriately entitled "Apparel and Apparel Apparatus." If the patented invention related to surgical garb, he would also check utility class 128 entitled "Surgery." The professional searcher would know not to waste his time looking in utility class 5 called "Beds and Bedding." Thus, during the course of most validity searches, there is only a finite number of reasonably appropriate technical areas that a professional searcher would investigate.

After the file wrapper has been studied and the field of search set up, the search is begun. It usually starts where the examiner looked in order to find out if the examiner may have missed any pertinent prior art reference, that is, an earlier patent or publication, either United States or foreign. The search then spreads out from that point to other appropriate, but perhaps less pertinent, areas. The examiner, limited by bureaucratic budgetary considerations, must necessarily confine his search to the most highly pertinent areas of subject matter related to the invention disclosed in the application.

Now let's suppose that, after a few hours or even a few days of work, the professional searcher comes across another United States patent, not cited by the examiner, that was issued one year before the recently issued patent being investigated for validity was issued. The

subject matter of the two patents is broadly the same. However, the patent being investigated discloses only one embodiment or method of practicing the invention. The newly discovered patent has four embodiments numbered one through four. The searcher is a hunch player and orders the file wrapper of the newly discovered patent. Sure enough, after the file wrapper is delivered an hour later, he finds out that a figure five is a "picture" of the embodiment disclosed in the patent being investigated but, for any number of reasons, had been crossed out in red ink and therefore "canceled" from the application before the newly discovered patent had been issued. Happy day! The patent which you are accused of infringing is invalid. Right? Maybe. It all depends upon whether the issuing date, on which the newly discovered prior art patent became publicly available, preceded the filing date of the investigated patent. If the issuing date of the newly discovered patent does indeed precede the filing date of the investigated patent, then the investigated patent may be invalid and you, as the small business person, would not be liable as an infringer to your larger competitor. However, the patentee is free to attempt to overcome the issuing date of the patent from which file the subject matter was canceled.

Let us now also look in on an examiner in the Patent Office. You, as the same small business person, have likewise filed an application for a patent on your own invention. Your application was channeled for study to an experienced examiner who has reviewed for years all of the applications relating to the particular technology to which your invention pertains. Eventually, after a long delay, the serial number of your application comes up for review. The examiner studies the application with its single embodiment of the invention and has a foggy recollection of having examined recently another application of the same or similar subject matter. He remembers that he allowed the application to pass to issue as a patent but he seems to recall that the subject matter pertinent to your application was canceled for some forgotten reason. The examiner thinks that, if he can find that earlier issued patent, he may be able to dispose of your application in a hurry. He goes into his own search files and, after rummaging around for a time, accidently knocks over a small pile of patents to be looked at. While picking them up from the floor, he finds the patent he is searching for. The patent issued about a year beforehand and, from its face, the examiner notes the application serial number, orders the single copy of the file wrapper, and finds the canceled subject matter to cite against your own application. Bad news! The application on which you are seeking a patent is not allowable. Right?

Maybe not. Again, it depends upon whether the issuing date, on which the allowed application became a patent — and on which the canceled matter became publicly available, preceded the filing date of your own application. If the issuing date of the patent arising from the earlier allowed application does not precede the filing date of your application, then the canceled matter in the file wrapper of the issued patent is not a proper prior art reference and your application may be allowable, provided all other conditions of patentability are met. Now let us review the known relevant cases.

The Cases

The earliest known decision is that of the Seventh Circuit in 1917 in the *Camp Bros.* case.[5] An inventor named Inks filed an application on August 28, 1900 and obtained a patent on October 8, 1901 on a combined dumper and elevator for a horse-drawn wagon. He thereafter sued the Camp brothers' company for infringement. The defendants had a validity search conducted and the best prior art reference located was subject matter canceled from an application filed June 6, 1896 and from which a U.S. patent issued to one Kidd on August 1, 1899. The canceled matter was placed by Kidd in a "divisional" application filed December 22, 1898 which eventually issued as a second patent on October 30, 1900, two months after Inks had filed his application. The court held that the subject matter in question, which was not claimed, appearing in this second patent to Kidd was not a proper prior art reference against the Inks application because this second patent had not been issued before Inks filed his application on August 28, 1900. This was in accordance with the practice at that time, a

[5] Camp Bros. & Co. v. Portable Wagon Dump & Elevator Co., 251 F. 603 (7th Cir. 1917), *cert. denied,* 248 U.S. 572 (1918).

practice which was later overruled by the Supreme Court in the famous *Milburn* case[6] and which is now codified in section 102(e).

The question arose in *Camp Bros.* as to whether or not the subject matter canceled from the application — but publicly available with the file wrapper when the first Kidd patent issued on August 1, 1899 — was a proper prior art reference against the Inks application which was filed almost 13 months later on August 28, 1900. Ruling that the first Kidd patent did not invalidate the later Inks patent, the Seventh Circuit also affirmed the district court's finding of infringement and went to great pains to explain why the canceled subject matter would not be considered by the court. Its reasoning is interesting:

> But is this [eliminated part of the specification of the earlier Kidd patent] such prior public disclosure or publication as would invalidate the Inks claim? Public disclosure or publication to be effective as such must be a revelation of an invention so publicly published or disclosed as to raise a presumption that the public concerned with the art would know of it.... It is within the domain of possibility that as to every patent which has been granted the original application disclosed some other invention unrelated to that for which the patent issued, and which only an examination of the file wrapper would reveal. If, therefore, disclosure of invention other than that for which the patent was issued, but which only the file wrapper would reveal, is to be considered as prior publication within the meaning of the law, no patentee could be certain that there had not been prior publication of his invention through its inclusion in some application as originally filed, unless every file wrapper in the Patent Office were searched to eliminate the possibility that the invention in question at some prior time had been in such manner disclosed. The resultant inconvenience of holding such contents of a file wrapper to be publication — indeed, the practical impossibility of making in each case the search necessary to learn whether or not there lies buried in some one file wrapper of the infinite number in the Patent Office, some paper disclosure of an invention, of itself, apart from its inherent want of the element of a

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[6] *See* note 13, *infra.* In *Camp Bros., supra,* note 5, at 607, the court said that the second Kidd patent could not be used as a prior art reference since it issued after the patent in suit was filed. The usual reasons given at that time are found at p. 608. The subject matter involved, while disclosed in the second Kidd patent, *was not claimed.* In those days, courts held that *only claimed subject matter* in a patent could be used as a prior art reference as of the filing date of the patent against which the reference is to be cited. This practice was reversed by the Supreme Court nine years later in the *Milburn* case which held that *unclaimed* subject matter could also be used as a prior art reference as of the filing date of the patent against which the reference is to be cited. Thus, if the factual situation in the *Camp Bros.* case arose today, the second Kidd patent would be a proper prior art reference under section 102(e) because the Inks invention was described in the second patent granted on the application filed by Kidd in the United States on December 22, 1898, which date was before the constructive invention thereof by the Inks application for patent filed on August 28, 1900.

> public disclosure — induces the conclusion that it may not be regarded as such a publication.[7]

It may be noted that there was not an "infinite number" of file wrappers in the USPTO to be investigated because the patent whose validity was being questioned was only No. 684,064.[8] Only prior patents would be pertinent. Secondly, not "every patent" would be within the field of search. The professional searcher would look only into the areas related to dumpers, elevators, and wagons. He would obviously not look in areas related to apparel, surgery, and beds. Thus, most patents can be eliminated from consideration simply by their subject matter classification. There remains then only a moderately finite number of patents to be searched. Thirdly, "the public concerned with the art" would find the first Kidd patent, as happened in this case, and a reasonable prudent professional searcher or an attorney handling the litigation would have ordered the publicly available file wrapper of the most pertinent prior art reference for review.

The court correctly ruled that the canceled subject matter may not be considered a description in a "printed publication" within the plain meaning of the words and within the interpretation of the predecessor statute of 35 U.S.C. § 102(a). The patent file wrapper containing the canceled matter, even though publicly available, was not a publication in the sense of being printed material prepared on a printing press. However, such canceled matter should have been certainly considered to be "known or used by others in this country" on August 1, 1899 within the interpretation of the predecessor to § 102(a). Since the issuing date of the first Kidd patent preceded the filing date of August 28, 1900 for the Inks application and Inks had not shown that he had made his invention prior to June 6, 1896, the filing date of the first Kidd patent, any patent arising from the Inks application should have been considered invalid if the appellate court had considered the canceled subject matter in the file wrapper of the first Kidd patent to disclose the subject matter of the Inks application.

Thus, it is the author's opinion that, although the appellate court properly found that the canceled subject matter in the file wrapper of the first Kidd patent was not a "printed publication," it committed an error of omission by failing to find that the subject matter of the Inks application was already "known or used by others in this country"

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[7] Camp Bros., *supra* note 5, at 607-8.

[8] U.S. Patent No. 4,000,000 issued on December 28, 1976. Thus, the number of file wrappers does now begin to approach infinity but it did not in 1901.

under the predecessor to § 102(a) because of the existence of the canceled matter in the publicly available file wrapper of the first Kidd patent. However, the court's error was rendered harmless because it also ruled that this matter canceled from the file wrapper of Kidd's first patent would not have invalidated Inks' later filed patent in any case.

In the second case[9] dealing with canceled subject matter, a United States Navy officer named Fessenden filed a patent application in 1915 relating to a method of electrical signalling. The examiner was of the opinion that the application described 22 separate inventions and therefore required the applicant to restrict his claims to only one invention. The inventor thereafter limited the application to a gun sight and canceled the subject matter referring to electrical signaling. The restricted application eventually issued as a patent in 1918, thus making the file wrapper containing the canceled subject matter publicly available.

In 1919, two co-inventors, Wilson and Schafer, filed an application on the method of electrical signaling which they had developed independently of Fessenden. A patent issued to Wilson and Schafer in late 1921 and, perhaps upon learning of the issuance of the patent, Fessenden filed an application two months later in early 1922 on his own electrical signaling invention that had been canceled from his first application filed in 1915. Thus, this second Fessenden application was not a continuation application and stood on its own filing date. The examiner, noting the similarity of the method described by Fessenden in his newly filed application and by Wilson and Schafer in their recently issued patent, declared an interference.

Because of Fessenden's lack of diligence for three years from 1918 to 1921 in failing to file a divisional application on his electrical signaling invention, the Patent Office Board of Appeals awarded priority to Wilson and Schafer. The Court of Customs and Patent Appeals (CCPA) affirmed and, in further deciding that the publicly available but canceled subject matter from Fessenden's 1918 patent did not invalidate the 1921 patent to Wilson and Schafer, stated, "For obvious reasons, the filing of an application, the description of which is canceled before it results in a patent or comes to the public notice is not such a published description of the invention . . . ."[10]

Those "obvious reasons" were, of course, that the "published de-

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[9] Fessenden v. Wilson, 48 F.2d 422, 9 U.S.P.Q. 274 (C.C.P.A. 1931), *cert. denied* 284 U.S. 640.

[10] *Id.*, at 425, 9 U.S.P.Q. at 277.

scription of the invention" was not a publication in the sense of printed material under the predecessor to § 102(a). Although the equities of the situation may have been on the side of Wilson and Schafer, it does not necessarily follow that they should have been left to maintain the patent against the public because, although the court refused to consider the canceled matter in the file wrapper of Fessenden's 1918 patent as "a published description of the invention," it was abundantly clear that the invention was "known or used by others in this country" within the meaning of the predecessor to § 102(a) due to the public availability of the canceled matter in the file wrapper for Fessenden's 1918 patent before Wilson and Schafer filed their application in 1919. Nevertheless, because this case was an interference proceeding, the later inventors, Wilson and Schafer, may have been able to "swear back" of the 1918 issuing date of the Fessenden patent by proving that they conceived their invention before the canceled subject matter in the file wrapper of Fessenden's 1918 patent became publicly available. Thus, the application of Wilson and Schafer filed in 1919 would have been considered allowable by the examiner even though they were not the first actual inventors.

Although the CCPA properly found that the canceled subject matter in the file wrapper of the 1918 Fessenden patent was not a "printed publication," it could not have answered the question as to whether or not the subject matter of the Wilson and Schafer application filed in 1919 was already "known or used by others in this country" under the predecessor to § 102(a) because of the existence of the canceled matter in the file wrapper of the 1918 Fessenden patent since such a question was a new issue that is precluded from consideration by the nature of the CCPA. Furthermore, we unfortunately have no way of knowing if Wilson and Schafer were able to establish the date of conception of their invention as prior in time to the 1918 date on which the canceled subject matter in the file wrapper of the Fessenden patent became publicly available. If Wilson and Schafer were able to establish the date of conception of their invention as prior to the date on which the canceled subject matter became publicly available, the entire issue regarding the citability of the canceled subject matter would be rendered moot in favor of Wilson and Schafer.

The apparent meaning of the ruling in *Fessenden v. Wilson* that matter appearing in a patent application as originally filed but can-

celed before the application issued as a patent, does not constitute a printed publication, was clarified in a 1958 case[11] in which the CCPA stated, "[the first inventor] had not urged that [his] *patented file* containing the canceled matter constitutes a printed publication [but] was merely urging that *all* matter contained in an application as filed constituted a disclosure sufficient to bar the granting of a patent [to the later inventors]..."[12] (emphasis in original.) In explaining away the generally accepted interpretation of its earlier decision in *Fessenden v. Wilson,* the court noted that in the *Fessenden* case it had cited the Supreme Court's decision in the famous *Milburn* case[13] which did not deal with the meaning of printed publications under the predecessor to 35 U.S.C. § 102(a) but rather had dealt with matter contained in an application and *not* canceled therefrom. Such matter would appear in the specification of the published patent and could be cited as prior art in the eyes of the Supreme Court. This so-called rule of the *Milburn* case was codified in 35 U.S.C. § 102(e)[14] by Congress when it enacted the 1952 Patent Act[15] six years before the CCPA clairfied the 1931 *Fessenden* case.[16]

Nevertheless, this 1958 clarification of the *Fessenden* case was either ignored or overlooked two years later by the District Court for the Northern District of Ohio. In the *Preformed Line Products* case,[17] four patents were in suit, only one of which is pertinent to the issue herein. The pertinent patent[18] issued to one Peterson in 1956 on a 1955 application related to dead ends for electrical cables. A competitor was charged with infringement and, during a validity search,

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[11] *In re* Tenney, 254 F.2d 619, 117 U.S.P.Q. 348 (C.C.P.A. 1958).

[12] *Id.* at 622, 117 U.S.P.Q. at 350.

[13] Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (1926).

[14] 35 U.S.C. § 102(e) (1975) provides:

> A person shall be entitled to a patent unless —
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> ....
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another... before the invention thereof by the applicant for patent....

[15] 35 U.S.C. § 1 *et seq.* (1953).

[16] *See* note 9, *supra,* and accompanying text.

[17] Preformed Line Products Co. v. Fanner Mfg. Co., 225 F.Supp. 762, 124 U.S.P.Q. 288 (N.D. Ohio 1960), *aff'd* 328 F.2d 265, 140 U.S.P.Q. 500 (6th Cir. 1964), *cert. denied,* 379 U.S. 846.

[18] U.S. Patent No. 2,761,273.

located a patent[19] issued to one Selquist in 1940. The Selquist patent had fifteen drawings including a figure 10 which was somewhat similar to the patented invention of Peterson. The specification on the face of the Selquist patent did not discuss figure 10 in detail but the file wrapper showed that claims had been specifically made to the invention disclosed by figure 10 but that such claims had been canceled before the patent issued. In denying the citability of the Selquist file wrapper as prior art, the district court quoted[20] the above-mentioned passage[21] from the *Fessenden* case and the MPEP rule[22] which followed the earlier generally accepted interpretation of the *Fessenden* case. The court also quoted from the plaintiff patent owner's brief: "Such canceled matter secreted in the files of the Patent Office is no more communicated to any one than if it were merely written out by the inventor and retained in his portfolio."[23]

It is unfortunate that the district judge failed to recognize the fallaciousness of the patentee's analogy. Canceled matter in file wrappers of issued patents is not "secreted" after the patent issues but is, on the contrary, publicly available thereafter. Having convinced the court to accept its erroneous position that canceled matter is "secreted" even after the patent issues, it was easy for the district judge to fall into the trap and make the incorrect analogy that such canceled matter is similar to ideas and notes retained in an inventor's portfolio which is usually not opened to all members of the public.

The Sixth Circuit Court of Appeals affirmed the district court's decision four years later and cited the plaintiff's brief but did not rely upon the *Fessenden* case as supporting authority. The appellate court instead referred to it only in a footnote as dealing with a "related question."[24] It is clear that the Sixth Circuit was aware of the CCPA's 1958 re-interpretation of the *Fessenden* case because the clarifying 1958 case was cited immediately after the *Fessenden* case in the pertinent footnote.[25] However, the appeals court went a little farther than the trial judge in upholding the validity of the patent in issue by

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[19] U.S. Patent No. 2,202,538.

[20] Preformed Line Products Co., *supra* note 17, at 779, 124 U.S.P.Q. at 302-3.

[21] *See* note 10, *supra,* and accompanying text.

[22] MPEP (2d ed. 1953) stated: "Cancelled matter in the application file of a United States Patent is not a proper reference, since it is neither a patent nor a printed publication. *See* Fessenden v. Wilson et al...."

[23] Preformed Line Products Co., *supra* note 17, at 779, 124 U.S.P.Q. at 302.

[24] *Id.* at 272, 140 U.S.P.Q. at 506n.6, and accompanying text.

[25] *Id. See also* note 11, *supra.*

ruling that, even if the canceled subject matter were citable as prior art, it did not describe the same invention as the patent in issue and therefore would not have invalidated it.[26] The Supreme Court denied certiorari.[27]

Two years after the Sixth Circuit's decision, the Patent Office Board of Appeals had an opportunity[28] to speak on the subject of canceled matter as citable prior art. An inventor named Stalego had filed a patent application on January 22, 1962 for a method and apparatus for causing streams of heat-softened material to flow from a supply source. Eight days later a patent issued to one Roberson on a closely related invention. The examiner of the Stalego application, in checking the file wrapper of the Roberson patent, discovered that the subject matter of Stalego's application had been disclosed but canceled from the Roberson application before it had issued as a patent. The examiner cited the canceled matter in the Roberson patent file wrapper on the grounds that already "the invention was known or used by others in this country" under 35 U.S.C. § 102(a)[29] and therefore rejected Stalego's application. The disappointed inventor appealed and the Patent Office Board of Appeals reversed the examiner's decision because there was no evidence that the invention was *publicly* known or used by others, to wit, Roberson, in this country *before* Stalego filed

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[26] Preformed Line Products Co., *supra* note 17, at 272, 140 U.S.P.Q. at 506.

[27] *See* note 17, *supra.*

[28] *Ex parte* Stalego, 154 U.S.P.Q. 52 (Pat. Off. Bd. App. 1966). This decision has been criticized in ROBBINS, THE DEFENSE OF PRIOR INVENTION (1977) as "contrary to its own logic" at 80 and as presenting "some difficulties" at 81. Although the *Stalego* opinion may not seem to be crystal clear upon a first reading, this author's review of the opinion leads him to the conclusion that the criticism is unwarranted. For example, Robbins discusses at 80 the part of the *Stalego* opinion that points out why § 102(g) is not pertinent and draws the conclusion that the Board is condoning the use of private or secret knowledge as prior art as long as it becomes publicly available at some later date. The Board is not condoning any such interpretation of § 102(g). The Board is saying only that *in an interference* to which § 102(g) applies, the private or secret knowledge of one inventor may be available as prior art against the private or secret knowledge of another opposing inventor. The private or secret knowledge is, of course, each other's patent application involved in the interference. Furthermore, Robbins seems to approve at 80 of the bad law made in *Ruskin* and *Hommel Mfg. Co., supra* note 2, in which the courts said that canceled subject matter in the file wrapper of an issued patent was a proper prior art reference against a later filed application under § 102(a) *as of the filing date when the canceled subject matter was still secret.* As pointed out in note 2, canceled subject matter is generally held to become a citable prior art reference only as of the *issuing date* of the patent from which file wrapper the subject matter was canceled.

[29] *See* note 1, *supra.*

his application. The opinion of the Board of Appeals was written by P.J. Federico, the Examiner-in-Chief who is generally recognized as one of the chief draftsmen of the 1952 Patent Act.[30]

However, the most interesting part of this 1966 decision is a plain statement as to what the *Stalego* case was *not* concerned with. The Board, per Federico, stated, "It should be noted that whether the *canceled subject matter constitutes prior art as of the date the patent issued, when it became available to the public,* is not involved in this appeal . . ."[31] [emphasis added].

It is also interesting to note that in a decision made about four months before the *Stalego* case was decided but which decision was not released until about four months after the *Stalego* case,[32] the Board, again per Federico, said in *Ex parte Thelin*[33] the following:

> First, it is noted that the date of the [prior art] patent is . . . more than two years after the filing date of the present application. We will assume for the purpose of this decision that *on that* [issue] *date* [of the prior art patent] *the subject matter cancelled can be considered as part of the stock of public knowledge*[34] [emphasis added].

After the passage of two more years, the administration of the Patent Office quietly changed the MPEP section[35] to reflect the decision of the Board of Appeals in the *Stalego* case and also to adopt a rule regarding the assumption stated for the purpose of the decision by the Board of Appeals in the *Thelin* case. Public hearings were not held for the change in the MPEP section but such public hearings are not required merely for instructions to the examiners. As of the writing of this article, the present version[36] of the MPEP section reads as follows:

> Canceled matter in the application file of a U.S. patent is not a proper reference as of the filing date under 35 U.S.C. 102e, see Ex parte Stalego, 154 USPQ 52. However, *matter canceled from the application file wrapper of a U.S. patent may be used as prior art as of the patent date in that it then* constitutes prior knowledge under 35 U.S.C. 102(a) [emphasis added].

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[30] *See* P. FEDERICO, COMMENTARY ON THE NEW PATENT ACT., 35 U.S.C.A. 1 (1953).

[31] *Ex parte* Stalego, *supra* note 28, at 53.

[32] It is the policy of the Board of Appeals not to publish a decision until a patent issues from the application under appeal. In this case, the opinion of the Board of Appeals was dated May 6, 1966 but the patent did not issue until about eight months later on January 17, 1967.

[33] 152 U.S.P.Q. 624 (Pat. Off. Bd. App. 1966).

[34] *Id.* at 625.

[35] *See* note 20, *supra.*

[36] MPEP § 901.01 (3d ed. 1961), *as amended* (Oct. 1968).

Conclusion

To summarize the case law to date, the *Stalego* case holds that canceled subject matter in the file wrapper of a patent cannot be cited as prior art as of the filing date of the application giving rise to the reference patent. There are no well-reasoned cases[37] to the contrary and this rule of the *Stalego* case makes good sense because the canceled subject matter is not publicly available as of its filing date.

Regarding the citation of canceled matter in file wrappers of issued patents as prior art, the older decisions in the *Camp Bros.*, *Fessenden,* and *Preformed Line Products* cases, as best as they can be understood, seem to say that canceled subject matter cannot be used as prior art at all, even after the patent issues, because such matter is not a "printed publication." However, these decisions do not deal with the question as to whether or not the single copy of pertinent canceled matter in the Public Search Room of the USPTO renders such matter not publicly available in any routine manner either because the existence of only a single copy renders the discovery of such matter only the result of a fortuitous finding or because there is no reference to the canceled matter on the face of the issued patent to render such canceled matter part of a printed publication by incorporation. To the contrary, the assumption of the Board of Appeals in the *Thelin* case and MPEP § 901.01 utilized by the patent examiners state that such canceled subject matter may be cited as prior art as of the issuing date of the reference patent because it constitutes prior public knowledge as of that issuing date under 35 U.S.C. § 102(a). The fact that finding the single copy of such canceled matter is difficult or the fact that such canceled matter is not a printed publication are irrelevant considerations according to this latter view.

Now let us return to you as the small businessperson facing the two dilemmas discussed in the beginning of this article. Regarding the patent which you are accused of infringing, under the reasoning of the old line of cases from the higher authorities, the canceled subject matter located by the hired professional searcher may not be used at all as prior art and, therefore, your larger competitor's patent would be valid and you would be found guilty of infringement. However, under the reasoning of the new line of decisions from the lower authorities, the canceled subject matter may be used as prior art and, assuming the issuing date of the reference patent precedes the filing date of the investigated patent, your larger competitor's patent could be invalid and you would not be guilty of infringement.

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[37] *Contra, see* note 2, *supra.*

Regarding the application on which you are seeking a patent, under the reasoning of the old line of cases, the canceled subject matter located by the examiner studying your application may not be used at all as prior art and, therefore, your application will be allowed. Also, under the reasoning of the new line of decisions, the canceled subject matter may not be used as prior art if the issuing date on which the reference patent became publicly available followed the filing date of your own application and, therefore, your application would also be allowed. However, if the issuing date on which the reference patent became publicly available preceded the filing date of your own application, then, of course, the canceled subject matter may be used as prior art and your application might not be allowed. Nevertheless, you would be free to attempt to overcome the issuing date of the patent from which file wrapper the subject matter was canceled by swearing that the conception of your invention occurred on a date prior to the issuing date of the prior art reference.

The present MPEP section still confronts the patent bar today and flies in the face of older case law from higher authority going back a half century[38] before the revision of the section in 1968. However, the author has attempted to point out that the 1966 *Stalego* and *Thelin* decisions of the Board of Appeals, which led to the appearance of the present MPEP section, are better reasoned and drawn from knowledge and experience in the Patent Office that was not possessed by the judges of the Sixth and Seventh Circuits and the CCPA who decided the earlier cases. The Board of Appeals and later the USPTO, in making *public availability* the determining factor in deciding the citibility of canceled subject matter as prior art, has done a service to the public in preventing the issuance of patents to the *second* inventor rather than to the first. However, it remains to be seen whether or not the higher authorities will acquiesce to the moves made by the USPTO and reverse themselves when a case on point arises. Perhaps a proper case has not yet been taken on appeal because the patent bar has generally recognized the wisdom of the rulings of the lower authorities. Nevertheless, the question of the viability of the older cases still exists and is awaiting resolution. Just waiting.

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[38] The first case was Camp Bros., *supra* note 5, decided in 1917.

Abandon, Suppress, or Conceal in an Interference Context*

PAUL T. MIEKLEJOHN**

An inventor is entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it."[1]

Abandonment, suppression, or concealment issues may arise in an interference context[2] if the first inventor has abandoned, suppressed, or concealed his invention. By doing so, he is denied the right to rely on his earlier date of invention.

Although interferences which are decided on the basis of abandonment, suppression, or concealment issues are extremely rare,[3] three cases[4] involving these issues have been decided in the last two years by the Court of Customs and Patent Appeals (CCPA). Attorneys and

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[1] 35 U.S.C. § 102(g).

[2] These issues may also arise in the context of an *ex parte* rejection by a Patent Examiner, as in *In re* Bass, 474 F. 2d 1276, 177 U.S.P.Q. 178 (C.C.P.A. 1973), or as a validity defense in infringement litigation, as in Sutter Products Co. v. Pettibone Mulliken Corp., 428 F.2d 639, 166 U.S.P.Q. 100 (7th Cir. 1970); and Grinnell Corp. Va. Elec. & Power Co., 277 F.Supp. 507, 156 U.S.P.Q. 443 (E.D. Va. 1967).

[3] *See Introduction to Interference Law and Practice,* 46 J. PAT. OFF. SOC'Y 755, 766 (1964).

[4] Cochran v. Kresock, 530 F.2d 385, 188 U.S.P.Q. 553 (C.C.P.A. 1976), discussed in text accompanying notes 9-26, *infra;* Peeler v. Miller, 535 F.2d 647, 190 U.S.P.Q. 117 (C.C.P.A. 1976), discussed in text accompanying notes 31-46 and 51-61, *infra;* and Howarth v. Lee v. Long, 564 F.2d. 948, 195 U.S.P.Q. 701 (C.C.P.A. 1977), discussed in text accompanying notes 47-61, *infra.*

agents who are responsible for the preparation and filing of patent applications should be particularly familiar with the decision in *Peeler* v. *Miller,* discussed below.

Abandonment

Abandonment in a § 102(g) interference context is different from the abandonment in § 102(c)[5] because different policy considerations are applicable. In an interference situation, the abandonment issue is always presented in the context of a dispute between two or more inventors over who has the better right to a patent.[6] On the other hand, an invention is abandoned for § 102(c) purposes when an inventor either expressly abandons his invention or his actions necessarily imply such an abandonment.[7]

Since very few abandonment cases have been decided under either § 102(g) or § 102(c), it is not clear whether the evidentiary burden is less in a § 102(g) context than it is in a § 102(c) context. This author suspects that there may be a lesser burden in proving § 102(g) abandonment if the court considers the relative conduct of all of the interference parties and not just that of the party who allegedly abandoned. If the equities in a particular case are entirely in one party's favor, and if that party filed his patent application promptly after reducing his invention to practice, while his opponent delayed for a relatively long period of time, conducting himself in such a way that an implied intent to abandon the invention arguably exists, the court may look at the conduct of both parties and conclude that the one who promptly filed his application has the better right to a patent. Thus the party who delayed implicitly intended to abandon his invention

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[5] 35 U.S.C. § 102(c) reads as follows: "A person shall be entitled to a patent unless... he has abandoned the invention..."

[6] *See* Brokaw v. Vogel, 429 F.2d 476, 166 U.S.P.Q. 428 (C.C.P.A. 1970).

[7] *See* Marvin Glass & Assoc. v. Sears, Roebuck & Co., 318 F. Supp. 1089, 1102, 167 U.S.P.Q. 33, 44 (S.D. Tex. 1970).

even though his conduct might not amount to a § 102(c) abandonment.[8]

Cochran v. Kresock[9] is not helpful in determining whether a lesser evidentiary burden exists for § 102(g) abandonment since the proof submitted by Cochran was not sufficient to establish that Kresock abandoned even in a § 102(g) context.

Cochran v. Kresock. The invention at issue was a circuit for improving the flesh tones in a color television receiver. Kresock (assigner to Magnavox Company) was the junior party patentee and Cochran (assignor to RCA) the senior party applicant. The Board of Patent Interferences found that Kresock had actually reduced his invention to practice in 1968. Cochran chose to rely on his filing date of 1970. Cochran alleged, however, that Kresock had abandoned, suppressed or concealed his invention after his actual reduction to practice. In deciding the issue, the Board looked to the following facts (as restated by the CCPA):

> Prior to the April, 1970 meeting of the Magnavox patent committee, RCA commercially introduced its version of a flesh correction circuit, which commercial introduction was reported in a periodical named Television-Digest... in March, 1970. The evidence shows that Magnavox personnel, at some point in time, learned of the specific details of the RCA circuit. However, there is no substantial evidence in the record to indicate whether those present at the Magnavox patent committee meeting in April, 1970 knew of the specific details of the RCA circuit when a decision was made to file a patent application on Kresock's invention. The evidence does indicate that at least some of those present at the patent committee meeting had a general knowledge of RCA's introduction of a flesh correction circuit.[10]

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[8] The issue whether § 102(g) abandonment constitutes § 102(c) abandonment was recently raised in Steierman v. Connelly, 192 U.S.P.Q. 446 (Bd. Pat. Int. 1976). In a prior decision, Steierman v. Connelly, 192 U.S.P.Q. 433 (Bd. Pat. Int. 1975), the board found that Steierman had proven a reduction to practice earlier than Connelly's filing date but that Steierman had abandoned, suppressed or concealed his invention. Accordingly, priority would have been accorded to Connelly but for the fact that Connelly was inequitable in his dealings with the Patent and Trademark Office in failing to set forth the best mode for carrying out his invention. In the second *Steierman* decision (192 U.S.P.Q. 446), Connelly argued that Steierman also was not entitled to a patent since the board concluded that Steierman "abandoned, suppressed, or concealed" his invention and since abandonment is an absolute bar under § 102(c). The board avoided the issue of whether § 102(g) abandonment necessarily implies § 102(c) abandonment by modifying its original decision to hold that Steierman "suppressed or concealed" his invention but did not abandon it.

[9] 530 F.2d 385, 188 U.S.P.Q. 553 (C.C.P.A. 1976).

[10] *Id.* at 389-90, 188 U.S.P.Q. at 555-6.

There was also some evidence to indicate that Magnavox began work on at least one other "low cost" flesh correction circuit in August 1969.

The Board concluded that these facts were not sufficient to constitute abandonment, suppression, or concealment. Neither the twenty-one month gap between the demonstration and the filing date of Kresock's application nor the dismantling of the Kresock circuit after the demonstration were sufficient to prove an intent to abandon. Rather, Kresock's preparation of a patent disclosure in July 1969 rebutted any presumption of abandonment. Furthermore, the Board found that there was "no substantial evidence that Magnavox was spurred by RCA's activities or that it suppressed or concealed the invention."[11]

The CCPA concluded that Kresock established an actual reduction to practice in 1968, two years prior to Cochran's filing date. They then considered whether Cochran had proven by a preponderance of the evidence that Kresock abandoned, suppressed, or concealed the invention.

Cochran pointed to three factors which he believed would support an abandonment conclusion. These factors were (1) the dismantling of the Kresock circuit after the demonstration in 1968; (2) the lack of activity on the Kresock circuit after it was dismantled; and (3) the Magnavox work on at least one other "low cost" flesh correction circuit in August 1969. The CCPA concluded that

> [m]ere lapse of time between the dismantling of the Kresock circuit in September, 1968, and the patent committee meeting in April, 1970, does not evidence an intent to abandon the invention. Similarly, we believe that work on other "low cost" flesh correction circuits by Magnavox does not lead to an inference that the Kresock circuit was abandoned.[12]

Furthermore, there was evidence to rebut any abandonment conclusion which might be based on the above stated facts. For example, the undisputed fact that Kresock was assigned the task of preparing a patent disclosure on the invention in June 1969, which he completed in July 1969, is inconsistent with any conclusion that the Kresock circuit was abandoned at least as of July 1969.

> Similarly, the later review of this patent disclosure by the patent committee, with the subsequent filing of an application, creates a strong inference that no abandonment took place after the submission by Kresock of the patent disclosure in July, 1969. There is also direct testimony by Heffron [Kresock's superior at Magnavox] to the effect that there was never

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[11] *Id.* at 390, 188 U.S.P.Q. at 556.

[12] *Id.* at 393, 188 U.S.P.Q. at 558.

> any intention on the part of Magnavox to abandon Kresock's circuit, but on the contrary that at some point in time the circuit was to be incorporated into a commercial receiver. Considering all the evidence before us, we conclude that there is lack of proof, by a preponderance of the evidence, that the Kresock circuit was abandoned after the actual reduction to practice.[13]

Cochran also urged that Kresock suppressed or concealed his invention. This contention was based on (1) the "lack of activity between the July 1969, patent disclosure and the April 1-3, 1970, patent committee meeting;"[14] and (2) the alleged spurring of Kresock "by the commercial introduction of a flesh correction circuit by RCA."[15]

The court concluded that "[m]ere delay, without more, is insufficient"[16] to constitute suppression or concealment. Thus, Cochran's case rested on an inference of suppression or concealment based on the "spurring" allegation. Concerning this latter point, the court stated:

> The evidence to which appellant points as support for his spurring contention is insufficient to establish an inference of suppression or concealment. As stated above, the evidence shows that at least three manufacturers already had commercial flesh correction circuits before RCA introduced its circuit. Such a state of affairs tends to lessen the likelihood that Magnavox was spurred into activity by a general information article describing the belated entrance of RCA into this field. The only other evidence which might tend to support appellant's spurring argument is the knowledge by some of the Magnavox personnel of the details of the actual circuit used by RCA. This knowledge was acquired at about the time of the patent committee meeting. However, the evidence fails to show that anyone present at the meeting knew of the details of the RCA circuit when a decision was made to file an application on Kresock's invention. In fact, the only witness present at that patent committee meeting who was called by appellant, a Mr. Seeger, testified that he did not know of the details of the RCA circuit at the time of the meeting. Therefore, on the facts before us, we cannot conclude that appellant has proven by a preponderance of the evidence that Magnavox had suppressed or concealed the invention and was spurred into filing Kresock's application only after learning of the RCA introduction of a flesh correction circuit. The inference which appellant seeks to draw from the evidence is weak and fails to measure up to the proof required on this issue.[17]

It will be seen that the majority view of the CCPA in *Peeler v. Miller*,[18] grafts onto § 102(g) at least with respect to "suppress or

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[13] *Id.*

[14] *Id.*

[15] *Id.* at 393, 188 U.S.P.Q. at 558-9.

[16] *Id.* at 393, 188 U.S.P.Q. at 559, *citing* Young v. Dworkin, 489 F.2d 1277, 180 U.S.P.Q. 388 (C.C.P.A. 1974).

[17] 530 F.2d at 394, 188 U.S.P.Q. at 559.

[18] 535 F.2d 647, 190 U.S.P.Q. 117 (C.C.P.A. 1976).

conceal," a policy "favoring ... the party who *expeditiously* starts his invention on the path to public disclosure ... by filing a patent application."[19] Thus, rather than looking at the action or inaction of the first inventor, under the "expeditious" standard the conduct of both the first inventor and the second inventor would be examined and priority accorded to a second inventor who is more expeditious than a first inventor. The dissent in *Peeler*[20] expressed the view that only the conduct of the first inventor should be considered, not that of his opponent.

If the "expeditious" standard were to apply to abandonment as it does to suppression or concealment, it would seem that the requirements for § 102(g) abandonment might not be as difficult to meet as they would be under the dissenting view in *Peeler*. In other words, one who is attempting to prove abandonment under the "expeditious" standard might not have to bear as heavy a burden concerning his opponent's *intention* to abandon if he can show that he himself was rather expeditious in getting his patent application on file soon after his reduction to practice while his opponent was much less expeditious.[21]

The issue of whether the "expeditious" standard may apply in an abandonment context has never been squarely presented. Under any view, however, proof of abandonment requires some kind of intention to abandon,[22] which intention may be either express or implied.[23] Factual situations in which abandonment is express are exceptional. In such a situation, sufficient evidence would have to be produced to show that the inventor either orally or in writing stated, in effect, "I hereby abandon this invention." Such factual situations are rare; there are few cases in which a court has held that there was an express abandonment.

An intention to abandon the invention may be implied, but it must be a necessary implication, at least for § 102(c) purposes.[24] Under this test, the inventor must not have engaged in any activities which would be inconsistent with the intention to abandon. In *Cochran,* for

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[19] *Id.* at 656, 190 U.S.P.Q. at 124 [Miller, J., concurring].

[20] *Id.*

[21] Furthermore, under the majority "expeditious" standard, the requirements for abandonment might also be less different to meet in a § 102(g) context than they would be for § 102(c) abandonment.

[22] *See* Marvin Glass, *supra* note 7 [§ 102(c) abandonment context].

[23] *Id.*

[24] *Id. But see* Moore v. United States, 194 U.S. 423 (Ct. Cl. 1977), where an "only reasonable explanation" standard is set forth in a § 102(c) context.

example, Kresock's conduct was far below that requirement. Although some of his activities were consistent with an abandonment conclusion, they did not *necessarily* imply such an intent. For the court to conclude that Kresock abandoned his invention, he would have had to commit some act or made some representation that indicated that he believed his invention to be worthless. For example, the destruction of the physical embodiments of the invention or the drawings associated with its conception, coupled with the other facts urged by Cochran in this case, might necessarily imply an intention to abandon. Such conduct might even suffice to imply an intention to abandon under § 102(c).

Since a court might look at the relative conduct of the interference parties in considering § 102(g) abandonment, a less strict test, possibly the "only reasonable explanation" test,[25] might be used to determine whether an intention to abandon may be implied in a § 102(g) context.

Suppress or Conceal

The "suppress or conceal" issue has been raised in two cases where at least part of the suppression or concealment was due to conduct by the applicant's assignee. This conduct was found to be imputable to the applicant.

In *Peeler v. Miller,* the majority of the CCPA held that "a four-year delay from the time an inventor is satisfied with his invention and completes his work on it and the time his assignee-employer files a patent application is, prima facie, unreasonably long in an interference with a party who filed first."[26] The court concluded that "Monsanto's delay was not 'mere delay', that the delay was excessive, and that as between Peeler and Miller, Peeler has the better right to a patent, on the statutory ground that Miller, through the acts of his assignee, suppressed the invention.[27]

In *Horwath v. Lee,*[28] a unanimous CCPA affirmed the Board, which concluded that more than a five and one-half year delay between actual reduction to practice of an invention and filing a patent application on it is an unreasonable or excessive delay which raises an "inference of intent to suppress and shifted to Horwath with burden of

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[25] *See supra* note 24.

[26] 535 F.2d 647, 190 U.S.P.Q. 117 (C.C.P.A. 1976).

[27] *Id.* at 654, 190 U.S.P.Q. at 122.

[28] 564 F.2d 948, 195 U.S.P.Q. 701 (C.C.P.A. 1977).

explaining the delay."[29] Since Horwath *et al.* were unable to adequately explain the five and one-half year delay, the court concluded that they suppressed the invention.

Peeler v. Miller. The invention in controversy in *Peeler* was a cavitation inhibitor used in power transmission fluids and a method of inhibiting cavitation. (Further discussion of this technology is not needed to appreciate the "suppress or conceal" issues involved here.)

Peeler was the senior party patentee and assignee to Chevron Research Co. Miller, the junior party applicant, was assignee to Monsanto Co. Peeler relied on his filing date, 1968. Both the Board majority and the CCPA majority concluded that Miller established an earlier actual reduction to practice in 1966. Peeler argued that Miller suppressed or concealed his invention after his actual reduction to practice.

On April 5, 1966 Miller submitted a "preliminary disclosure of invention." Within two weeks, this disclosure was rated "A (Ready [to file])" by his superiors in the Research Department of Monsanto's Organic Chemicals Division.[30] The record does not show when this disclosure was forwarded to Monsanto's patent department.

More than four years elapsed from the time Miller's disclosure was rated "A (Ready)" until he filed his patent application. There was no evidence of action in Monsanto's patent department until Mr. Black, the attorney who ultimately prepared and filed Miller's patent application, was hired by Monsanto in October 1968. Black submitted an affidavit in which he stated "that as of January 1969 he was responsible for (1) about 60 to 70 pending U.S. applications; (2) over 400 foreign pending applications; (3) over 100 active invention disclosures of which 27 were A-ready to file and 21 were A-not ready to file."[31] He recalled that as of January 1969, Miller's invention disclosure was, in order of filing priority, thirty-first on his list of 48 cases. Black generally filed invention disclosures according to their order of priority.

The Board majority concluded that the above facts were not sufficient to constitute suppression "on the basis that there was no evidence that Miller intended to suppress the invention or in fact did so."[32] A dissenting Board member concluded that the Monsanto delay was "an unreasonable delay analogous to *res ipsa loquitur* trans-

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[29] *Id.* at 951, 195 U.S.P.Q. at 704.

[30] 535 F.2d at 649, 190 U.S.P.Q. at 119.

[31] *Id.* at 650, 190 U.S.P.Q. at 119.

[32] *Id.*

ferring the burden of proof to Miller to prove that the invention *was not* suppressed, concealed, or abandoned under the provisions of 35 U.S.C. § 102(g)" [emphasis in original].[33]

Judge Rich, writing for the CCPA majority, reversed the Board on the suppression issue. He first stated the elementary legal principle that Monsanto's conduct was imputable to Miller.[34] Although there was no evidence of spurring in the instant case, the court, citing *Young v. Dworkin*,[35] stated that spurring was not an essential element of suppression. Furthermore, although neither Miller nor anyone else at Monsanto had the specific intent to suppress the invention, that intention could be inferred if "the time between actual reduction to practice and filing is unreasonable."[36] In the court's opinion, "a four-year delay from the time an inventor is satisfied with his invention and completes his work on it and the time his assignee-employer files a patent application is, prima facie, unreasonably long in an interference with a party who filed first."[37]

The court was clearly blaming Monsanto for "its neglect of Miller's application for the 2½ years preceding Mr. Black's arrival and its failure to replace two of the three attorneys who resigned . . .."[38]

Monsanto attempted to rebut the inference of suppression by arguing that (1) "the invention disclosure was handled in accordance with normal business practices;"[39] (2) Miller and his immediate superior consistently urged that a patent application be filed;[40] and (3) the invention disclosure rating was never changed from "A-Ready to file."[41] The court did not address the second and third arguments. However, with respect to Miller's contention that "the invention disclosure was handled in accordance with normal business practices," the court replied:

> This excuse is lame on two counts: First, there is no evidence of what Monsanto's 'established practices' were or that the review meetings ever took place. We will not accept statements in briefs as substitutes for evi-

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[33] *Id.* at 650-51, 190 U.S.P.Q. at 120.

[34] *Id.* at 653, 190 U.S.P.Q. at 122. *See In re* Clark, 522 F.2d 623, 187 U.S.P.Q. 209 (C.C.P.A. 1975); and Wilson v. Goldmark, 172 F.2d 575, 80 U.S.P.Q. 508 (C.C.P.A. 1949).

[35] *See supra* note 16.

[36] 535 F.2d at 653, 190 U.S.P.Q. at 122.

[37] *Id.* at 654, 190 U.S.P.Q. at 122.

[38] *Id.*

[39] *Id.* at 654, 190 U.S.P.Q. at 123.

[40] *Id.*

[41] *Id.*

> dence. Second, and more importantly, assuming the truth of Monsanto's assertions, we do not consider this four-year delay to be in accordance with any 'normal' business practice that we should accept as part of a sound patent system. Whether Monsanto's behavior is, in fact, a normal business practice is immaterial. Concepts of normality in business, and in patent law, change; that a practice is normal does not mean that it is one that courts should approve. We certainly cannot approve of the supine attitude toward delay exhibited by the statement in Monsanto's excuse, supra, that the 'delay in filing *was encountered*' [emphasis added], as though it had been come upon by surprise. The record, however, contains nothing to show that the delay was other than fully within Monsanto's control at all times."[42]

Judge Rich then analyzed the word "mere" and concluded that "Monsanto's delay was not 'mere delay', that the delay was excessive and that as between Peeler and Miller, Peeler has the better right to a patent, on the statutory ground that Miller, through the acts of his assignee, suppressed the invention."[43]

Judge Miller concurring,[44] disagreed with the majority who, he said, engrafted onto the statute "a policy 'favoring ... the party who expeditiously starts his invention on the path to public disclosure ... by filing a patent application'."[45] Judge Miller believed that the policy behind § 102(g) requires the court to be concerned with the action or inaction of the first inventor in this case not with that of his opponent. He agreed with the result, however, since the delay involved was excessive and gave rise to an inference of intent to suppress, shifting the burden to the first inventor to explain the delay by showing that there was no intent to suppress. Since appellee Miller failed to adequately explain the delay, Judge Miller concluded that he suppressed the invention.

Horwath v. Lee. Count 1 is representative of the subject matter involved and reads as follows: "A process for preparing a glucose-isomerizing enzyme which comprises inoculating a carbohydrate-containing nutrient medium with a micro-organism belonging to the genus Arthrobacter, maintaining the inoculated medium for a period of time under conditions suitable for production of said enzyme by said organism and recovering said enzyme."[46]

Lee *et al.* admitted that as between Lee *et al.* and Long, "Long is the original and sole inventor of all the subject matter of the counts

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[42] *Id.*

[43] *Id.* at 655, 190 U.S.P.Q. at 123-24.

[44] *Id.* at 655-56, 190 U.S.P.Q. at 124.

[45] *Id.* at 656, 190 U.S.P.Q. at 124.

[46] 564 F.2d at 949, 195 U.S.P.Q. at 703.

in interference." Thus, the interference was a contest between Horwath *et al.* and Long. Long is the senior party applicant and relied on her filing date of 1969. Horwath is the junior party applicant. The Board found that Horwath proved an actual reduction to practice in 1966. The dispositive issue, then, was whether Long proved, by a preponderance of the evidence, that Horwath suppressed or concealed the invention.

The board held that Horwath suppressed or concealed the invention and Chief Judge Markey, writing for a unanimous CCPA, affirmed the Board. The court adopted as its own the Board's view that "a nearly six-year delay from the time an inventor is satisfied with his invention to the time his assignee-employer files a patent application is prima facie unreasonable in an interference with a party who filed first."[47] This unreasonable delay, coupled with a statement in the record that it was intended to keep information concerning the invention "restricted to only a very few key people in our Company,"[48] was enough to infer an intent to suppress or conceal.

The CCPA did not accept Horwath's attempt to rebut this inference.

> Before us, Horwath's principal argument is a response to the Board's assertion that his patent application did not reflect improvements over an April, 1967 invention disclosure. Horwath directs our attention to four portions of his patent application said to reflect such improvement.
>
> The first portion is a list of eight preferred Arthrobacter species of which two were used in 1966. Though screening additional species may have stared prior to 1971, the bulk of the work was performed during 1971. An unexplained five year delay in performing the additional screening is inconsistent with an intent to provide early public disclosure.
>
> The second portion mentions cobalt salt as a source of metal ions for propagating the microorganism. Use of a source of metal ions is not, however, mentioned in any claims. More importantly, a cobalt salt was used in Horwath's 1966 research. The result of work done prior to actual reduction to practice cannot serve to explain a five year delay in disclosing that result.
>
> The third portion is the general statement, 'The glucose isomerase may also be bound to an inert carrier and used for the isomerization.' It is inconceivable that five years of research were required to support that statement.
>
> The fourth portion is an example and table, reflecting glucose isomerizing activity of various Arthrobacter species and said to support the broad claims in Horwath's application. The record fails, however, to demonstrate or point out consistent Horwath efforts to develop the information in the example and table over the five year span preceding his filing date.

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[47] *Id.* at 951-52, 195 U.S.P.Q. at 705.

[48] *Id.* at 952, 195 U.S.P.Q. at 705 n 5.

> Horwath began the research leading to his invention in November, 1965, and reduced it to practice in five months. Factors necessitating a period of sixty-six months to refine and perfect the invention, if such factors existed, are simply not adequately supported in the record.[49]

The United States patent system is rapidly approaching a "first-to-file" system in view of the recent suppression cases. Although it has been stated in the past that diligence is not required after reduction to practice,[50] that statement appears to be no longer true.[51] Both inventors and attorneys or agents must now be diligent in filing a patent application after reduction to practice.

From the above-discussed cases, *Cochran, Peeler,* and *Horwath,* and several others which preceeded them, a three-step test may be designed to predict when the CCPA would conclude that suppression or concealment has taken place. First, it should be determined whether there is any direct evidence of "spurring" the alleged suppressor into filing a patent application when he otherwise would not have filed. Although it is true that spurring is not an essential element of suppression,[53] it is also true that in virtually every recent case in which there was evidence that the first inventor was spurred into filing by the activities of others who were making substantially the same invention, the court inferred an intent to suppress.[54]

If there is no spurring, the second step requires a determination of whether the delay is "mere" delay or whether it is "unreasonable" or "excessive" delay. In deciding whether a delay is "mere" or "unreasonable," the CCPA seems to look only at the length of time

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[49] *Id.* at 950-51, 195 U.S.P.Q. at 704.

[50] *See* Bowers v. Valley, 140 F.2d 284, 287, 65 U.S.P.Q. 493, 497 (C.C.P.A. 1945).

[51] *See* Naber v. Cricchi,___F. 2d___196 U.S.P.Q. 294, 297 (C.C.P.A. 1977), where the court states (note 5) that "'reasonable diligence' in reducing an invention to practice, [is] not unlike the requirement that, to avoid a holding of suppression or concealment, there be no unreasonable delay in filing an application once there has been a reduction to practice" [citation omitted].

[52] The words suppress and conceal appear to be used interchangeably and synonymously in these cases. "Suppress" will be used below in place of "suppress or conceal."

[53] *See* Horwath, *supra* note 4, at 950, 195 U.S.P.Q. at 704 n. 31, Peeler v. Miller, *supra* note 4, at 653, 190 U.S.P.Q. at 122; and Young v. Dworkin, *supra* note 16, at 1281, 180 U.S.P.Q. at 391-92.

[54] *See, e.g.,* Pingree v. Hull, 518 F.2d 624, 186 U.S.P.Q. 248 (C.C.P.A. 1975); Palmer v. Dudzik, 481 F.2d 1377, 178 U.S.P.Q. 608 (C.C.P.Q. 1973); and Brokaw v. Vogel, *supra* note 6.

from the actual reduction to practice of the first inventor until his filing date.[55]

If there is no spurring and the delay is found to be a mere delay, then the intent to suppress is not inferred. Absent any express or specific intent to suppress, the court would likely conclude that there was no suppression resulting from this "mere" delay.

If the court decides either that the inventor was spurred into filing or that the delay between his actual reduction to practice and his filing date was unreasonable, an intent to suppress would be inferred. The party would then have to rebut that inference by presenting evidence which might justify the delay.[56] If the evidence is insufficient to rebut the inference, the court would find suppression; if the evidence is sufficient to rebut the evidence, suppression would not be found.

In applying this three-step test, there are a number of factors that the court seems to consider. One such factor is the length of time between actual reduction to practice and filing. The court characterizes such delays as either "mere" delays if they are short enough or "unreasonable" delays if they are too long. In *Peeler,* a four-year delay was considered "unreasonably long in an interference with a party who filed first."[57] In *Young v. Dworkin, supra,* a delay of 27 months was considered unreasonable under the circumstances.[58] Thus, any delay in excess of 27 months might be considered unreasonable by the

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[55] The majority in *Peeler v. Miller* stated than an "unreasonable delay may raise an inference of intent to suppress." 535 F.2d at 653, 190 U.S.P.Q. at 122. However, the majority opinion seems to imply that the court may have looked at the alleged suppressor's conduct to "persuade [them] of the correctness" of the unreasonable conclusion, 535 F.2d at 654, 190 U.S.P.Q. at 122. According to the three step test, such conduct would not be considered in determining whether the delay was mere delay or unreasonable delay. Rather it would be considered only when determining whether the inference of suppression had been successfully rebutted. Furthermore, it does not seem very satisfying to have the court consider conduct in arriving at its unreasonableness conclusion since the very same conduct would be considered in determining whether the inference of suppression, raised by the unreasonableness of the delay, has been rebutted. *See also* McLaughlin v. Roberts, 197 U.S.P.Q. 831, 837 (Bd. Pat. Cert. 1978) discussed at note 59 *infra.*

[56] Obviously, the longer the delay, the harder it is to rebut the inference.

[57] 535 F.2d at 654, 190 U.S.P.Q. at 122.

[58] In *Cochran v. Kresock, supra* note 4, a delay of 21 months was not deemed unreasonable.

court.[59] Other than these general guidelines, it is not clear how much time must pass before a mere delay becomes unreasonable.

Probably the most important factor that the court considers in deciding the suppression issue is the evidence which is presented to rebut the inference of suppression once either spurring and/or unreasonable delay is established. The kind of evidence that will successfully rebut the suppression inference would be evidence that during the Period of delay the inventor was taking steps to improve or perfect the invention after it was reduced to practice.[60] Such evidence would excuse the delay and thereby support a finding that it was reasonable.

Mere statements that "the invention disclosure was handled in accordance with established [corporate] practices which [are] consistent with normal business practices"[61] obviously will not suffice. In view of *Peeler* and *Horwath* it is clear that the inventor, his assignee, and the assignee's patent attorney must demonstrate consistent efforts throughout the period, from actual reduction to practice until filing to rebut the suppression inference. Thus, the inventor and the assignee's patent attorney should record the progress they make in either improving upon the invention or drafting the patent application. Furthermore, the corporate assignee cannot hide behind the fact that his patent department is understaffed.

A final point to keep in mind in attempting to prove or disprove a suppression case is that the court is divided as to the exact manner in which to view the suppression issue. Judge Rich and the majority of the CCPA seem to look at the conduct of both parties and determine who has the "better right" to a patent. Judge Miller, however, would

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[59] The Board of Patent Interferences in *McLaughlin v. Roberts, supra* note 55, concluded that a thirty month delay between reduction to practice and filing was not prima facie unreasonable, arguably contrary to the conclusion reached in Young v. Dworkin, *supra* note 16, where a 27 month delay was considered unreasonable. The *Young* decision was not treated in the board's opinion since the board chose to distinguish the *McLaughlin* case from *Peeler, supra* note 4, where a four year delay was deemed unreasonable.

The result in *McLaughlin* may be reconciled with the C.C.P.A. approach described in the text when the following quotation from the board's *McLaughlin* opinion is considered: "[T]here is moreover some evidence that McLaughlin was continuing work on the invention subsequent to his actual reduction to practice." 197 U.S.P.Q. at 837. The board's opinion does not describe the kind or amount of "work" that was carried out by McLaughlin subsequent to his actual reduction to practice, however.

[60] Frey v. Wagner, 87 F.2d 212, 32 U.S.P.Q. 239 (C.C.P.A. 1937).

[61] *See* Peeler v. Miller, *supra* note 4, at 654, 190 U.S.P.Q. at 123.

look only at the action or inaction of the one who is alleged to have suppressed, and not at the conduct of his opponent.

Although some have suggested that this may be a distinction without a difference,[62] it is submitted that differences would result in certain situations. For example, suppose Inventor A reduces an invention to practice in 1940 and shortly thereafter decides to conceal it from the public. In January 1970, Inventor B reduces to practice the same invention. In February 1970, Inventor A, spurred by B's activities, files his patent application. In July 1972, B files his patent application. Inventor B did nothing with his invention from the date of actual reduction to practice (January 1970) until July 1972 when he took it to a patent attorney who promptly filed a patent application. Both allege a reduction to practice prior to their respective filing dates. On the issue of whether Inventor B suppressed the invention, the court might conclude as follows: Under *Young v. Dworkin*[63] the delay would be found to be an unreasonable one and thus raise an inference of suppression under either Judge Rich's "better right" view of Judge Miller's view. In rebutting that inference, Judge Rich would apparently look not only at B's conduct during the delay but also at the conduct of A in order to determine who has the "better right" to a patent. In the fact situation presented above, B's thirty month delay seems almost insignificant in view of A's express intent to suppress coupled with spurring and more than a 30-year delay. Thus, Judge Rich might allow B to rebut the suppression inference by evidence which might not otherwise suffice but for A's blatant suppression. On the other hand, Judge Miller would look only to B's conduct during the delay to determine whether he suppressed.

Thus, the ultimate outcome of the suppression issue might depend upon which of the above two theories the court ultimately adopts. The court does not appear as yet to have decided any case where the outcome would be different depending upon the particular theory adopted.[64] Only in a rather extreme fact situation, such as the example proposed above, might the outcome be different depending upon the particular theory adopted by the court.

Conclusions

The "abandon, suppress, or conceal" problem arises in a very small percentage of cases. However, the CCPA seems ready to infer an in-

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[62] *See* 3 PATENT LAW PERSPECTIVES § C.10 at 27-9.

[63] *See* Young v. Dworkin, *supra* note 16, at 1277, 180 U.S.P.Q. 388.

[64] Judge Miller concurred with the majority in Peeler v. Miller, *supra* note 4.

tention to suppress or conceal from a delay of 27 months or more from actual reduction to practice to filing. That inference may be rebutted, particularly by evidence that the inventor was attempting to perfect his invention. The invention-related activities of the inventor, his assignee, and his attorney, during the time period between actual reduction to practice and filing, should be carefully documented. An inventor should record in his notebook the various ways in which he is attempting to perfect his invention and/or the reasons why he is unable to work on the invention for a particular period of time. The attorney should keep a diary of his work on the preparation of the patent application.

The best way to deal with any potential suppression or concealment problems is to eliminate them by filing the patent application as soon as possible after actual reduction to practice, certainly within about two years.

The abandonment issue arises even less frequently than that of suppression or concealment. The kind of evidence needed to prove abandonment may differ significantly from that needed to prove suppression since abandonment connotes "throwing away" and suppression connotes mere hiding of the invention. It is not clear whether the burden of proving abandonment under § 102(g) is as great as it would be under § 102(c). If Judge Rich's "better right to a patent" theory is the view ultimately adopted by the court when the appropriate factual setting is presented, it is submitted that the § 102(g) burden would be less than that of § 102(c).

Compulsory Licensing of Patents — The Paris Convention Model

DR. SHLOMO COHEN*

Patents are intended to encourage inventors and corporate research and development by granting limited exclusivity in return for proper disclosure of new technology. Because the purpose of the patent system is to promote science and technology, most countries are careful to ensure that abuse and non-use of patent rights do not defeat this goal.

There are various limitations on the patent monopoly which are intended to provide for the efficient exploitation of patents. In addition to limitations on patents covering technology which can affect national security or defense, essential goods and services, and public health, most patent statutes insist on optimal and efficient working of any patented technology. To ensure efficient exploitation of patented technology most patent systems provide the following sanctions: (a) endorsing patents to "license as of right;"[1] (b) compulsory licensing; and (c) revocation of patents.

The compulsory license is as old as the patent system itself. It is intended to assure that patent rights will not be abused by

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[1] The license of right is provided for in numerous countries, e.g., Algeria, Ireland, West Germany, Greece, New Zealand, Rhodesia, South Africa, United Kingdom. *See* J. BAXTER, WORLD PATENT LAW AND PRACTICE at 122 (1968) [hereinafter BAXTER]. Where a patent is not "sufficiently" exploited, it is endorsed to 'license of right,' which permits exploitation by any person who files a request with the Commissioner of Patents. The British Patents Act, 1977, c. 37, §§ 46, 47. *See also* G. TERRELL, ON THE LAW OF PATENTS at 656 *et seq.* (12th ed. 1971) [hereinafter TERRELL]; *and see* Casson's Patent [1971] R.P.C. 91.

pre-emption and suppression, to the detriment of the social and economic system.

Theoretically, compulsory licensing is an extension of the revocation of patents. In most countries the two methods exist side by side, with revocation reserved for those extreme cases where compulsory licensing fails to result in sufficient working.[2] Some countries have eliminated revocation and retained compulsory licensing as the only means to ensure working of patents.[3] Compulsory licensing has changed over the years, particularly with regard to the circumstances under which compulsory licenses are granted. The grace period, that period of time after the grant of a patent in which a compulsory license will not be issued despite non-working by the patentee, has been extended,[4] and the terms of the typical compulsory license have been revised.

Old English letters patent provided that where a patent was "hurtful to trade, or generally inconvenient," or if "the grant was prejudiced or inconvenient to the King's subjects," it was void.[5] Formerly then, patents were revoked for various reasons, including non-working and failure to work by way of manufacture.[6]

The Patent Act of 1883 authorized the Comptroller of Patents to issue a compulsory license where a patentee abused its patent monopoly. A patent was considered abused where (1) the patent was worked within the United Kingdom; (2) the public's demand for the product in question was not reasonably met; or (3) the patent was used to block the use of another patent.[7] Few applications for a compulsory license based on abuse were submitted under this Act, and there are no recorded applications under the British Patent Act of

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[2] Convention of Paris for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at the Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, 21 U.S.T. 1583, T.I.A.S. No. 6923, Art. 5A [hereinafter cited as The Paris Convention].

[3] *See* The Role of Patents in the Transfer of Technology to Developing Countries: Report to the Secretary General of the United Nations, 65 U.N. Report at 24 (1964) [hereinafter The U.N. Report].

[4] To three or four years. *See* section in text entitled Grounds for Compulsory Licensing.

[5] *See also* the British Statute of Monopolies, 21 Jac. 1 at 1623.

[6] British law has changed since then and now manufacturing is not essential. Any form of using the patent is sufficient to preclude revocation. Badische Anilin und Soda Fabrik v. Thompson (W.G.) & Co., Ltd., [1904] 21 R.P.C. 473.

[7] Section 22.

1902.[8] The Act of 1907 made the Comptroller's decision subject to appeal.

Collectively, the Patent Acts of 1919, 1929, 1932 and 1949 have given the Comptroller jurisdiction to issue a compulsory license, endorse the patent to license as of right, or revoke the patent,[9] subject to appeal to the Appeal Tribunal.[10] The new Patent Act of 1977 incorporated the 1949 provisions for compulsory licensing, although it eliminated the special treatment previously accorded food and drug patents.[11] The harsh treatment of these patents was eliminated.[12]

Compulsory licensing is covered by the Paris Convention for the Protection of Industrial Property.[13] The Convention recognizes the rights of the signatory states to compel licensing for failure to use the patent. It states:[14]

> 1. Member states may legislate measures providing for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example for failure to work.
> 2. Forfeiture of the patent will not be provided for except where the grant of compulsory licenses is not sufficient to prevent abuses. Forfeiture or revocation of a patent will not be instituted before the expiration of three years from the grant of the first compulsory license.
> 3. A compulsory license may not be applied of [sic] on the ground of failure to work or insufficent working before the expiration of four years from the date of the grant of the patent whichever period expires last. It shall be refused if the patentee justifies his inaction by legitimate reasons. Such compulsory license shall be non-exclusive and shall not be transferable even in the form of the grant of a sub-license except with that part of the enterprise or goodwill which exploits such license.

Most countries of the world are members of the Paris Union, and most, regardless of their political systems or level of industrial development, provide for compulsory licensing and revocation of unworked patents. Developed and under-developed, capitalist and

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[8] *See* TERRELL, *supra* note 1, at 279.

[9] *See* the British Patents Act, 1977, c. 37 §§ 46, 47; *and see* TERRELL, *supra* note 1, at 272.

[10] Part of the Chancery Division of the High Court. (§§ 84, 85 *as amended* by § 24 of the British Administration of Justice Act of 1969.)

[11] *See* section in text entitled Compulsory Licensing of Patents for Foods and Drugs.

[12] Since the 1977 Patent Act essentially re-enacts the 1949 Act provisions of compulsory licensing and since most cases discussed here were decided on the basis of the 1949 Act, references, unless otherwise indicated, will be made to sections of the British Patents Act, 1949, 12, 13 & 14 Geo. 6, c. 87.

[13] The Paris Convention, *see* note 2, *supra*.

[14] *Id.*

socialist countries alike employ these safeguards.[15] They are designed to encourage working of the patented technology, and to discourage abuse of patent rights which inhibits national development. They are intended to ensure sufficient supply of the patented products and access to patented processes, to prevent the use of patent rights to block the working of other patents, and to serve as an incentive for licensing on a fair and reasonable basis.[16]

The scope of the patent grant is limited, and compulsory licensing should be viewed in that context. Patent rights should be exercised in ways which protect consumers, maintain competition, and prevent monopolistic practices and cartels. Often, as is the case in the United States, a patentee who misuses a patent may be prevented from enforcing his patent rights and, thus, be forced indirectly to "license" infringers. The United Kingdom and Canada employ both the Paris Union type of compulsory licensing and various antitrust remedies for dealing with different patent abuses. In the United Kingdom, a Commission which was instituted specifically to deal with restrictive patent practices may order that a patent be endorsed to license of right.[17]

This note deals with the procedural and substantive aspects of compulsory licensing. It focuses on the laws of the United Kingdom and Canada, with references to some other countries.

A United States Perspective

In the United States it is presumed that the dynamics of the marketplace will dictate the working or non-working of patents. Thus, although the United States is a member of the Paris Union, it has not adopted statutory compulsory licensing of patents of the type prescribed by the Paris Convention. Non-working of a patented invention in the United States is within the discretion of the patentee. A patentee is not obliged to use the patented technology and indeed may, if the patentee wishes, suppress the patented technology altogether. This has traditionally been the position of both the United States legislature and of the private sector.[18]

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[15] *See* The U.N. Report, *supra* note 3, at 62.

[16] *Id.* at 23, 24.

[17] *See* Monopolies and Restrictive Practices (Inquiry and Control) Act, 1948, 11 & 12 Geo. 6, c. 66.

[18] The Board of Trustees of the Licensing Executive Society of the U.S.A. recently adopted a resolution in opposition to any compulsory licensing legislation.

A form of compulsory licensing does exist in the United States, however. Statutes dealing with matters of public interest such as the Atomic Energy Act of 1954,[19] the Plant Variety Protection Act,[20] and The Clean Air Act of 1970[21] all provide that in certain specified circumstances a patentee may be compelled to permit the use of the patented invention.

In recent years Congress has examined a number of proposals for compulsory licensing of patents in other areas, some of which are still pending. Senator Jackson[22] (D-Washington) and Representative Udall[23] (D-Arizona) have introduced legislation for compulsory licensing of the area of energy. Senators Nelson (D-Wisconsin) and Hart (D-Colorado) introduced legislation relating to compulsory licensing of patents for drugs, and Representative Rosenthal (D-New York) introduced the Prescription Drug Patent Licensing Act[24] which provided for compulsory licensing of patents and trademarks for drugs, where the wholesale price charged for the drug is 500 percent or more above the cost of production, packaging, and marketing.[25]

De facto compulsory licensing also exists in the United States by virtue of legislative and judicial activity in the area of patent infringement. The courts have based their decisions on two distinct theories: general public policy considerations, and antitrust. They have refused to enjoin patent infringement for public policy reasons in a number of cases,[26] one of which was *City of Milwaukee v. Activated Sludge, Inc.*[27] In that case, the City of Milwaukee was found to be infringing plaintiff's patent, but the court refused to enjoin the City on the

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[19] 42 U.S.C. § 2011 (1954).

[20] 7 U.S.C. §§ 2321-2583 (1973).

[21] 42 U.S.C. §§ 1857-1858a (1955); current version at 42 U.S.C. §§ 7401-7642 (1977).

[22] S. 1283, 93d Cong., 1st Sess. (1973) and S. 2176, 93d Cong., 1st Sess. (1973).

[23] H.R. 11856, 93d Cong., 1st Sess. (1973) and H.R. 11857, 93d Cong., 1st Sess. (1973).

[24] H.R. 44 and H.R. 46, 95th Cong., 1st Sess. (1977).

[25] *See also* similar proposed legislation, Comprehensive Drug Amendments of 1977, S. 2040, 95th Cong., 1st Sess. (1977), limiting trade secret protection but offering 17-year patent protection for drugs after FDA approval. This proposed legislation also provides for compulsory licensing of patents.

[26] Richmond Co. v. United States, 275 U.S. 331, 343 (1928); Evans v. McDonnell Aircraft Corp., 270 F.Supp. 778, 780-1, *remanded* 395 F.2d 359 (8th Cir. 1968); McMullen Associates, Inc. v. State Board of Higher Education, 268 F.Supp. 35, *aff'd* 406 F.2d 497 (9th Cir. 1969); Bereslavsky v. Standard Oil Co. of New Jersey, 82 F.Supp. 1939, *aff'd* 175 F.2d 148 (4th Cir. 1949); *and see,* for infringement by agents of the United States government, Sperry Gyroscope Co. v. Arma Engineering Co., 271 U.S. 232 (1926).

[27] 69 F.2d 577 (7th Cir. 1934).

grounds that should the injunction issue, Milwaukee would be forced to dump its sewage into Lake Michigan. Public health and preservation of the environment were the reasons cited by the court for denying the injunction, and the patentee was awarded reasonable compensation.[28]

Abuse of a patent right which amounts to a violation of the antitrust laws may also result in denial of patent rights.[29] In such cases, the courts have allowed patent infringement to continue, despite objections by the patentee.[30] In a recent case, the Federal Trade Commission (FTC) ordered compulsory licensing of a trademark as a positive remedy against monopolization based on a trademark.[31] In the REALEMON case, the FTC ordered Borden, which controlled a large share of the lemon juice market in the United States, to license its REALEMON trademark to competitors.

An example of federal legislation which closely approximates compulsory licensing in the United States is 28 U.S.C. § 1498 which prohibits the issuing of an injunction against the United States Government as a remedy for patent infringement. Under the statute, a patentee's sole remedy against infringement of his patent is "reasonable and entire compensation."

Thus, although the Paris Union model of compulsory licensing of

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[28] *See* Wetzel, *A Discussion of the Compulsory Licensing of Patents in the U.S.*, AM. PAT. L. ASS'N. Q.J. 146 (1974).

[29] *See, e.g.,* Continental Paper Bag v. Eastern Paper Bag Co., 210 U.S. 405 (1908); Allied Research Products, Inc. v. Heathbath Corp., 300 F.Supp. 656 (N.D. Ill. 1969); Zenith Radio Corp. v. Hazeltine Research, Inc., 161 U.S.P.Q. 577 (1968); Foster v. American Machine & Foundry Co., 492 F.2d 1317, *cert. denied,* 95 S.Ct. 58 (1974); For other antitrust actions by the government, *see, e.g.,* F.T.C. v. American Cyanamid Co., 150 U.S.P.Q. 135 (1966); Hartford-Empire Co. v. United States, 65 U.S.P.Q. 1 (1945); United States v. Nat'l Lead Co., 73 U.S.P.Q. 498 (1947); United States v. General Electric Co., 99 U.S.P.Q. 76 (1955); Vitamin Technologies, Inc. v. Wisconsin Alumni Research Foundation, 146 F.2d 941 (9th Cir. 1945); United States v. Singer Manufacturing Co., 137 U.S.P.Q. 808 (1962); United States v. Glaxo Group Ltd., 176 U.S.P.Q. 289 (1974); F.T.C. v. Xerox Corp., (consent decree), CCH Trade Reg. Rep. Para. 20 at 869 (July 29, 1975).

[30] Similarly, the Canadian Patent Act provides specifically that a compulsory license will serve as a remedy against a tying arrangement. Thus, where a patentee attempts to use the patent to monopolize a market, either by marketing methods, by tying the patented technology to non-patented materials or technology, a compulsory license will be issued. The Canadian Patent Act, R.S.C. 1952, c. 203, *as amended,* § 67(2)(b).

[31] *In re* Bordon Inc., Docket No. 8978, 5677, Initial Decision of Administration Law Judge, filed Aug. 19, 1976. For a thorough discussion of this case, *see* J. McCarthy, *Compulsory Licensing of Trademarks: Remedy or Penalty?* 67 T.M.REP. 197 (1977).

patented inventions for non-use does not exist in the United States, remedies which resemble compulsory licensing in effect have been developed by the legislature and the judiciary.

Conceptually, the Paris Union model of compulsory licensing parallels the remedies prescribed by United States laws. Both antitrust law in the United States and the Paris Union model of compulsory licensing are based on the premise that the patent grant is limited. National legislative policy determines the scope of the patent grant and of the limitations to be imposed. Both use the same legal mechanism, *i.e.,* preventing the patentee from enforcing what otherwise would be considered within the scope of the patent right. In the case of Paris Union compulsory licensing, the patentee is forced to license the patented technology; in the case of United States antitrust law, the patentee is prevented from enjoining infringement.

The goals of the two models are different. United States antitrust law is intended to apply to anti-competitive acts, while Paris Union compulsory licensing is intended to prevent suppression of the patented technology. Though the abuses sought to be controlled differ, the means are the same.

The Proceeding

The cause of action which may result in compulsory licensing is the "abuse by the patentee of its patent monopoly."[32] Such "abuse" is defined differently in most statutes and consists of various acts and omissions on the part of the patentee.[33] The Commissioner of Patents in Canada or Comptroller of Patents in the United Kingdom is called upon to determine, upon the initiation of proceedings by an applicant, if the patent has in fact been abused.

In accordance with the Paris Convention,[34] an application for a compulsory license cannot be filed before four years have elapsed from the date of filing of the application for a patent, or three years from the date of the grant of the patent, whichever period expires later.[35] Thus, the patentee is afforded a grace period of approximately three years to exploit the patent.

The proceeding commences with an application or a petition against the patentee for a compulsory license on the basis of abuse of

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[32] The British Patents Act, 1949, 12, 13 & 14 Geo. 6, c. 87, § 37; the Canadian Patent Act, R.S.C. 1952, c. 203, *as amended,* § 67(1).

[33] *See* section in text entitled Grounds for Compulsory Licensing.

[34] *See* note 2 *supra.*

[35] British Patents Act, 1977, c. 37, § 48(1).

the patent monopoly.[36] In some countries,[37] an applicant may request the Commissioner to inquire to what extent the patentee is exploiting the patent in the country. That information can serve as a basis for a subsequent application for a compulsory license.

In the United Kingdom and in Canada the Comptroller or the Commissioner, respectively, will consider actions by the patentee which occur after an application for compulsory license has been filed, if they are bona fide. Under the British Patent Act,[38] such a determination is within the discretion of the Comptroller.[39] The Comptroller or Commissioner must verify that the patentee's actions were bona fide and that they indicate a sincere intention to correct the situation which existed prior to the filing of the application. It must be determined that the patentee did not act solely to defeat the application for compulsory license.[40] Canadian cases do emphasize, however, that the Commissioner of Patents will be suspect of actions by the patentee which occur after the application for compulsory license has been submitted.[41]

This policy of considering late actions by the patentee has been criticized both in Britain and in Canada. It has been argued that it permits the patentee to wait until an application for compulsory license has been submitted before it acts, and that it discourages potential licensees from filing applications.[42]

The Comptroller, satisfied that all the prerequisites have been met, may take one or more of the following actions:[43]

- Endorse the patent to licenses as of right (except in cases where

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[36] In one unusual case, the applicant filed his petition for a compulsory license against both the patentee and another compulsory license. *See* F. Hoffman-La Roche & Co. A.G.'s Patents and Berk Pharmaceuticals Ltd., Application for a Compulsory License [1973] R.P.C. 587; *see* the Canadian Patent Act, *supra* note 32, at § 66; *and see* FOX'S CANADIAN PATENT LAW AND PRACTICE at 542 (4th ed. 1969) [hereinafter FOX].

[37] Canada and Israel, for example.

[38] British Patents Act, 1949, *supra* note 32, at § 39(2); British Patents Act, 1977, c. 37, § 49.

[39] *See also* Boult Patent [1909] 26 R.P.C. 383, 386-7; Colborne Engineering Co. Ltd.'s Application [1955] 72 R.P.C. 169, 179; Zanetti-Streccia's Patent [1973] R.P.C. 227.

[40] Metaliflex, Ltd. v. Rodi & Weinberger, [1966] 33 Fox Pat. Cas. 412.

[41] DeFrees v. Dominion Auto Accessories, Ltd., [1966] 33 Fox Pat. Cas. 137.

[42] *See* Fox, *supra* note 36, at 543.

[43] British Patents Act, 1949, *supra* note 32, at §§ 37, 38.

the abuse is by failure to export or where the technology concerned involves food and drugs);[44]

- Issue a compulsory license;
- Issue a license to the customers of the applicant regardless of whether a license is also issued to the applicant;[45]
- Amend or revoke the license, or issue a new one, where the applicant is a licensee.[46]
- Refuse to take any action, either because the applicant has not complied with all the conditions and is therefore not entitled to a license or because the granting of a license is unreasonable since it involves the infringement of another patent which is not susceptible to compulsory licensing.[47]

The Comptroller's decision is subject to appeal.[48] While the appeal is pending, the patentee is entitled to an injunction against infringement by the applicant.[49] The Court of Appeal exercises wide discretion in reviewing the Commissioner's decision.[50]

Grounds for Compulsory Licensing

Abuse of the Patent Monopoly. Different national patent systems set different standards to determine the limit of patent rights and the activities which will constitute abuse of those rights. The Canadian statute, for instance, enunciates the theoretical basis upon which patents are granted so that activity which contravenes those rights may be detected more easily:

> [F]or the purpose of determining whether there has been any abuse of the exclusive rights under a patent, it shall be taken that patents for new inventions are granted not only to encourage inventions but to secure that new inventions shall, so far as possible, be worked on a commercial scale in Canada, without undue delay.[51]

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[44] *Id.* at §§ 37(3), 40(2), 37(1), 40(1) and 40(4).

[45] *Id.* at § 38(3). It is not clear, however, whether the comptroller is authorized to cancel an existing exclusive license and replace it with a non-exclusive license to a different licensee, without also giving the original licensee a non-exclusive license. *See* Colborne Engineering Co. Ltd.'s Application, *supra* note 39.

[46] *Id.* at § 38(2).

[47] Cathro's Application, 51 R.P.C. 475, 488 (1934).

[48] British Patents Act, 1949, *supra* note 32, at § 44.

[49] *See* DeFrees v. Dominion, *supra* note 41, at 144.

[50] *Id.* at 144.

[51] Canadian Patent Act, *supra* note 32, at § 67(3).

The particular abuse of the patent monopoly which the compulsory license is intended to correct is the failure to exploit the patented technology in the issuing country. Non-working or inadequate working of a patented technology which prevents working of that patent by others is regarded as an even more serious abuse. Under such circumstances most legal systems provide for compulsory licensing.

The Canadian Patent Act defines abuse of patent rights as any one of the following:[52]

- Non-working;
- Preventing the working of the invention in the country by importing the product from abroad;
- Failing to meet local demand with reasonable quantities and at reasonable prices;
- Refusing to grant a license on reasonable terms, and consequently hurting a trade or industry, in circumstances where it is in the public interest that a license be granted;
- Licensing patent rights under unreasonable or unfair conditions with resulting damage to any trade or industry;
- Unfairly exercising process patent rights, in a manner damaging the manufacture, use or sale of unprotected materials which are necessary for the working of that process.

Grounds for compulsory licensing are similar under British law. A compulsory license will issue where one of the following occurs:[53]

- The patented invention, capable of being commercially worked in the United Kingdom, is not worked or is not sufficiently worked within the United Kingdom.[54]
- The demand for the patented product or a product manufactured under the patented process is not sufficiently met or is met on unreasonable terms, or is met primarily by importation.
- The commercial working of the invention in the United Kingdom is prevented or hindered by the importation of the patented article.
- The patentee refuses to grant a license on reasonable terms and as a result the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced.[55]

The underlying principle is that the patent system will not permit abuse of patent rights which may damage the national economy. The patentee is not under a positive obligation to work the patent, but by

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[52] *Id.* at § 66; *see* Fox, *supra* note 36, at 541; *and see* Celotex Corp. v. Dannacona Paper Co., Ltd. [1939] Ex.C.R. 128, 130.

[53] The British Patents Act, 1949, *supra* note 32, at § 37.

[54] Some countries specifically require working by way of manufacture in the country.

[55] *Id.*

non-working he exposes his patent to the threat of a compulsory license. The compulsory license is not intended to penalize. Rather, it is a corrective measure which the law provides to ensure efficient exploitation of patented technology, now and in the future. Thus, non-working of a patent in the past would normally not create any rights for an applicant, where the patentee is working the patent in the present.[56]

Failure to Work the Patented Technology in the Country. The compulsory license is primarily intended to prevent non-use. It is designed to preclude the use of patent rights as an obstacle to development of local trade or industry. Thus, non-working and failure to work the patent commercially are bases for the granting of a compulsory license. This is stated clearly in most national patent laws.[57]

In some countries the working of the patented technology abroad is considered sufficient commercial working to avoid compulsory licensing.[58] Other countries consider importation as sufficient working of the patented technology.[59] Still other countries require only nominal working of the patent.[60]

The recent Patent Convention of the European Economic Communities (EEC)[61] provides that member states may not grant compulsory licenses if the invention is being worked within the Community and demand in the country is being met by importation from another member state. The new British Patent Act[62] and the patent statutes of other member states have similar provisions.

Non-working is defined according to the nature of the patented invention. Where the patented invention is a process, non-working is the failure to utilize the process. Where the patented invention is a product, non-working is the failure to manufacture and supply the product in sufficient quantities or the failure to manufacture it at all within the issuing country. The major tests for insufficient working of the patented technology are insufficient supply in the market or less than full exploitation of export potential.

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[56] *See, e.g.,* in Canada: McArthur Irwin Ltd. v. Nat'l Lead Co., [1963] 24 Fox. Pat. Cas. 184, 189.

[57] The British Patents Act, 1949, *supra* note 43, at § 37(2); the Canadian Patent Act, *supra* note 32, at §67(2)(a).

[58] For example, West Germany.

[59] For example, Cuba, Hungary, Portugal.

[60] For example, Bulgaria, Ireland, Peru, Greece, Luxemburg and Iraq.

[61] O.J. Eur. Comm. (No. L 17) 1 (1976), Comm. Mkt. Rep. (CCH) Para. 5795.

[62] The British Patents Act, 1977, c. 37, § 53.

The patentee is required to work the patented invention only. The proper scope of this obligation is determined by the patent claims. Where, for example, the patent involves an improvement to an existing instrument, the patentee is obliged to work the improvement only. Where the patent involves a combination of known elements, the patentee will be required to work the combination, but not the elements.[63]

A Canadian court has held that where the patent involves a combination of elements which can be used only when assembled into a final product, the assembly of the imported elements does not constitute working of the patented invention in Canada.[64] Where the patented product is a machine, the demand for the machine will be considered, not that of the product which is manufactured by the machine, if the product can be manufactured by other means.[65]

Whether or not a patented technology is sufficiently worked is determined by considering the nature of the product, the nature of the market for the product, the investment involved in manufacturing and marketing the product, the nature of the industry involved, and other relevant factors affecting the business decision-making process.[66]

Under British law, the patent is considered "worked in the country," even where there is an infringing use.[67] In Canada, however, infringing use of the patented technology will not be deemed sufficient working of the patent, since it contravenes the policy underlying compulsory licensing: to encourage full working of patented inventions within the patent system.[68] In Great Britain the patentee cannot escape a compulsory license merely because the patent was commercially worked in Britain in the past, where such working has ceased.[69]

The applicant bears the burden of proving that the patented invention is not fully or efficiently worked in the issuing country. For in-

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[63] Lake's Patent [1909] 26 R.P.C. 443, 447; Wardwell's Patent (1913) 30 R.P.C. 443, 447; Cooperative Union Ltd. and Others' Application [1933] 50 R.P.C. 161.

[64] Metaliflex Ltd. v. Rodi & Weinberger, *supra* note 40.

[65] Welker & Sons, Ltd. v. Lever Bias Machine Corp. [1953] Fox Pat. Cas. 190, 194.

[66] *See, e.g.,* Weber's Patent [1910] 27 R.P.C. 30.

[67] Mercedes Daimler Co.'s Patents [1910] 27 R.P.C. 762, 768.

[68] DeFrees v. Dominion, *supra* note 41. *But cf.* Metaliflex Ltd. v. Rodi & Weinberger, *supra* note 40, where infringing use of the patent was the basis for rejecting an application for a compulsory license, but only in view of the fact that the infringer was sincerely challenging the validity of the patent.

[69] Cathro's Application, *supra* note 47, at 79.

stance, failure to meet local demand amounts to insufficient commercial working of the patent, and the applicant must show precisely what the demand is and that it is not being met presently.[70]

Section 37(2)(b) of the British Act of 1949 states that a compulsory license will be granted when "the demand for the patented article in the United Kingdom is not being met on reasonable terms or is being met to a substantial extent by importation." The applicant must demonstrate that the product has a present as well as a potential future demand[71] and that the demand is not being met by locally manufactured products. Demand for a similar product, even a substantially cheaper substitute, is not evidence of the existence of demand for the patented product.[72] Supply must be reasonable in quantity, quality, and price. In Canada, where the patent is for a machine or manufacturing process, the criterion is whether the Canadian consumer receives an adequate supply of the final product. Thus, where a competitor applies for a compulsory license for a machine or a process in order to produce a competing final product, the application will be rejected if the patentee manufactures the product and supplies it in sufficient amounts.[73] The rationale for this rule is obvious, since to do otherwise would encourage competitors to wait for the patentee to experiment with the marketability of the new product and to enter the market only after demand has been ensured.

Injury to the National Economy. A major purpose of compulsory licensing is to protect the national economy from abuse of industrial property rights. The rights of the inventor are balanced against the right of society to pursue its national economic goals, such as the development of new industries, particularly of export industries. Consequently, the degree to which the national economy may suffer will have a considerable influence on the outcome of an application for a compulsory license.

Prejudice to the development of commercial or industrial activities will be found where the working of the patented technology locally is prevented or decreased by importation of the product. A like conclusion will be reached where the patentee refuses to license the patented technology on reasonable terms and local consumers are de-

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[70] Metaliflex Ltd. v. Rodi & Weinberger, *supra* note 40; Kamborian's Patent [1961] R.P.C. 403, 405.

[71] Cathro's Applicat[illegible], *supra* note 47, at 82.

[72] Kamborian's Patent, *supra* note 70, at 405.

[73] Welker & Sons, Ltd. v. Lever Bias Machine Corp. *supra* note 65.

prived of the product or are forced to pay higher prices for imported products.

The words "commercial or industrial activities" in the British statute are interpreted very broadly.[74] When applying for compulsory licensing, it must be shown that a trade or industry in general has been injured, and not only that the applicant's business has suffered.[75] The prejudice to the establishment or development of commercial or industrial activities in the United Kingdom must be a direct result of the patentee's exercise of his patent rights.[76]

Most patent laws incorporate compulsory licensing as a means of improving the balance of trade of the country by increasing exportation and decreasing imports. In Canada the law[77] has been amended to provide that importation of patented products or products manufactured under a patented process, even where local demand requires such importation, will not be regarded as sufficient working of the patent.[78] The British statute[79] provides that importation which prevents commercial exploitation of the patented technology in the United Kingdom is sufficient grounds for compulsory licensing.

However, the patentee is not obligated to exploit the entire spectrum of potential products. Where the patented technology is being "substantially" exploited, a compulsory license is refused, even though some potential products are not being manufactured.[80] The British Act has been amended. The words "working on a commercial scale" have been substituted with the words "commercial working." This seems to crystalize judicial decisions.[81]

The British Patent Act also provides that where the application for a compulsory license is based on insufficient exploitation of the export

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[74] Brownie Wireless Co. Ltd.'s Application [1929] 46 R.P.C. 457, 459; Robin Electric Lamp Ltd.'s Petition [1915] 32 R.P.C. 202, 213. These cases were decided on the basis of the 1907 Patents and Designs Act (7 Edw. 7, c. 29), which provided, in Section 27(2)(d), that "it is in the public interest that a license or licensees should be granted." This policy statement has been eliminated in subsequent legislation.

[75] Brownie Wireless Co. Ltd.'s Application, *id.;* Colborne Engineering Co. Ltd.'s Application, *supra* note 39.

[76] British Patents Act, 1949, *supra* note 32, at § 37(2)(d)(III).

[77] Canadian Patent Act, *supra* note 32, at § 67(2)(b).

[78] Celotex Corp. v. Dannacona Paper Co. Ltd., *supra* note 52, at 139.

[79] British Patents Act, 1949, *supra* note 32, at § 37(2)(c).

[80] Cathro's Application, *supra* note 47.

[81] British Patents Act, 1949, *supra* note 32, at § 37(2)(d); *and see* decisions regarding this issue in T. BLANCO-WHITE, PATENTS FOR INVENTIONS AND THE REGISTRATION OF INDUSTRIAL DESIGNS at 307n.73 (4th ed. 1974) [hereinafter T. BLANCO-WHITE].

market, the compulsory license will be delineated to apply to exportation to specific countries.[82] The test which is applied is the patentee's inability to meet demand in those foreign markets. Obviously, the practicality of this provision depends upon the laws of the countries to which the applicant intends to export.

Refusal to License

Where the patentee neither manufactures in the country nor exports, and refuses to permit a local manufacturer to produce or to export on reasonable terms, and the national economy is damaged by loss of exports or of the development of a new trade or industry, a compulsory license may be granted.[83] A compulsory license is issued where the applicant approaches the patentee for a license, and the latter either rejects the request or offers a license on unreasonable terms.[84] The applicant is not estopped from applying for a compulsory license, even if he already has a license which the patentee voluntarily granted.[85] The applicant need not approach an exclusive licensee for a sublicense. But where an exclusive licensee is also entitled to sublicense, his refusal to do so is deemed equivalent to a refusal by the patentee.[86]

Where the patentee flatly refuses to grant a license, a compulsory license is likely to be issued almost automatically. The majority of cases are more complicated, however, and many involve the question of how "reasonable terms" will be interpreted. The reasonableness of the terms is examined according to the specific circumstances of each case. Among the factors considered are: the nature of the invention, the terms of existing licenses, the expenses and obligations incurred by the patentee in the course of developing the patented technology, the needs of consumers, and the market conditions in that area of trade in general.[87] As far as royalties are concerned, it has been held that reasonableness of royalties will be determined according to market prices for the final product, with due regard to the practice in the trade. The cost of research and development to the patentee should be

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[82] British Patents Act, 1949, *supra* note 32, at § 37(3)(b).

[83] British Patents Act, 1977, c. 37, §§ 48, 49; Canadian Patent Act, *supra* note 32, at § 67.

[84] British Patents Act, 1949, *supra* note 32, at § 37(2)(d); Loewe Radio Co. Ltd.'s Application [1929] 46 R.P.C. 479, 489-90.

[85] British Patents Act, 1949, *supra* note 32, at § 37(4).

[86] Colborne Engineering Co. Ltd.'s Application, *supra* note 39.

[87] Brownie Wireless Co. Ltd.'s Application, *supra* note 74, at 453, 457.

considered, as well as any marketing costs incurred by either the patentee or the applicant.[88] In Canada, a similar formula has been proposed, emphasizing research and development, manufacturing and marketing costs.[89]

One criterion for measuring the reasonableness of the patentee's conditions is their anti-competitive nature. In most western legal systems, compulsory licensing exists in addition to and not as a substitute for antitrust laws. Compulsory licensing is only incidentally a measure against anti-competitive acts by the patentee. In the area of anti-competitive activity, however, patent law and antitrust law overlap. For example, where a patent license involves antitrust violations, the license will be subject to review under normative concepts of antitrust law. Similarly, where a patent license fails to materialize due to the patentee's anti-competitive conditions, a compulsory license will most likely be granted on the basis of the patentee's "refusal to license on reasonable terms."

Where the anti-competitive conditions set by the patentee are rejected by a potential licensee, compulsory licensing will be the remedy. Where the anti-competitive conditions of the patentee are met by the licensee, antitrust laws will control. But in both cases the criterion for judging the legality of the patentee's demands is the one prescribed by the antitrust laws.

The following conditions have been held unreasonable: setting the royalties rate on the basis of different sale quantities, package licensing where the licensee is required to pay royalties for patents which he did not intend to use,[90] and post-expiration royalties.[91] Vertical price fixing between patentee and licensee, where the patentee sets a minimum price level which was not unreasonably high and did not unreasonably burden consumers, has been held reasonable.[92] Field of use limitations, particularly restrictions on sales of the product to specific groups of consumers for specific purposes, have also been held reasonable[93] when they did not constitute an act of monopolization but increased competition. It should be noted, however, that the view of courts with regard to the reasonableness of certain conditions

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[88] *Id.*

[89] International Cone Co. Ltd. v. Consolidated Wafer Co. [1927] 1 D.L.R. 402 *see* TERRELL, *supra* note 1, at 272.

[90] Brownie Wireless Co. Ltd.'s Application, *supra* note 74, at 476-8.

[91] Kamborian's Patent, *supra* note 70, at 406.

[92] Robin Electric Lamp Ltd.'s Petition, *supra* note 74.

[93] Cooperative Union Ltd.'s Application, *supra* note 63, at 164.

changes with the rapid development of the antitrust laws in the different countries.

Restricting exports and demanding royalties for related products (tying) is reasonable in certain circumstances. In those circumstances, it is reasonable to insist on package licensing and to refuse to license only a single profitable patent.[94]

To be "reasonable," therefore, proposed or existing licensing arrangements should not restrict competition unreasonably or burden the *consumer*. Compulsory licensing has been viewed as a statutory remedy for antitrust violations. A "rule of reason" is invoked, and certain licensing arrangements are examined to determine the potential effect on consumers. Where these effects are judged reasonable, a compulsory license will not issue.

But compulsory licensing is not intended to limit the patentee from exercising his legal rights in the patent. The patentee may, for example, refuse to grant a license because he has not had an opportunity to exploit the initial market potential of the patent and recover his research and development expenses.[95] And under antitrust rules, the patentee's refusal to license a major competitor, is within the patentee's legal rights and, normally, will not serve as grounds for compulsory licensing.[96] Refusal to license a blocking patent, however, would be grounds for compulsory licensing, although not in every case. The blocking patent must be one "which makes a substantial contribution to the art."[97]

Justifications for Failure to Work the Patent

The compulsory license is a corrective, not a punitive, measure. It is not intended to penalize the patentee for the patentee's failure to work the patent in the past. Rather, it reflects the concern of the law that the patent will be worked in the future. An application for a compulsory license signifies the willingness of the applicant to work the patent. The patentee, therefore, can avoid the compulsory license only if the patentee demonstrates that working the patent in the country is not feasible, or that he has not had a fair chance to work the patent.

It has been held in the United Kingdom and in Canada that once

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[94] *Id.*

[95] Colborne Engineering Co. Ltd.'s Application, *supra* note 39.

[96] Kamborian's Patent, *supra* note 70.

[97] British Patents Act, 1949, *supra* note 32, at § 37(2)(d).

non-working or insufficient working has been established, a rebuttable presumption arises that the patentee is abusing the patent right,[98] and the patentee must show cause why a compulsory license should not issue.[99] A similar presumption will arise that local trade or industry has been damaged, and the patentee bears the equally heavy burden of rebutting this presumption.[100]

A patentee may argue that the state of the relevant industry does not permit efficient manufacture, or that the nature of the technology is such that it is impossible to work it in the country. The fact that only small profits will be realized is not an acceptable justification.[101] Nor is the fact that working will be unprofitable because the patentee has consented to the importation of the product an adequate reason.[102] But where profitable working of the patent in the country is not feasible in fact, a patentee can establish a legitimate justification for non-working.[103]

The patentee can also justify non-working by showing a sincere attempt to negotiate with local manufacturers, and that the negotiations are likely to be successful.[104]

Absence of demand within the local market alone is not sufficient to justify non-working. The patentee is obligated to attempt to manufacture and, thus, create local demand.[105] Further, it has been held in Canada that the patentee should attempt to meet foreign demand by exporting locally manufactured products, especially where the same patentee owns foreign patents and meets foreign demand by foreign manufacture.[106] When the patented invention is still workable profitably, but the patentee saturates the local market with imported products and permits only token local working of the patented

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[98] Johnson's Patent (1909) 26 R.P.C. 52, 56; Hatschek's Patent [1909] 26 R.P.C. 228, 231.

[99] The same rule applies in Canada: Novopharm Ltd. v. Hoffman-La Roche Ltd. [1970] 44 Fox Pat. Cas. 64; Sterilab Corp. Ltd. v. Establissements Clin-Byla 61 C.P.R. 247 (1974).

[100] Farbwerke Hoechst A.G. (Sturm & Others') Patent [1973] R.P.C. 253; *see* Fox, *supra* note 36, at 545.

[101] Hatscheck's Patent, *supra* note 98; Atwater Bag Corp. v. Bahamas Paper Co., [1970] 43 Fox Pat. Cas. 98; Light v. Setter Bros. Inc. [1953] 17 C.P.R. 60.

[102] Hatschek's Patent, *supra* note 98.

[103] Kent's Patent [1909] 26 R.P.C. 666, 670.

[104] Jottrand's Patent [1909] 26 R.P.C. 130; Fell's Patent (1910) 27 R.P.C. 25.

[105] Boult's Patent [1909] 26 R.P.C. 383; Providence Manufacturing Co. v. Scopt & Williams Inc. [1939] 4 D.L.R. 41.

[106] Celotex Corp. v. Dannacona Paper Co. Ltd., *supra* note 52, at 128, 149.

invention, such token working is not sufficient.[107] However, it has been determined that in some circumstances, absense of local demand for the product is sufficient justification for non-working.[108] A patentee may also justify failure to supply local demand where such demand was sudden and unexpected.[109] Also, a patentee in Canada can justify manufacturing or otherwise working the patented invention abroad if it also benefits the Canadian consumer and if Canadian industry cannot work the patented invention because it lacks essential skills or materials.[110] In a case where the price of a locally manufactured product becomes artificially inflated so that it is more expensive than the imported product, it will be assumed that the price of the local product has been raised in order to destroy demand for it and increase the marketability of the imported one.[111]

The patentee must make a bona fide attempt to work the patent.[112] Merely advertising or circulating brochures is not sufficient. The patentee should survey the market, appoint distributors or agents, and take other steps that will indicate a serious attempt to work and market the patented product.[113]

Where a patentee, defending against an application for a compulsory license, presents a license agreement and claims an intention to work the patent in the country, the test is whether the license provides for timely working in the country, or whether it is merely an exercise to defeat the application for compulsory licensing. Where the license was signed after a long period during which the patentee refused to license the patent, it will be assumed that it is intended primarily to defeat the application. The manufacturing clauses of the license, the timetable, as well as any restrictive clauses will be examined. The following items will be closely scrutinized: the royalty rate, restrictions and limitations on manufacture, whether the patentee or his licensee intends to work the patent fully in the country, and whether such intention is evidenced by steps already taken.

But even where the patentee has licensed someone to work the patent, and where that licensee is in fact working the patent, the appli-

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[107] Fabricmeter Co. Ltd.'s Application [1936] 53 R.P.C. 307, 312; Fettes Patent [1961] R.P.C. 396.

[108] Welker & Sons Ltd. v. Lever Bias Machine Corp. *supra* note 65.

[109] *Id.* at 193.

[110] *Id.*

[111] Kent's Patent, *supra* note 103.

[112] Taylor's Patent [1915] 29 R.P.C. 256.

[113] Celotex Corp. v. Dannacona Paper Co. Ltd., *supra* note 52, at 128, 137.

cation for a compulsory license may still succeed since the various statutes require optimal exploitation of the patented invention. Thus, even where a license is reasonable, that is, it includes no restrictive practices and encourages a licensee to manufacture in the country, a compulsory license may be granted if the patented invention can be exploited more fully to further benefit the national economy. The applicant must show that such is the case.

In England it has been held that lack of know-how or skilled manpower will not justify failure to work the patent, even where working the patent in the country may require a longer period of time and greater expense than it would if worked in other countries.[114] The British Comptroller of Patents has rejected the argument that a patent could never be worked optimally in Britain because it could be worked more efficiently and profitably elsewhere.[115] In such instances, hesitation on the part of the patentee in the initial stages of working his patent through manufacture are regarded as reasonable, and will justify staying the application even beyond the three or four year statutory period.[116]

A patentee may avoid compulsory licensing by showing that the patentee is able and intends to manufacture to the maximum extent possible within a reasonably short period. The patentee is entitled to a reasonable period of time in which to begin working the patent. Where non-working is justified the time can be extended beyond the statutory period of three years by adjournment of the application for a compulsory license.[117]

Prior statutes in Britain[118] held that where failure to manufacture in Britain is the result of circumstances over which the patentee has no control, and where the patentee has reasonably attempted to work the patent in Britain, a compulsory license will not be issued.[119] Such a holding is consistent with the view that compulsory licenses are not penal in nature, but corrective. Where a patentee has made a bona fide attempt to work a patent and has failed, this will be taken as an indication that it is impossible indeed to work the patent in the coun-

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114 Johnson's Patent, *supra* note 98; Hamson's Application [1958] R.P.C. 88, 89-90.

115 Kent's Patent, *supra* note 103, at 670.

116 See British Patents Act, 1949, *supra* note 32, at § 37(3)(a).

117 *Id.*

118 Bremer's Patent [1909] 26 R.P.C. 449.

119 A number of countries, *e.g.*, Australia, Austria, Belgium and Brazil, recognize *force majeure* as a legitimate reason for nonworking of the patented invention, one which can defeat an application for a compulsory license.

try. It has been suggested[120] that in view of the changes in the language of the statute, this rule no longer applies.

The various justifications for non-working enumerated here may seem to contradict the notion that compulsory licensing is a corrective rather than a punitive measure. The law recognizes that compulsory licensing has punitive effects and, therefore, that it should be exercised cautiously. The potential damage to society resulting from failure to work the patent is balanced against the seriousness of invading a patentee's property rights. The relative weight assigned to these elements will vary as the level of economic development and respect for private property vary among the countries.

Applicant's Ability to Correct Patentee's Abuses

The applicant bears the initial burden of establishing grounds for compulsory licensing. The applicant must product prima facie evidence that the patentee is not exploiting the patented technology sufficiently, and that the applicant can remedy the situation. The burden the applicant bears is relatively light, however. Once a prima facie case of abuse has been established, the burden of proof shifts to the patentee who must show that there are difficulties inherent in the patented technology which will justify rejecting the application.[121] The applicant must demonstrate that he has the necessary experience and resources to exploit the patented technology through manufacture, that he faces no insurmountable difficulties, and that he will be breaking no law and infringing no rights if he exploits the patent.[122]

In England[123] and in Canada[124] the applicant must be an "interested party." An applicant is sufficiently "interested" if he shows the intention and ability[125] to make required investments subsequent

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120 TERRELL, *supra* note 1, at 697.

121 Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100; Wardwell's Patent [1913] 30 R.P.C. 408, 411; in Canada, Novapharm Ltd. v. Hoffman-La Roche Ltd., *supra* note 99.

122 Gaigy S.A.'s Patent [1964] R.P.C. 391.

123 British Patents Act., 1949, *supra* note 32, at § 37(1).

124 Canadian Patent Act, *supra* note 32, at § 67(1).

125 Cathro's Application, *supra* note 47; Hulton & Bleakley's Petition [1898] 15 R.P.C. 749, 753; Cooperative Union Ltd.'s Application, *supra* note 63, at 165; Hoffman-La Roche & Co. A.G.'s Patent [1969] R.P.C. 504. In Canada: Sharp & Dohme (Canada) Ltd. v. F.W. Horner [1951] 13 C.P.R. 127 [1952] 15 C.P.R. 68; Light v. Setter Bros., Inc., *supra* note 101.

to receiving a license.[126] For example, an applicant need not purchase the equipment necessary for manufacture prior to receiving the compulsory license.

In Canada, an applicant who cannot meet local demand fully and, therefore, does not wish to obtain an exclusive license, may not be granted a license at all.[127] Similarly, an applicant who cannot manufacture the entire product or exploit the entire process, but who can work the patented technology only partially, will not be granted a compulsory license.[128] An applicant must show that he can manufacture all versions of the patented product, not only those which are profitable.[129] Ironically, a patentee cannot argue that an applicant will be unable to exploit the patent safely and efficiently, since doing so may be construed as an admission to insufficient disclosure of patent specifications.[130]

It is beyond the scope of a compulsory licensing proceeding to question whether or not an applicant is able to comply with various laws pertaining to quality standards.[131] In England it has been held that a quality control clause may not be inserted into a compulsory license unless the applicant consents.[132] This rule, which has been adopted by a number of legal systems, is consistent with the underlying principle of compulsory licensing. The compulsory license is intended to assure that the patented technology is fully exploited within the issuing country. These patents and the technology to which they apply often involve sensitive areas, such as food and drugs. All questions of quality, standards, restrictions on use of the product, etc., are left to the applicant who, having been granted a compulsory license, assumes the patentee's responsibility to comply with all relevant legislation pertaining to quality and standards.

As in equity, an applicant for a compulsory license must come with clean hands. He should fully disclose his intentions, particularly if he intends to exploit the patented technology by way of manufacture. He must deal honestly with the patentee, both prior to the application for

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126 Hoffman-La Roche & Co. A.G.'s Patent [1971] R.P.C. 311; Sherman & Ulster Ltd. v. Merck & Co., Inc. [1971] 44 Fox Pat. Cas. 16.

127 Providence Machinery Co. v. Scott [1939] D.L.R. 41, 45.

128 *Id.*

129 Furnham Mfg. Co. v. Walker Jones Co. [1955] 22 C.P.R. 5; *and see* W. Meredith, *Canadian Patent Practice,* 2 PAT. L. REV. 383, 389 (1970).

130 Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd. [1963] 24 Fox Pat. Cas. 182, 194.

131 Sterilab Corp. Ltd. v. Chas. Pfizer & Co. Ltd., [1970] 44 Fox Pat. Cas. 71.

132 Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100.

compulsory license and after it has been filed. In certain cases, the applicant's clean hands can be a decisive element in the dispositon of his application[133] for compulsory licensing. The clean hands doctrine will bar the grant of a compulsory license only in extreme cases, however, since it is normally outweighed by public policy considerations.

Compulsory Licensing of Patents for Food and Drugs

Most legal systems have devised specific compulsory license arrangements for patented inventions relating to food and drugs.[134] These arrangements apply to: (1) [p]atented products which are used as a drug or in the manufacture of a drug;[135] and (2) [a] patented method, device, or instrument possessing curative or restorative qualities, employed for therapeutic purposes or as a part of a therapeutic process.[136] Such arrangements have been widely adopted.[137] They are intended to ensure that "food, medicines and surgical and curative devices shall be available to the public at the lowest prices."[138]

Generally, compulsory licenses represent legislative attempts to coordinate the interest of the public and those of the individual. These statutes, on the other hand, give the public interest clear priority over private property rights in the area of food and drugs. They are designed to insure an efficient supply of food and drugs at reasonable cost.[139]

Certain aspects of compulsory licensing of food and drugs are unique:

- The applicant need prove only that a compulsory license is necessary to assure that certain foods or drugs are available to the public at reasonable prices. An applicant is not required to prove "abuse," and the patentee is not permitted to raise the defense of "reasonable justification" for failure to work the patent.

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133 Atwater Bag Corp. v. Bahamas Paper Co., *supra* note 101.

134 The new British Patent Act (1977) eliminated the special provisions relating to compulsory licensing of patents for foods and drugs. This section of the text, insofar as it relates to British law, refers to the British Patents Act of 1949, *supra* note 32.

135 In Canada for both humans and animals: Horner Ltd. v. Hoffman-La Roche [1971] 44 Fox Pat. Cas. 49.

136 British Patents Act, 1949, *supra* note 32, at § 41; Canadian Patent Act, *supra* note 32, at § 41(3); *and see* Eastman Kodak Co.'s Patents [1968] R.P.C. 390, which held that cigarette filters are not "a curative device" because they have no restorative power.

137 *See* BAXTER, *supra* note 1, at 125-6; The U.N. Report, *supra* note 3, at Para. 121.

138 British Patents Act, 1949, *supra* note 32, at § 41(2).

139 Glaxo Laboratories Ltd.'s Application [1941] 58 R.P.C. 12.

- Most statutes do not provide for a grace period in which the patentee may work the patent. A compulsory license for food and drugs may be issued at the same time the patent for such an invention is granted.[140] Compulsory licenses for food and drugs may be issued not only for purposes of manufacturing in the country, but also for such purposes as importation.

In the case of food and drugs, there is a legislative preference for free and unrestricted competition over the individual rights of inventors. Exercising patent rights in ways which may limit the availability of such products to the public will not be permitted.[141] Both the British and the Canadian statutes require the automatic granting of a compulsory license "unless it appears... that there are good reasons for refusing the application."[142]

In Canada the rules of procedure and of evidence in a proceeding for compulsory licensing of food and drugs are unusually harsh for patentees. The Commissioner is authorized to consider information presented in previous litigation between the parties and to take judicial notice of facts on the basis of the Commissioner's own general and professional knowledge. The Commissioner may issue a preliminary order even without a hearing.

Most applications for compulsory licenses and most compulsory licenses that have been issued in the United Kingdom and Canada involved food and drugs.[143] To date, only two applications for compulsory licensing of food and drugs have been rejected in Canada.[144]

As a rule, the applicant bears the burden of showing that if the license issues, he can supply the product (ideally through manufacture), and that he can also market the patented item.[145] The size of

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[140] *See, e.g.,* Parke Davis & Co. Ltd. v. Fine Chemicals of Canada Ltd. (No. 1) [1959] 18 Fox Pat. Cas. 125, 128.

[141] Hoffman-La Roche Ltd. v. Bell Craig Pharmaceutical Division of L.D. Craig [1966] 32 Fox Pat. Cas. 156, 159.

[142] British Patents Act, 1949, *supra* note 32, at § 41(1); Canadian Patent Act, *supra* note 32, at § 41(3); *and see* Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd. [1964] 27 Fox Pat. Cas. 178, 182; Borden Co. Ltd. v. Salada Sheriff Chorsey Ltd. (1960) 34 C.P.R. 238.

[143] *See* Meredith, *Canadian Patent Practice, supra* note 129, at 399.

[144] Parke Davis & Co. Ltd. v. Fine Chemicals of Canada Ltd., *supra* note 140; Aktienbolaget Astra Apotekarnes Kemiska Fabriken v. Novocal Chemical Mfg. Co. Ltd. [1964] 27 Fox Pat. Cas. 156, 159.

[145] Micro Chemicals Ltd. v. Societe des Usines Chemiques Rhone Poulenc [1964] 25 Fox Pat. Cas. 148.

the applicant's corporation or business is not determinative, and no preference is given to large manufacturing enterprises.[146]

In a proceeding for compulsory licensing of food or drugs, it is inappropriate to question the validity of the patent involved. When the application is examined, the validity of the patent is presumed.[147] A compulsory license of a patented invention involving food and drugs is ordered almost automatically if the necessary elements are established, and if there are no "good reasons" to refuse it. Further, the Commissioner has no authority in these cases to endorse the patent to "a license of right." The statutes do not restrict applications for a compulsory license to "interested persons" only. Rather, decisions of the Commissioner and of the courts indicate that the Commissioner enjoys wide discretion in considering whether or not the applicant is an appropriate candidate for a compulsory license. A candidate's ability to alter the situation created by the patentee will be a key factor in the decision-making.

Often, the applicant for a compulsory license of food and drugs and the patentee are large pharmaceutical or food manufacturers, and the dispute concerns either a blocking patent or a patent for a food or drug which the applicant wishes to manufacture in order to maintain a complete line of products in a certain area. In these cases, the compulsory license can provide needed leverage in a highly competitive market.

In Canada, a patentee cannot avoid compulsory licensing by arguing that the applicant is incapable of manufacturing the product efficiently and economically. Neither may a patentee argue that the market is saturated.[148] In Great Britain it has been held that an applicant's inability to forecast demand for the product or to explain why the patentee has not recovered research and development costs will not affect the request for a compulsory license.[149]

In one of the two Canadian cases in which applications for compulsory licenses for food and drugs were rejected, the patent related to a product which already existed in other forms in sufficient quantities.[150] In the other case, the applicant requested a compulsory

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146 Parke Davis & Co. Ltd. v. Fine Chemicals of Canada Ltd., *supra* note 140, at 178.

147 *Id.* at 173.

148 Delmar Chemicals Ltd. v. American Cyaniamid Corp. [1959] 20 Fox Pat. Cas. 51; Smith Klein & French Interamerican Corp. v. Micro Chemicals Ltd. (1967) 37 Fox Pat. Cas. 1, 7.

149 British Brewery Houses Ltd.'s Application [1955] 72 R.P.C. 2, 11.

150 Borden Co. Ltd. v. Salada Sheriff Chorsey Ltd., 20 Fox Pat. Cas. 169.

license for the purpose of importing a drug.[151] The second case no longer states the law in Canada, however. The Canadian Act was amended in 1968, and now permits the grant of a compulsory license for importation of a patented product relating to food or drugs. Until recently, the British also would have issued a compulsory license for importation of a drug or food, even where the imported product was manufactured abroad by a third party.[152]

A patentee who has been compelled to license may appeal. Both in Canada and in the United Kingdom, the reviewing court is authorized to examine the grant itself, as well as the terms and conditions of the license. Where denial of compulsory license is the subject of appeal, the court will not interfere with the "justifications for abuses" which were the basis for refusal, unless it finds a clear and obvious error. Any question as to the appropriateness of compulsory licensing of food and drugs, whether at the level of the Commissioner or on appeal, will operate in favor of the applicant.[153]

The Nature of the Compulsory License

Most statutes provide that a compulsory license is issued primarily to achieve working of a patented technology through manufacture in the issuing country. Consequently, a compulsory license normally is not issued to an applicant who cannot manufacture. As discussed in the previous section, the exception is a compulsory license for food and drugs. Where food and drugs are concerned, a compulsory license may be issued not only for manufacture, but also for importation, since the prime objective is immediate and sufficient supply at reasonable prices. But even in such cases, a compulsory license permits importation only in cases where manufacture in the country is impossible.

The compulsory license covers product and process claims.[154] It will apply, if necessary, to intermediate processes and intermediate products.[155]

Two major elements affect the terms of the compulsory license: (1)

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[151] Reg. v. Patents Appeal Tribunal, Ex Parte Hoffman-La Roche & Co., A.G., The Times of London, July 7, 1972, at 8.

[152] *Id.*

[153] Hoffman-La Roche Ltd. v. Delmar Chemicals Ltd., *supra* note 142, at 187; Gilbert Surgical Supplies Co. v. Parke Davis & Co. [1958] 18 Fox Pat. Cas. 62.

[154] Sherman & Ulster Ltd. v. Merck & Co. Inc. [1970] 44 Fox Pat. Cas. 16; F.W. Horner, Ltd. v. Hoffman-La Roche Ltd. [1971] 44 Fox Pat. Cas. at 29.

[155] Hoffman-La Roche & Co. A.G.'s Patent [1971] R.P.C. 311.

reasonable royalties to the patentee, based on the prevailing custom in similar cases of voluntary licenses; and (2) assurance that the license permits quality manufacture and adequate supply of the product to the public at a reasonable price.[156] The Patent Office has wide discretion in determining the terms and conditions of the compulsory license. It may prescribe royalties, set the duration for which the license will be in effect, define circumstances which will terminate the license or justify amending its terms, require marking of the patented product, regulate quantity, and impose other restrictions it deems necessary.

Once granted, the compulsory license is considered to be equivalent to a voluntary license. As in the case of a voluntary license, an attempt is usually made to bring the parties into agreement on the terms of the license. In many cases, after a determination has been made that a patentee is compelled to license an applicant, the parties will negotiate the terms of the compulsory license. Generally, they are free to structure the license as they see fit and to insert any terms they find appropriate.[157] The Patent Office, however, retains authority to interfere in such negotiations and to alter the terms of the license. It may decide to include an arbitration clause or, in the case of food and drugs, a mutual non-exclusive grant-back provision, or clauses requiring disclosure of health hazards or prescription limitations.

A compulsory license is always subject to review. Both the licensee and the patentee may appeal, and both may ask the court to alter the license or any of its terms due to a change in circumstances. The Patent Office is authorized to amend or revoke the license at any time. Either party may seek relief for non-performance of the terms of the license, and may do so in the courts or through arbitration, but not in the Patent Office. Since a compulsory license is contractual in nature, the injured party may bring an action for breach. The licensee may require the patentee to support any action for infringement of the licensed technology. Where a patentee refuses to sue for infringement, the patentee will be joined as a defendant by the licensee.[158]

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[156] *See* the Canadian Patent Act, *supra* note 32, at § 41(2).

[157] *For example,* Cathro's Application, *supra* note 47, at 488; Hanson & Son (London) Ltd.'s Application (1958) R.P.C. 88, 91. *But cf.* two cases where licensee was refused permission to sublicense: Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100; and Hoffman-La Roche & Co. A.G.'s Patent, *supra* note 126.

[158] British Patents Act, 1949, *supra* note 32, at §§ 38(4), 38(3); Canadian Patent Act, *supra* note 32, at § 68(a).

The Commissioner is authorized to direct the licensee to purchase materials from a certain specified source,[159] and to regulate the importation of products or materials presently being manufactured or imported by the patentee.[160] The Commissioner may allow the licensee to import patented products or equipment which are necessary for the manufacture of the licensed product or for use as part of the patented process.[161]

A compulsory license is normally non-exclusive.[162] Therefore, subject to the terms of the license, a patentee may grant voluntary licenses to others. A compulsory license does not prevent the patentee from granting other licenses at a lower royalty rate. The compulsory licensee is not "a most favored licensee."[163]

In Canada the Commissioner is authorized to order an exclusive compulsory license where the invention is not being worked on a commercial scale and where working the invention requires a large capital investment to justify exclusivity.[164] Under these circumstances, it must be shown that the patentee is either unable or unwilling to raise the necessary capital, and that the applicant can and will acquire the funds.

In cases of tying, the Canadian statute authorizes granting a compulsory license for a process patent to both the applicant and the applicant's customers. Both must be licensed in order to use the process or the products which are manufactured by this process.[165]

A compulsory license normally includes provisions intended to prevent unfair competition and consumer confusion regarding patented products.[166] In some instances, particularly in the case of drugs, a licensee may be permitted to use a patentee's trademarks, but it will then be required to mark the products to eliminate possible consumer

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159 Light v. Setter Bros. Inc.[1952] 13 Fox Pat. Cas. 58.

160 Canadian Patent Act, *supra* note 32, at § 68(a); *In re* Application of E.H. Tate Co. [1941] 2 Fox Pat. Cas. 156.

161 *In re* Application of E.H. Tate Co., *id.*, at 164.

162 Canadian Patent Act, *supra* note 32, at § 68(b); British Patents Act, 1977, c. 37, § 49. *Also see* in Britain, Hoffman-La Roche & Co. A.G.'s Patent, *supra* note 125; in Canada, Compagnie Pharmaceutique Vita Ltee v. Hoffman-La Roche, Ltd. [1970] 44 Fox Pat. Cas. 158.

163 Hoffman-La Roche & Co. A.G.'s Patent, *id.;* Atwater Bag Corp. v. Bahamas Paper Co., *supra* note 101.

164 Canadian Patent Act, *supra* note 32, at § 68(b).

165 *Id.* at §§ 68(c), 67(2)(f).

166 Atwater Bag Corp. v. Bahamas Paper Co., *supra* note 101; F.W. Horner, Ltd. v. Hoffman-La Roche, *supra* note 154.

confusion.[167] A licensee may also be required to agree to the patentee's exercising quality control over the product.

The compulsory license may include a termination clause. The Canadian statute provides that if the applicant/licensee is unable, within a specified period of time, to manufacture or make available sufficient amounts of the product by other means, the license will be revoked.[168] Normally, however, the duration of the compulsory license will parallel the duration of the patent. And, as is often the case, where a number of patents are licensed, the duration of the license will equal the life of the "youngest" patent.[169] Of course, the compulsory license is subject to reassessment and review if the circumstances change.[170]

Importation. A compulsory license may permit importation of the patented product, especially when food and drugs are involved, but also under other circumstances. This was the law in Canada even before Section 41 of the Patent Act was amended expressly to permit importation of the patented product by a compulsory licensee. Until recently, this was also the law in Britain. Compulsory licenses permitting importation usually were granted where the patented invention related to food and drugs.[171] In one case, however, an application for a compulsory license for importation was denied on public policy grounds.[172]

The amendment of Section 41 of the Canadian statute has improved the applicant's situation both as to intermediate steps and to final disposition of the application. The Commissioner is now authorized to grant a temporary compulsory license permitting importation of patented drugs.[173]

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[167] Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100.

[168] Canadian Patent Act, *supra* note 32, at § 69(1).

[169] Novopharm Ltd. v. Hoffman-La Roche Ltd., *supra* note 99.

[170] *See* in England, Hoffman-La Roche A.G.'s Patent [1971] R.P.C. 311; *see* in Canada, F.W. Horner, Ltd. v. Hoffman-La Roche, *supra* note 154; Novopharm Ltd. v. Hoffman-La Roche, *id.;* Sterilab Corp. v. Chas. Pfizer & Co., *supra* note 131.

[171] Hoffman-La Roche & Co., A.G. and Geigy A.G. v. Intercontinental Pharmaceuticals Ltd. [1965] R.P.C. 116, 131; Hoffman-La Roche & Co. A.G.'s Patent [1971] R.P.C. 311, [1973] R.P.C. 130, [1973] R.P.C. 601; Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100.

[172] Farmer's Marketing and Supply Co. Ltd. Patent [1966] R.P.C. 546.

[173] Canadian Patent Act, *supra* note 32, at § 41(4); Sterilab Corp. v. Etablissements Clin-Byla [1970] 44 Fox Pat. Cas. 49; Novopharm Ltd. v. Hoffman-La Roche Ltd., *supra* note 99.

Exportation. In Britain compulsory licenses ordinarily do not permit licensee to export the patented product.[174] In Canada, however, the opposite is generally the case.[175] The fact that a compulsory license permits exportation is itself not sufficient to assure that a licensee will export in fact. A patent is a national institution, and it is limited to the territory of the issuing country. Thus, even where a compulsory license in one country permits exportation to another, a licensee may be frustrated in his attempts to export by conditions in the receiving country.

The issue of exportation under a compulsory license raises difficult and complex problems relating to the patent laws of the member states of the EEC. Case law has established that the free circulation of goods between the member states cannot be impaired on the basis of national industrial property rights, where these rights stem from a common source. For example, the British firm, Sterling Drugs, relying on its Dutch patents, attempted to prevent the sale in Holland of its drugs which were manufactured in Britain under its British patents.[176] The European Court of Justice ruled against Sterling. It determined that the Dutch importer, Centrafarm B.V., was fully within the law when it imported the patented drugs from Britain, and that Sterling could not rely on its Dutch patent and trademark rights to obstruct the free circulation of drugs from Britain to Holland.

The issue becomes more complicated when the dispute involves patented goods produced by the holder of a compulsory license in the exporting member state, and where the patentee who was compelled to license in the exporting state was not required to do so in the importing state. This can be illustrated using the facts of the Centrafarm case.[177] Assume that Sterling Drugs, the patentee in Britain and in Holland, was not working its drug patents in Britain by way of manufacture, and a compulsory license was issued to applicant X in Britain. Centrafarm would then buy the drugs in Britain from licensee X, and import them into Holland. Sterling (Holland) would then challenge the legality of the importation of the patented drug on the basis of its local Dutch patents. Centrafarm would counter with the

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[174] Hoffman-La Roche & Co. A.G.'s Patent, *supra* note 169; Farbwerke Hoechst A.G. (Sturm & Others') Patent, *supra* note 100; *But cf.* Penn. Eng. & Mfg. Corp.'s Patent [1973] R.P.C. 233 where exportation was permitted.

[175] Sherman & Ulster Ltd. v. Merck & Co. [1970] Fox Pat. Cas. 16; Sterilab Corp. v. Chas. Pfizer & Co., *supra* note 131.

[176] Centrafarm B.V. v. Sterling Drug, Inc. 14 Comm. Mkt. L.R. 480 (1974), 2 COMM. MKT. REP. (CCH) Para. 8246.

[177] *Id.*

fact that the drugs are protected in Holland by patents which have the same origin as the British patents. Centrafarm's argument would most likely defeat Sterling's claim. Even when compelled, a patentee cannot license more than the patentee has. According to principles which have emerged from cases in the EEC member states, a licensee is subject to the same limitations on the patent right as were imposed on the patentee, and the laws will operate to ensure that the rights accorded each are not disproportionate. In our hypothetical, the imported product was manufactured under Sterling's British patents, and even though Sterling had been compelled to license X in Britain, it probably could not rely on its Dutch patents to restrict importation of the product into Holland.

These and other problems have been the subject of litigation in the member states. The case law which has developed represents attempts to reconcile the various articles of the Treaty of Rome. The articles which have been controversial are those relating to free circulation of goods, competition, and scope of industrial property rights. The compromise outlined by the Court of Justice, and subsequently adopted by the EEC legislature in the Community Patent Convention, is as follows: Patent and other industrial property rights are exhausted when first exercised anywhere in the EEC. Where several patentees within the EEC have independent rights which do not originate from the same source, they may each exercise their rights in the different member states. However, where patent rights in different countries of the EEC have a common origin, however remote, such rights cannot be exercised by one party to preclude the free circulation of goods.

Rights derived from a compulsory license are basically an extension of the rights of the patentee. Therefore, a patentee cannot invoke his patent rights in other EEC countries to restrain a compulsory licensee from circulating the patented goods freely throughout the EEC.

The new Community Patent Convention provides[178] that compulsory licensees will not be granted in member states if the invention is being worked anywhere in the EEC and demand for it is being met. Thus, the patent can be worked in one EEC member state and exported to the others without exposing the patentee to compulsory licensing in the importing member states.[179]

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[178] *See supra* note 61.

[179] *For example,* the British Patents Act of 1977, c. 37, § 53 provides specifically for that situation.

Royalties. Although a patentee may be compelled to license, he retains the right to be fully compensated for the expropriation of his patent. The laws of most countries require that the patentee receive royalties at a rate which most closely approximates the rate prevailing in the relevant market. Thus, determination of royalty rates takes into account production expenses, potential income, research and development expenses, sales promotion expenses, and income generated by the specific technology through spinoffs. The rate of royalties is also influenced by the nature of the license. An exclusive license will justify higher royalty rates than will a non-exclusive license. The Comptroller has the authority to review royalty rates at any time upon the request of any party.

Since the licensee does not bear the cost of research and development of the technology, the licensee may be tempted to sell the patented product at a much lower price. Occasionally it is necessary, therefore, to stipulate in the license the price at which the licensee may sell the product to assure that the patentee is compensated for the patentee's research and development. The licensee's duty to compensate, then, is eventually passed on to the consumer.

For purposes of determining royalties, a compulsory license is regarded as a voluntary license. The parties are encouraged to negotiate the terms of the license,[180] guided by the principle that the patentee is entitled to a fair return based on the nature of the invention, the degree of exploitation by the patentee and the licensee in the country, the research and development efforts of the patentee, the marketability and profitability of the patented product or process, and the resources required for working it.[181] When determining royalties, the rule that compulsory licensing is not intended to penalize the patentee should be emphasized.

In Canada, fair compensation has been held to include actual expenses incurred by the patentee, as well as loss of projected profits which the patentee would have received if the patentee were allowed to proceed with the exploitation of the patented invention according to the patentee's original plans.[182] Royalties are set according to the normal practice in the particular field or trade of the patented

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[180] Hoffman-La Roche Ltd. v. Bell-Craig Pharmaceuticals Division of Elda D. Craig Ltd. [1965] 29 Fox Pat. Cas. 123.

[181] Canadian Patent Act, *supra* note 32, at § 69(1); *and see* Smith Kline & French Laboratories Ltd.'s Application [1968] R.P.C. 415.

[182] Compagnie Pharmaceutique Vita Ltee v. Hoffman-La Roche Ltd., *supra* note 161; Hoffman-La Roche & Co. A.G.'s Patent [1973] R.P.C. 601.

technology.[183] In compulsory licensing of drugs, the Canadian Commissioner and courts have usually determined a royalty rate of four percent of the net selling price of the drug in its final dosage form to purchasers at arm's length.[184] In other cases, the Commissioner set rates based on net selling price of the bulk material to wholesalers.

In most countries the Commissioner is also authorized to include royalties for skills and techniques which the patentee will supply to the licensee along with the patented technology. Similarly, the cost of goodwill and management are taken into consideration. The parties normally are asked to provide a projection of sales, and the royalty rate is then based on volume. A sliding scale of royalties based on volume of sales may be developed.

Appellate courts review royalty rates only on rare occassions. In one Canadian case,[185] the court returned the case to the Commissioner with an order to base royalties on retail sale price. In a case concerning pharmaceutical products, the Commissioner determined royalties on the sale price to consumers at the retail level,[186] but on appeal, the court held that the proper basis for the computation of royalties is sale price in bulk to wholesalers.[187] Similarly, in Britain it has been held that in the case of pharmaceuticals, the proper basis for determining royalties is price of bulk sale by weight to wholesalers.[188] In determining royalties it is customary to receive expert testimony on the rate of royalties in the field of the patented technology.

Conclusion

Compulsory licensing and revocation of patents, as sanctions against the non-use of patented technology, are usually opposed by supporters of free trade and by anti-protectionists. They consider

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[183] DeFrees v. Dominion, *supra* note 41, at 141; Metaliflex Ltd. v. Rodi & Weinberger, *supra* note 40, at 416.

[184] F.W. Horner, Ltd. v. Hoffman-La Roche, Ltd., *supra* note 153; Sterilab Corp. v. Etablissements Clin-Cyla, *supra* note 172; Sterilab Corp. v. Chas. Pfizer & Co., *supra* note 131.

[185] Parke Davis & Co. v. Fine Chemicals of Canada Ltd. (No. 2) [1959] 19 Fox Pat. Cas. 115.

[186] Hoffman-La Roche Ltd. v. Bell-Craig Pharmaceuticals Division of L.D. Craig Ltd. [1965] 29 Fox Pat. Cas. 123.

[187] Hoffman-La Roche Ltd. v. Bell-Craig Pharmaceuticals Division of L.D. Craig Ltd. [1966] 32 Fox Pat. Cas. 106.

[188] Hoffman-La Roche & Co. A.G.'s Patent [1969] R.P.C. 504; (1973) R.P.C. 601; Geigy's Patent [1964] R.P.C. 391.

compulsory licensing to have the same effect as tariffs and other barriers to international trade. They argue that the international economy should be allowed to balance supply and demand for patented products, and that patentees are best qualified to decide whether or not to work their patents. It is also claimed that compulsory licensing is unjustifiable morally because it permits one who has not sown to reap. Some maintain that compulsory licensing is not a legitimate means of aiding a national economy, since it acts to discourage inventors and corporate research and development, and results eventually in retarding technological progress. Other arguments advanced are that compulsory licensing and revocation damage the international patent system in general, and encourage secrecy rather than free exchange of advanced technology; that it forces patentees to charge higher prices for patented products to avoid subsequent compulsory licensing; that compulsory licensing hurts rather than helps developing countries because when a patentee is forced to work the technology in a developing country, the consumer pays more for a product which would have been less expensive if imported.

Third world commentators argue that the international patent system has become a vehicle through which the more developed countries and the multinational corporations have gained control of the international market. They claim that the patent system impedes the industrial development of the third world, and cite studies which show that 84 percent of the patents granted by developing countries are owned by foreigners and that 90 to 95 percent of these patents are not in use at all in these countries.[189] They argue further that sophisticated patent draftsmanship has resulted in overprotection of patented technologies to the extent that existing methods of compulsory licensing are an inadequate remedy. They maintain that a more efficient form of compulsory licensing is essential to offset the disadvantages of the modern patent system and to serve the cause of economic development, which is impossible without access to certain technologies which are protected by patents.

A recent UNCTAD study concluded that the Paris Union model of compulsory licensing has proven to be ineffective.[190] It criticizes both the three-year non-working grace period as causing unnecessary delay in the availability of a compulsory license, and the defense of

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[189] *See* The U.N. Report, *supra* note 3, at 400, 401. *See also* the International Patent System as an Instrument of Policy for National Development at 2, Para. 3, a report by the UNCTAD Secretariat, TD/B/C. 6/AC.2/3, 1975 [hereinafter The UNCTAD Report].

[190] The UNCTAD Report, *id.* at 13.

"legitimate reasons" for non-working of a patent which defeats applications for compulsory licenses entirely.[191] It states that patentees are able to manipulate the "legitimate reasons" doctrine by contracting with a subsidiary or local agent to work the patent until some unspecified time in the future in order to postpone compulsory licensing or avoid it altogether. Further, the study claims that compulsory licensing of patents is ineffective since there is need for additional know-how to supplement the information disclosed in the specifications of the patent. It criticizes the Paris Convention provision that importation of patented products is sufficient to preclude revocation of the patent. Even if a compulsory license is granted, it argues, a patentee may still import a product of higher quality at lower prices, and consequently destroy the local licensee's opportunity to compete.

Proponents of compulsory licensing in developed countries are not insensitive to the problems inherent in the system. They recognize that the patent system should not be used to prevent consumers from getting a product at the lowest possible price, even if importation is necessary, and that patents should not serve as a means to further international price discrimination arrangements.[192] In the United Kingdom compulsory licensing has recently been re-examined and it has been decided that compulsory licensing, as it existed under the previous British Patent Act of 1949,[193] will be retained.

Some countries do not interfere at all with the non-working of patents.[194] Other countries do interfere, but do not provide for compulsory licensing. Some of them merely resort to revocation of patents for expropriation.[195] Still others do not provide for revocation, but do employ compulsory licensing.[196]

In developing countries, a foreign patentee may welcome compulsory licensing which guarantees working of the patent locally. A licensee in a developing country will probably require the patentee's

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[191] *See* section in text entitled Justifications for Failure to Work the Patent.

[192] *See* Economic Council of Canada, Report of Intellectual Industrial Property at 90 (1971).

[193] *See* Report of the Committee to Examine the Patent System and Patent Law at 101-6, Chairman M.A.L. Banks, Esq., (London 1970) [hereinafter The Banks Report]. This report is the basis for the 1977 British Patent Act.

[194] Albania, the Bahamas, Chile, Colombia, El Salvador, Somalia, United States, Soviet Union, Vietnam. *See* BAXTER, *supra* note 1, at 117.

[195] For example, Liberia, East Germany, Iran. *Id.*

[196] Denmark, Finland, France, Iceland, Japan, Luxemburg, Mexico, Holland, Norway, the Philippines, South Africa, Spain, Turkey, Sweden. *Id.*

assistance, especially where the national market is not very promising and the licensee's export potential is minimal.

But compulsory licensing is not a solution to the technological problems of developing countries. In most cases, technology cannot be transferred effectively without the active participation of the transferor. The licensor cannot be compelled to transfer the skills essential to the working of the patented technology. Efficient transfer of technology requires a comprehensive industrial approach where the transferor invests not only its technology, but also its management skills, sales expertise, and capital. The disassociation of the patented technology from the industrial investment process is certain to produce poor results.[197] The key to the success or failure of compulsory licensing is its impact on the patentee. Where the patentee is induced by compulsory licensing to cooperate with the licensee, the process may succeed. However, if the patentee fails to cooperate fully with the licensee, the success of the transfer is doubtful, particularly in developing countries.

Compulsory licensing is a hotly debated issue in international negotiations, particularly as it relates to proposed revisions of the Paris Convention.[198] A substantial part of efforts toward revision of the Paris Convention is devoted to compulsory licensing and revocation of patents.[199]

Actually, the compulsory license is used very seldom. In the United Kingdom, for example, in the ten year period between 1959 and 1968 there were only 12 applications for compulsory licenses. Two applications were allowed, one was refused, and nine were withdrawn. There were two appeals to the Patents Appeal Tribunal, but both were dismissed.[200]

Seven out of 12 applications for compulsory licenses submitted between 1958 and 1960 related to food and drugs, and all seven were granted. Among the remaining five which did not involve patents for food and drugs, two were successful, two were withdrawn, and one was refused.[201]

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[197] *See* The U.N. Report, *supra* note 3, at 43.

[198] See Vaitsos, *Patents Revisited: Their Function in Developing Countries,* J. DEV. STUD., at 89 (1975). *See also* U. ANDERFELDT, INTERNATIONAL PATENT LEGISLATION AND DEVELOPING COUNTRIES at 83-4 (the Hague 1971).

[199] *See* The U.N. Report, *supra* note 3, at 25; The UNCTAD Report, *supra* note 188, at 4. 188, at 4.

[200] See The Banks Report, *supra* note 192, at 101 and Appendix B.

[201] See T. BLANCO-WHITE, INDUSTRIAL PROPERTY AND COPYRIGHT at 63 (1963). *See also* T. BLANCO-WHITE, *supra* note 81, at 393n.45.

The infrequent use of compulsory licensing may be attributed to the fact that the courts, especially in developed countries, have placed substantial obstacles in the path of applicants seeking a compulsory license. It may indicate, however, that compulsory licenses are an effective remedy, and that patentees prefer to negotiate a voluntary license to avoid the sanctions of compulsory licensing. In some instances, a patentee may be induced to work the patent itself rather than expose it to a compulsory license. In some countries revocation or forfeiture of a patent is added incentive for the patentee to attempt local working of the patented technology.

Private Compensation for Oil Discharge Damage

JAMES M. TEXTOR*

The recent European and New England maritime catastrophes and the ensuing oil spill damage have made vessel-point source oil pollution a universal concern of an environmentally conscious public and an image troubled oil industry. Much has been written on the federal government's role in the prevention of oil spills, the clean-up operations and the environmental consequences that result when oil spills do occur. This article is primarily concerned with the legal remedies available to the private pollution claimant who one day discovers that his property has been inundated with oil from either a known or an unknown source.

This discussion will be limited to pollution caused by marine transport of persistent oils, *i.e.,* crude oil, diesel fuel and heating oil whose chief characteristics are an inability to dilute readily in water and a stability and bouyancy when compared to refined products, such as kerosene, gasoline and aviation fuel which evaporate and disperse quite rapidly.[1]

Today, vessel-point source oil pollution enters waterways in two manners. First, there are normal pollution risks associated with load-

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[1] After a few weeks exposure to air and sun, evaporation, absorption, biodegradation and auto-oxidation, the oil is reduced to approximately 15% of its original volume in the form of a dense, asphaltic tar ball about the size of a softball. *See* H.W. Anderson, *National and International Efforts to Prevent Traumatic Vessel Source Oil Pollution,* 30 U. MIAMI L. REV. 985, 994 (1976).

ing and discharging operations, deliberate operational discharge from bilge pumping, tank washing and deballasting all of which have been contained by legislation[2] or international treaty.[3] The traumatic oil spills that result from collision, grounding and foundering of oil tankers, are the second and most widely publicized point-sources, but they contribute the least amount of oil pollution.[4]

The public is not dealing with a direct peril to human life from marine disasters but rather with the consequential damages which occur most often to beaches, marine life, piers or other vessels. Oil spills causing such damage may give rise to a governmental or private claim for clean-up expenses as well as for property loss. Private parties may undergo damage to their immediate economic interests, *i.e.,* reduced profits, loss of tourism. Prolonged economic damage may befall those who harvest marine life if the productivity of the water is destroyed by an oil spill.

The following is an overview of the various avenues of redress available to a private pollution claimant.

Compensation Based on Traditional Concepts of Tort Liability

Common law doctrines developed by English and American courts over the centuries which offer remedies for oil pollution are trespass, negligence and nuisance. The following discussion is a brief overview of a private party's burden of proof, including the elements needed to establish a prima facie case for an oil pollution tort.

Trespass. At common law, trespass is a direct infringement of another's exclusive right to property.[5] Actual damages need not be proven, since trespass is actionable per se; nevertheless, if no actual damages are established, recovery will be limited to minimal mone-

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[2] Oil Pollution Act of 1961, *as amended* by Pub. L. No. 89-551, 33 U.S.C. § 1002 (2), *as amended* by Pub. L. No. 93-119, Oct. 4, 1973.

[3] International Convention for Prevention of Pollution of the Sea by Oil, 1954, *as amended* 1962 and 1969, to take effect on January 19, 1978. *See* 7 E.L.R. 1616 and 43 Fed. Reg. 16886-16891 (International Conference on Tanker Safety and Pollution Prevention, 1978).

[4] Each year approximately 60% of the work production of oil is transported by sea. About 1/10 of 1% of this amount is lost at sea. This amount is divided between overboard and accident-related spills. Tug Ocean Prince, Inc. v. United States, No. 77-6190, 6195 (2d Cir., filed Aug. 7, 1978).

[5] "Trespass would lie for all forcible, direct injuries, even though they were not intended, onto the property of another." W. PROSSER, LAW OF TORTS at 3 (6th ed. 1976).

tary damages. Due to the restrictive nature of the burden of proof, the trespass doctrine has been used infrequently in environmental oil spill litigation.[6] According to modern tort theory, trespass is actionable only when the injury is either the result of an intentional or negligent intrustion.[7] Therefore, a property owner must establish fault to recover for damages resulting from an oil discharge. Trespass would appear to be a convenient means of recovery, since most oil spills occur as a result of either negligence or an intentional action, *i.e.*, pumping bilges or tank cleaning. However, the difficulty of establishing intent or negligence of a vessel (possibly many miles out at sea) would normally prevent private pollution claimants from instituting a trespass action.

Since one of the prima facie elements of trespass is actual entry or intrusion onto property, beachfront property owners whose property is not inundated with oil, but whose use of adjacent waters (swimming, boating and fishing) may be diminished, would be precluded from bringing a trespass action. Therefore, beachfront property owners must show some property interest in these adjacent waters, such as clam or oyster harvesting, under a specific state charter or lease.[8] This same burden of proof would prevent nonbeachfront businesses from utilizing the trespass theory to recover lost profits due to pollution of neighboring beaches.

Of particular note is that the statute of limitation begins when the invasion commences, and continues to run for a continuing trespass.

Negligence. One of the principal theories relied upon to recover damages for oil pollution is negligence. In establishing the elements[9] of a negligence cause of action, the pollution claimant may be confronted with serious difficulties in proving the existence of proximate or legal cause and the identification of the exact polluter.[10] Furthermore, the burden of proving either that the responsible vessel's equipment was in a negligent state of repair or that negligent naviga-

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[6] *See* 3 BENEDICT'S ON ADMIRALTY, § 114 at 9-103 (7th rev. ed. 1977).

[7] Vodopija v. Gulf Refineries, 198 F.2d 344 (5th Cir. 1952).

[8] Blake v. United States, 181 F.Supp. 584, 587, *aff'd,* 295 F.2d 91 (4th Cir. 1961). *Also see* 23 ALA. L. REV. 100, 106 (1970).

[9] The elements of negligence are (1) duty, (2) breach, (3) proximate cause by defendant's conduct, and (4) damages. W. PROSSER, *supra* note 5, at 146. *See* United States v. M/V Big Sam, 454 F.Supp. 1144, 1148 (E.D. La. 1978).

[10] Salaky v. The Atlas Barge No. 3, 120 F.Supp. 225, *rev'd on other grounds,* 208 F.2d 174 (2nd Cir. 1953); O'Donnell Transp. Co. v. M/V Maryland Trader, 228 F.Supp. 903, 909 (S.D.N.Y. 1963).

tion was responsible as in the *Amoco Cadiz, Argo Merchant or Torrey Canyon* catastrophes is usually beyond the means and energies of a private beachfront claimant. In addition, the plaintiff must prove the forseeability of the injury[11] by establishing that a reasonable person discharging oil far out at sea could have anticipated a particular injury to the claimant as the result of his negligent conduct.

The doctrine of *res ipsa loquitor*[12] would seem to be an appropriate legal tool. However, evidence of vessel discharges usually lies wholly with the ship operator. Also, there are a large number of possible alternative point sources, such as oil rigs and bilge discharge from freighters, complicated by ocean winds and currents. Consequently, the doctrine of *res ipsa loquitor* is not always helpful.[13] In some instances, the doctrine may reduce the necessary quantity of proof; nevertheless, proof that the defendant alone caused the discharge that damaged the plaintiff's property is still required.[14]

Proof of negligence is too cumbersome for an individual claimant. The costs of preparing negligence cases and the difficulty of proving proximate cause will continue to limit the value and number of law suits pursued under this cause of action.

Nuisance. Depending on the circumstances surrounding a private citizen's actions for oil pollution damage, nuisance[15] has proven to be very useful.

In oil spill litigation a private claimant may maintain either a private or public nuisance action, depending on the nature of the damage. As in a trespass action, only a property owner whose loss of use or enjoyment of his property may maintain a private nuisance. On the other hand, public nuisances usually include a wide variety of activities deemed to be improper and indictable because they harm the general public. Public nuisance and private nuisance have little

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[11] *See* Annot., 32 A.L.R.3d 215, 273 (1970).

[12] *See* Johnson v. United States, 333 U.S. 46, 48, 68 S.Ct. 391 (1947): "[t]he facts of the occurrence warrant the inference of negligence, not that they compel such an inference."

[13] United States v. Tanker Monsoon, 433 F.2d 95 (1st Cir. 1970).

[14] Bianchini v. Humble Pipe Line Co., 480 F.2d 251, *reh. denied,* 478 F.2d 1402 (5th Cir. 1973); and State of California By and Through Dept. of Fish & Game v. SS Bournemouth, 318 F.Supp. 839, 842 (D.C. Cal. 1970). *See* F.E. Sisson III, *Oil Pollution Law and the Limitation Act: A Murky Sea for Claimants Against Vessels,* 9 J. of M.L. & COMM. 285, 298 (1978).

[15] "Of all the common law remedies, (public) nuisance has been applied most frequently to environmental law." J. YANNACORE, 1 ENVIRONMENTAL RIGHTS AND REMEDIES, at 77 (1972).

in common except that the conduct which interferes with the private use of property may also be the conduct which interferes with the well-being of the community. The location and nature of the oil damage will usually determine whether the nuisance is private or public. In 1976, the 7.3 million gallon oil spill of No. 6 fuel oil on Georges Bank from the *Argo Merchant* created a public nuisance which the Commonwealth of Massachusetts would have been required to abate as *parens patriae* for the common benefit of its citizens.[16] However, the fishermen sustained damage of a character distinct from the injury suffered by the public generally. Consequently, this situation has elements of both public and private nuisance. The question thus arises whether the fishermen may maintain a private action.

In a private suit for public nuisance for all pollution damage, the courts require that the claimant be specially injured, suffering damages different in kind from the rest of the community and that the nuisance be continuous or recurring by nature.[17] In *Oppen* v. *Aetna Insurance Company,*[18] the plaintiffs sued for loss of navigational rights due to an oil spill obstructing navigation in the Santa Barbara Channel. Since the plaintiffs were unable to establish a special injury, the action was determined to be in public nuisance and relief was denied. However, when a grounded tanker spilled oil into offshore waters, Maine fishermen and clammers in *Burgess* v. *Tamaro*[19] sufficiently alleged "particular" injury to support private actions in public nuisance.[20]

In the case of a public nuisance where the pecuniary loss is common to an entire community, the claimant must establish a particular

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[16] Illinois v. Milwaukee 406 U.S. 91, 106-107, 92 S.Ct. 1385, 31 L. Ed.2d 712 (1972); Puerto Rico V. SS Zoe Colocotroni, Nos. 73-252, 73-309, (D.P.R. filed Aug. 15, 1978); *In re* Oswego Barge Corp., 439 F.Supp. 312, 321 (N.D.N.Y. 1977); Maine v. M/V. Tamaro, 357 F.Supp. 1097 (D. Me. 1973); United States V. U.S. Steel, 356 F.Supp. 556, 558 (N.D. Ill. 1973); and Maryland v. A. Hess Corp., 350 F.Supp. 1060 1067, *motion denied,* 356 F.Supp. 975 (D. Md. 1973).

[17] *In re* Oswego Barge Corp., *supra* note 16, at 322.

[18] 485 F.2d 252 (9th Cir. 1973).

[19] Burgess v. Tamaro, 370 F.Supp. 247, 250 (D. Me. 1973). *See* Potomac River Ass'n Inc. v. Lundeberg Maryland Seamanship School, Inc., 402 F.Supp. 344, 358 (D.Md. 1975).

[20] "The commercial fishermen and clam diggers in the present case clearly have a special interest, quite apart from that of the public generally, to take fish and harvest clams from the coastal waters of the State of Maine." Burgess v. Tomaro, *supra* note 19, at 250.

injury.[21] In *Burgess,* owners of motels, trailer parks, camp grounds, restaurants, grocery stores and similar establishments whose businesses were adversely affected by the spill, but who suffered no direct injury to their private property, had no right to compensation. Beachfront businesses whose property is invaded, as in *Burgess,* would suffer an injury distinct from that of the general public. As a result, they would be able to maintain an action for pecuniary loss.[22] In *Kirwin* v. *Mexican Petroleum Company,*[23] a beachfront property owner who rented bathhouses and bathing suits maintained an action for damages from an oil discharge which created a public nuisance but caused a particular injury to the landowner, *i.e.,* the riparian right of access to the water.[24] Furthermore, recovery may be possible on a nuisance theory where beachfront property is not actually invaded but the property owner's littoral rights (fishing, swimming, and boating) are impaired by an oil discharge.[25] Note, however, that a non-riparian property owner may not maintain an action for pecuniary loss from the same discharge.

Since negligence and nuisance are similar remedies, the former a cause, the latter a result, the private pollution claimant has a similar causation problem because he must prove the origin of the oil discharge. This particular element of the prima facie case will usually be difficult to prove in a pollution action especially one by a private claimant who has limited resources and damage from an oil spill with an unknown point-source near congested shipping lanes.

Admiralty

Jurisdiction and Admiralty Extension Act. Since the common law remedies available to private pollution claimants are inadequate, federal and state governments have enacted legislation designed to both prevent and remedy vessel-point source oil pollution. However, a private claimant also has available a general maritime or admiralty

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[21] Ind. Stream Pollution Control Bd. v. U.S. Steel, 62 F.R.D. 31, 34 *aff'd,* 512 F.2d 1036 (7th Cir. 1975).

[22] Pecuniary loss will be regarded as different in kind if the individual plaintiff was engaged in a business making commercial use of the public right invaded by the defendant's conduct. W. Prosser, *Private Actions for Public Nuisance,* 52 VA. L. REV. 997 (1966).

[23] 267 F. 460, 462 (D.R.I. 1920).

[24] *But see* Union Oil Co. v. Oppen, 501 F.2d 558, 563-8 (9th Cir. 1974).

[25] *In re* New Jersey Barging Corp., 168 F.Supp. 925, 937 (S.D.N.Y. 1958).

remedy. This section will discuss the sufficiency of the legal redress offered by admiralty and maritime law.

The United States Constitution extends the judicial power of federal courts to all cases of admiralty and maritime jurisdiction.[26] District courts have original jurisdiction without reference to the amount in controversy or to diversity of citizenship.[27]

Historically, federal admiralty jurisdiction was defined by the strict "locality test"[28] which limited admiralty jurisdiction to those acts committed and consummated upon navigable waters.[29] As explained above, the critical factor in determining whether a tort claim came within admiralty jurisdiction was the situs of the wrongful act. If the tort occurred on navigable waters, the claim was within admiralty jurisdiction.[30] However, because this locality test excluded ship-related damage as well as oil pollution damage to shore property from admiralty jurisdiction, Congress in 1948 enacted the Admiralty Extension Act[31] which includes sea-to-shore pollution damage within admiralty jurisdiction.[32] The Act extends admiralty and maritime jurisdiction to include all cases of damage to property caused by a vessel on navigable waters whether the injury is consummated on water or land.[33] Accordingly, it would appear that a private pollution

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[26] U.S. CONST. art. III, § 2.

[27] 28 U.S.C.A. § 1333(1). *Also see* Hall & Co. v. SS Seafreeze Atl., 423 F.Supp. 1205, 1207 (S.D.N.Y. 1976).

[28] "Every species of tort ... if upon the high sees or navigable waters, is of admiralty cognizance." Victory Carriers, Inc. v. Law, 404 U.S. 202, 214, 92 S.Ct. 418, 30 L.Ed.2d 383 (1971); and The Plymouth, 70 U.S. (3 Wall) 20, 36, 18 L.Ed. 125 (1866).

[29] On the other hand, a federal maritime claim may be asserted on the civil side of federal district court pursuant to the "savings to suitors" clause of 28 U.S.C. § 1333 (diversity of citizenship).

[30] Kermarec v. Compagnie Generale Translantic, 358 U.S. 625, 628, 79 S.Ct. 406, 3 L.Ed.2d 550 (1959); *Also see* Weinstein v. Eastern Airlines, Inc., 316 F.2d 758, 761 (3rd Cir. 1963) *which was expressly overruled* in Executive Jet Aviation, Inc. v. Cleveland, 409 U.S. 249, 269, 93 S.Ct. 493, 34 L.Ed.2d 454 (1972).

[31] Admiralty Extension Act of 1948, ch. 19A, 46 U.S.C. § 740 (1970).

[32] Askew v. American Waterways Operators, Inc., 411 U.S. 325, 340-1, 343, 93 S.Ct. 1590, 36 L.Ed.2d 280, *reh. denied,* 412 U.S. 933, 93 S.Ct. 2746, 37 L.Ed.2d 162 (1973); and *In re* Cook Transp. Sys., Inc., 431 F.Supp. 437, 441 (W.D. Tenn. 1976).

[33] The Act provides that "the admiralty and maritime jurisdiction of the United States shall extend to and include all cases of damage or injury, to person or property, caused *by a vessel* on navigable water, notwithstanding that such damage or injury be done or consummated on land" [emphasis added]. 46 U.S.C. § 740 (1970). *See* Nat'l Sea Clammers Ass'n v. New York, No. 77-126 (D.N.J. filed Aug. 14, 1978).

claimant must look to individual state law rather than to admiralty law, to determine whether injured property such as wild sea birds, fish and shrimp, is "property" within the meaning of the 1948 Act.[34]

In addition to the extension shoreward of the strict locality rule pursuant to the 1948 Act, there must now be a maritime incident or connection between the wrongful act and a vessel, navigation or commerce upon the navigable waters.[35] In modifying the rigid "locality" doctrine, the Supreme Court fashioned the "maritime nexus" or "locality plus" test[36] requiring that the activity of the injured party, rather than the tortfeasor, involve or be connected with some traditional maritime activity. Clearly, an oil discharge causing damage to commercial fishing,[37] clamming,[38] or boats[39] is actionable as a maritime tort but loss of the use of a private pleasure boat[40] will not be compensated under maritime law.

The maritime nexus test is also satisfied in situations where the injury occurs upon navigable waters, but the cause of the damage is initiated from the shore. In *State of Maryland* v. *Amerada Hess Corp.*,[41] a shoreside tanker facility transfer line ruptured causing an extensive oil spill in Baltimore Harbor. Clearly, the harm was incident to maritime activity. In most oil pollution cases, however, the negligent act occurs on navigable waters and the resulting damage is

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[34] Moore v. Hampton Roads Sanitation Comm'n., 557 F.2d 1030, 1977 A.M.C. 1162 *cert. denied,* 98 S.Ct. 725 (1978).

[35] "A waterway is navigable provided that it is used or susceptible of being used as an artery of commerce." Adams v. Montana Power Co., 354 F.Supp. 1111, *aff'd,* 528 F.2d 437, 439, (9th Cir. 1975). *See also* Kohlasch v. New York State Thruway Auth., 460 F.Supp. 956 (S.D.N.Y. 1978).

[36] Executive Jet Aviation, Inc. v. Cleveland, *supra* note 30, at 268. *Also see* Carroll v. Protection Maritime Ins. Co., 512 F.2d 4, 8 (1st Cir. 1975); Chapman v. Grosse Pointe Farms, 385 F.2d 962, 965 (6th Cir. 1967); National U. Fire Ins. Co. of Pitt. v. United States, 436 F.Supp. 1078, 1080-1 (M.D. Tenn. 1977); and O'Connor & Co. v. Pascaqoula, Miss., 304 F.Supp. 681, 683 (S.D. Miss. 1969).

[37] Union Oil Co. v. Oppen, *supra* note 24, at 561; and Potomac River Assoc. v. Lundeburg Maryland Seamanship School, Inc., 402 F.Supp. 344, 358, (D.Md. 1975).

[38] Burgess v. Tamaro, *supra* note 19, at 250.

[39] Oppen v. Aetna Ins. Co., *supra* note 18, at 257; Salaky v. The Atlas Barge No. 3, *supra* note 10; Kohlasch v. New York State Thruway Auth., *supra* note 35, at 963.

[40] Oppen v. Aetna Ins. Co., *id. Also see,* M.K. Depoy, *Pleasure Boat Torts in Admiralty Jurisdiction: Satisfying the Maritime Nexus Standard,* 34 WASH & LEE L. REV. 121 (1977).

[41] 350 F.Supp. 1060, 1064, *motion denied,* 356 F.Supp. 975 (D.Md. 1973). *But see* D.R. Tyrrell, *Admiralty Tort Jurisdiction,* 27 U. FLA. L. REV. 805, 810 (1975).

felt ashore on public or private property.[42] According to the Supreme Court decision in *Askew,*[43] *supra,* oil pollution damage to public and private property caused by vessel-point sources is clearly included within admiralty jurisdiction pursuant to the Admiralty Extension Act of 1948.

Thus, if the oil spill is caused by a vessel and results in property damage ashore, admiralty jurisdiction exists under the Act regardless of the nature of the property (as determined by state law) or the location of the resulting harm. Shoreside damage to a privately owned oyster bed or shoreline is actionable as long as the effect is not too remote from the time and place of the vessel point-source.[44]

In Rem: Negligence and Unseaworthiness. In a case of first impression, decided prior to *Executive Jet, supra, State of California* v. *S.S. Bournenmouth,*[45] the California Department of Fish and Game filed an admiralty in rem[46] action against a Liberian tanker accused of discharging bunker oil on California's navigable waters. The basis of the action was the property damage or tortious "conversion" of the waters and marine life. Since admiralty in rem actions usually involve vessel collisions or personal injury suits, California's action for unwarranted conversion of property was a novel approach. Therefore, the court expressly limited the in rem action to the state and excluded such actions by private pollution claimants.

Another novel approach to the problem of private compensation for oil discharge damage has been the suggested use of the maritime doctrine of unseaworthiness. The shipowner has an *absolute* duty to fur-

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[42] *In re* New Jersey Barging Corp., *supra* note 25.

[43] Askew v. American Waterways Operators, Inc., *supra* note 32, at 340.

[44] We think it sufficient for needs of this occasion to hold that the case is within the maritime under 46 U.S.C. § 740 when, as here, it is alleged that the shipowner commits a tort while or before the ship is being unloaded, *and the impact of which is felt ashore at a time and place not remote from the wrongful act* [emphasis added]. Gutierrez v. Waterman S.S. Corp., 373 U.S. 206, 210, 83 S.Ct. 1185, 10 L.Ed.2d 297 (1962).

[45] 307 F.Supp. 922 (C.D.Cal. 1969).

[46] Since oil pollution damage is classified as a maritime tort, maritime law gives the private pollution claimant a procedural remedy not usually associated with shoreside actions, by way of a maritime lien. This lien gives the claimant the right to proceed *in rem* against the offending vessel, be seizing the vessel and cargo, the wreck of these, for the proceeds of sale and freight. *See* G. GILMORE & C. BLACK, *The Law of Admiralty* at 622 (2d ed. 1975) [hereinafter GILMORE & BLACK] *See also* United States v. M/V Big Sam, *supra* note 9, at 1151.

nish a seaworthy vessel and appliances,[47] thereby absolving his liability only by a *force majesture*. Therefore, if a private claimant's injury is the consequence of a discharge resulting from some defect in the vessel or equipment, the vessel owner or operator should be liable for that damage. Unfortunately, private parties have been precluded from utilizing this doctrine. This maritime cause of action has its principal application in the area of personal injury suits by seamen other than longshoremen or cargo owners who have sustained losses due to the unseaworthiness of a vessel.[48]

In 1972, in *State of Maryland* v. *Amerada Hess Corp.*,[49] the court held that the doctrine of seaworthiness, a shipowner's duty to provide a seaworthy vessel, was unavailable to the State as a means of recovering for oil spill damage due to the rupture of an oil transfer line between a tanker and the shoreside facility. Since this doctrine traditionally has been limited to the benefit of those performing the historic function of seamen,[50] the court refused to extend it for the benefit of an oil discharge claimant.

Finally, the private pollution claimant always has available the standard maritime negligence remedy. As explained, the private property owner has a difficult and costly burden of proof. The claimant must prove causation[51] and establish negligent conduct. Crew members and officers of the discharging vessel might be the only witnesses available and they would be unlikely to admit to any involvement of wrongdoing; such proof would be harder to obtain because of the unwillingness of crew members to testify against the interest of their employer.[52]

Limitation of Liability Act. An additional obstacle to recovery by private pollution claimants pursuant to federal law is the Limitation

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[47] GILMORE & BLACK, *id.* at 617.

[48] *See* Sweeney, *Oil Pollution of the Oceans,* 37 FORDHAM L. REV. 155, 167 (1968).

[49] *See* note 41 *supra.*

[50] Seas Shipping Co. v. Sieracki, 328 U.S. 85, 96, 66 S.Ct. 872, 90 L.Ed. 1099 (1946).

[51] Salaky v. The Atlas Barge No. 3, *supra* note 10.

[52] *But see* Burgess v. Tamaro, 373 F.Supp. 839, *vacated,* 564 F.2d 964, 967-69, *cert. denied,* 98 S.Ct. 1520 (1978), for the testimony of a bosun who witnessed his vessel's collision with a ledge buoy.

of Liability Act[53] which governs suits brought in admiralty against shipowners for damage caused by their vessels. Regardless of the amount of damages claimed, the private claimant's recovery is limited to the value of the vessel and its pending freight.

This feature of maritime commerce was enacted in 1851 to bolster the development of a strong merchant marine by limiting the possible liability due to disasters thus placing American shipping interests on a competitive footing with British interests.[54] The Act is, however, still a powerful limitation on the liability of maritime insurance clubs, for both water and shore situs damage.[55]

However, even if a private pollution claimant is able to establish the requisite in rem or in personam jurisdiction against a vessel operator and proves that the destruction or property loss was proximately caused by the offending vessel, he may still be precluded from a reasonable recovery if the vessel and cargo are a total loss[56] Following the *Torrey Canyon* disaster in 1967, the shipowner and operator involved in that case successfully invoked this law in the American courts to limit their liability to $50, the value of a single remaining lifeboat.[57]

The shipowner's right to limit his liability depends on his lack of any "privity or knowledge" concerning the cause of the discharge. If he is without knowledge, his liability may be limited; if he is chargeable with privity or knowledge, his personal liability remains unaffected. Since the facts are peculiarly within the owner's knowledge, the burden on proving absence of privity and knowledge is on the

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[53] 46 U.S.C. §§ 181-96 (1970) (originally enacted as Act of March 3, 1851, ch. 43, 9 Stat. 635). The Act provides in part: "The liability of the owner of any vessel, whether American or foreign ... for any loss, damage or injury ... done, occasioned or incurred, without the privity or knowledge of such owner or owners shall not ... exceed the amount or value of the interest of such owner in such vessel, and her freight then pending." *Id.* at § 183(a).

[54] University of Tex. Med. Branch at Galveston v. United States, 557 F.2d 438, 441, 454 (5th Cir. 1977); Clinton Board of Park Comm'r v. Claussen, 410 F.Supp. 320, 326 (S.D. Iowa 1976).

[55] "So far as vessels are concerned the federal Limitation of Liability Act extends to damages caused by oil spills even where the injury is to the shore." Askew v. American Waterways Operators, Inc., *supra* note 32, at 330.

[56] "The shipowner may, on the occurrence of some event for which the ship is liable, restrict his liability to whatever value the ship may have after the event." GILMORE & BLACK, *supra* note 46, at 818.

[57] *In re* Barracuda Tanker Corp., 281 F.Supp. 228, 232, *modified in part,* 409 F.2d 1013 (2nd Cir. 1969).

shipowner[58] once the claimant has established the fault of the shipowner[59] or demise character.[60] Unless the private pollution claimant can establish negligence and attribute it to the owner or prove the unseaworthiness of the vessel which may be destroyed or sunk, he will be precluded from an adequate recovery.

Fortunately, in cases involving owners of wrecked vessels, courts have been reluctant to apply the Limitation of Liability Act in a civil action by the federal government pursuant to section 15 of the Rivers and Harbors Act[61], favoring instead the strong public policy of minimizing pollution damage by encouraging prompt cleanup.[62] In *In re Chinese Maritime Trust, Ltd.*,[63] the court declared that a federal agency's claim against a shipowner for wreck removal costs was not subject to limitation against the interest in the vessel and its freight since the owner could not contend that failure to remove was without his "knowledge or privity". The court did not address the question whether clean-up expenses were subject to limitation.[64] This is of little consolation to private parties who are still faced with the traditional burdens of proof against powerful oil consortiums and insurance clubs, with the possibility of a limited damage award.

Federal Legislation

Federal Water Pollution Control Act. The primary thrust of the federal government's involvement with the discharge of oil from vessels on the navigable waters of the United States has been an attempt to control oil pollution by prohibiting it or by providing for its abate-

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[58] Providence and N.Y. S.S. Co. v. Hill Mfg. Co., 109 U.S. 578, 592 (1883). *See* Paumier v. Barge B.T. 1793, 395 F.Supp. 1019, 1035 (E.D. Va. 1974).

[59] Coryell v. Phipps, 317 U.S. 406, 409, 63 S.Ct. 291, 87 L.Ed. 363 (1943); *In re* Allied Towing Corp., 409 F.Supp. 180, 188 (E.D. Va. 1976).

[60] *In re* Cook Transp. System, Inc., 431 F.Supp. 437, 443 (W.D. Tenn. 1976).

[61] 33 U.S.C. § 409 (1976) provides: "and whenever a vessel, raft, or other craft is wrecked and sunk in a navigable channel, accidentially or otherwise ... it shall be the duty of the owner of such sunken craft to commence the immediate removal of the same, and prosecute such removal diligently, and failure to do so shall be considered as an abandonment of such craft, and subject the same to removal by the United States as provided for in sections 411 to 416, 418 and 502 of this title."

[62] University of Texas Med. Branch at Galveston v. United States, *supra* note 54, at 443-450. *Also see* Wyandotte Transp. Co. v. United States, 389 U.S. 191, 205, 88 S.Ct. 379, 19 L.Ed.2d 407 (1967).

[63] 361 F.Supp. 1175, *aff'd.*, 478 F.2d 1357, *cert. denied,* 414 U.S. 1143, 94 S.Ct. 894, 39 L.Ed.2d 98 (1974).

[64] *Id.* at 478 F.2d 1359 n.1.

ment once it has occurred. Neither of these approaches compensates the private pollution claimant for the damage suffered in the interval between an actual oil discharge and its subsequent removal.

Reliance on common law, admiralty, and maritime law for sufficient private remedies with regard to vessel-point source oil discharges is necessary because of serious weaknesses in the present federal legislation which is designed to prevent and combat such pollution. Of course, the major federal oil pollution control statute is the Federal Water Pollution Control Act (FWPCA), as amended by the Federal Water Pollution Control Act Amendments of 1972.[65] The key sections of the FWPCA were enacted as amendments known as the Water Quality Improvement Act (WQIA) of 1970[66] which expressly repealed the Oil Pollution Act of 1924.[67] FWPCA only strengthened federal enforcement procedures, in particular the recovery of federal clean-up expenses. The Act prohibits discharges of oil or hazardous substances[68] which it defines as any spilling, leaking, pumping, emitting or emptying.[69] FWPCA's greatest contribution is its emphasis on immediate clean-up and prevention of widespread ecological damage following an oil discharge and its provisions allowing automatic recovery by the government or a private claimant of clean-up expenses from the polluter[70] or revolving fund.[71] The federal government need only offer proof of an oil discharge to establish a prima facie case of strict liability.

On December 27, 1977, FWPCA was amended by The Clean Water Act of 1977.[72] As a result, jurisdiction of the FWPCA was extended to cover both discharges in connection with activities under the Outer Continental Shelf Lands Act and the Deepwater Port Act of 1974, as

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[65] 33 U.S.C. § 1251 (Supp. II 1972) (originally enacted as Act of June 30, 1948, ch. 758, 62 Stat. 1155), *as amended* 33 U.S.C. §§ 1251-1376 (1976).

[66] Water Quality Improvement Act of 1970, Pub. L. No. 91-224, 84 Stat. 91 (*amending* 33 U.S.C. § 466 (1948)).

[67] Act of June 7, 1924, ch. 316, 43 Stat. 604, *as amended* by Pub. L. No. 89-753, 80 Stat. 1252-54 (1966). Repealed, Act of April 3, 1970, Pub. L. No. 91-224, Tit. I, 108, 84 Stat. 91 (1970).

[68] 33 U.S.C.A. § 1321(b)(2)(A) (1978). *Also see* Toxic Substances Control Act of 1976, § 2, 15 U.S.C. § 2602(2)(A) (1976), 43 Fed. Reg. 10474, 10481, 10489 (1978) and Manufacturing Chemists Assoc. v. Costle, 455 F.Supp., 968 (W.D. La., 1978).

[69] 33 U.S.C.A. § 1321(a)(2) (1978).

[70] *Id.* at 1321(f)(1) (1978).

[71] *Id.* at 1321 (k) (1978). *See* United States v. Marathon Pipe Line Co., No. 78-1453 (7th Cir., filed Dec. 22, 1978).

[72] 91 Stat. 1566, at 1593.

well as discharges which may affect natural resources under the exclusive management authority of the federal government pursuant to the Fishery Conservation and Management Act of 1976.[73] In short, FWPCA jurisdiction was extended 200 miles to include any costs or expenses incurred by the federal government or any state government in the restoration or replacement of damaged or destroyed natural resources. Originally, the FWPCA did not purport to deal with damages other than oil spill clean-up costs.[74] As of this date, there is still no federal act covering damage to private property. Private claimants are confronted with many obstacles in claiming and recovering damages under the FWPCA because the Act is essentially for the benefit of the federal government[75], the state government and interested third parties. An individual must first wait for the federal government to file an action. Then he must overcome any of the permitted *force majesture*[76] or third party defenses.[77] If the federal government can prove that the oil discharge resulted from "willful negligence or misconduct" with the privity or knowledge of the owner, the vessel owner or operator is subject to unlimited liability for all clean-up expenses, which includes compensation for all private property damage. In the alternative, if the federal government cannot establish "willful negligence or misconduct," the recovery of clean-up costs is limited to a specified amount.[78] The Clean Water Act Amendments reestablish minimum liability amounts and liability

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[73] 33 U.S.C.A. § 1321(f)(4) (Supp. 1978). *But see* L. Wood, *An Integrated International and Domestic Approach to Civil Liability for Vessel-Source Oil Pollution,* 7 J. OF MAR. L. & COMM. at 52-3 (1975), for possible international conflicts.

[74] Askew v. American Waterways Operators, Inc., *supra* note 32, at 331; *In re* Steuart Transp. Co., 435 F.Supp. 798, 806 (E.D. Va. 1977), *appeal docketed* No. 77-2426 (4th Cir. Nov. 16, 1977); Portland Pipe Line Corp. v. Envir. Imp. Comm'n, 307 A.2d 1, 44 *appeal dismissed,* 414 U.S. 1035, 94 S.Ct. 532, 38 L.Ed.2d 326 (1973).

[75] *In re* Steuart Transp. Co., *id.* at 806.

[76] 33 U.S.C.A. § 1321(f)(1) (1978).

[77] Burgess v. Tamaro, *supra* note 19. *But see* United States v. General Motors Corp., 403 F.Supp. 1151, 1163-5 (D.Conn. 1975). Although a third party could be the *sole* cause of the discharge, a civil penalty is still assessed against the innocent discharging party.

[78] "An amount not to exceed, in the case of an inland oil barge, $125 per gross ton of such barge, or $125,000, whichever is greater, and in the case of any other vessel, $150 per gross ton of such vessel or, for a vessel *carrying* oil or hazardous substances as cargo, $250,000, whichever is greater." 33 U.S.C.A. § 1321 (f)(1) (1978).

categories whereby, for the first time, different types of vessels have different liabilities, depending on the type and, in some situations, the amount[79] of prohibited substance discharged as well as the "toxicity"[80] of a hazardous substance. Determinations of inland barge liability depend on how the word "carrying" is interpreted. If it is interpreted literally, empty barges would have a higher liability ($150 per gross ton) than loaded barges ($125 per gross ton).[81]

Over and above the interpretation of toxicity and liability categories, the topic of third party liability should be of concern to both private claimants and shipowners. To cite an example, if a properly anchored tanker collides with an underway tugboat, and an oil discharge results, the tanker would definitely come within the third party exception.[82] However, the innocent tanker would only recover its clean-up expenses to the gross tonnage of the tugboat.[83] The revolving fund[84] should compensate the shipowner for the difference and thus motivate shipowners or private property owners to promptly commence clean-up procedures.

Through the implementation of regional contingency plans, the FWPCA provides for expedient clean-up of oil and hazardous substance discharges. The Act also provides for the replacement of damaged natural resources, but only to the extent of the costs incurred by the federal or state government. Thus, the FWPCA affords no further assistance to private claimants.

Rivers and Harbors Act of 1899 and The Coastal Zone Management Act of 1972. The Coastal Zone Management Act of 1972[85] and the

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[79] For accidents concerning non-removable hazardous substances, the amount discharged determines the civil penalty, 33 U.S.C.A. § 1321(b)(2)(B)(iii)(bb) (1978).

[80] The toxicity of the substance is determined by the harmful characteristics or acute toxicity of the substance and not the circumstances surrounding the discharge. *See* 43 Fed. Reg. 10474, 10491; and J. OF COM., June 7, 1978, at 19, col. 8.

[81] 43 Fed. Reg. 16772, 16773 (1978).

[82] 33 U.S.C.A. § 1321(g) (1978).

[83] A third party vessel which is the *sole* cause of an oil discharge will be liable with reference to *his* vessel rather than the vessel which actually spilled the oil, regardless of the latter vessel's tonnage. Tug Ocean Price, Inc. v. United States, 436 F.Supp. 907, 923, *rev'd in part,* Nos. 77-6190, 6195 (2nd Cir. filed Aug. 7, 1978). On appeal, the court ruled that the tug operator acted with "willful misconduct;" therefore, the third party liability amount was not discussed. The operator was not entitled to limit his liability. As a result, he was also held liable for all clean-up expenses.

[84] 33 U.S.C.A. § 1321(k) (1978).

[85] 16 U.S.C. § 1451-1464 (1976).

Rivers and Harbors Act of 1899[86] are concerned with prevention of pollution on the navigable waters of the United States.

The Rivers and Harbors Act has in recent years played a major role in environmental litigation although it was originally only intended to protect the navigability of the nation's waterways.[87] The Rivers and Harbors Act is best interpreted by a trilogy of Supreme Court decisions.[88]

For oil spill removal and the ensuing environmental consequences, the key provision is section 407, "Deposit of Refuse in Navigable Waters". Section 407, along with sections 411 and 413, is often referred to as the Refuse Act. However, a great deal of controversy has arisen concerning the available remedies of section 406[89] as compared with those of section 411[90]. Both sections provide the standard $2,500 penalty. Specifically, section 406 provides injunctive relief for the removal of section 403 "structural" obstructions in the conventional sense plus *any* filling of navigable waters which may diminish the

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[86] 33 U.S.C. § 401-419 (1976). *See* United States v. Stoeco Homes, Inc., 498 F.2d 597, 608 (3rd Cir. 1974) for a discussion of the legislative history.

[87] Reserve Mining Co. v. E.P.A., 514 F.2d 492, 530 (8th Cir. 1975); United States *ex rel.* Scott v. U.S. Steel, 356 F.Supp. 556, 559 (N.D. Ill. 1973). *See* Loveladies Property Owners Ass'n., Inc. v. Raab, 430 F.Supp. 276, 279n.4, *aff'd mem.* 547 F.2d 1162, *cert. denied,* 432 U.S. 906, 97 S.Ct. 2945, 53 L.Ed.2d 1077 (1977). Claimants must make an allegation that the discharger's activities affect their interest in navigable waters.

[88] Wyandotte Transp. Co. v. United States, *supra* note 62; United States v. Standard Oil Co., 384 U.S. 224, 86 S.Ct. 1427, 16 L.Ed.2d 492 (1966); United States v. Republic Steel Corp., 362 U.S. 482, 80 S.Ct. 884, 4 L.Ed.2d 903 (1960). *See* United States v. Pennsylvania Chemical Corp., 411 U.S. 655, 670-2, 93 S.Ct. 1804, 36 L.Ed.2d 567 (1973).

[89] Every person and every corporation that shall violate any of the provisions of sections 401, 403, and 404 of this title ... shall be deemed guilty of a misdeameanor, and on conviction thereof shall be punished by a fine not exceeding $2,500 nor less than $500, or by imprisonment ... in the discretion of the court. And further, the removal of any structures ... may be enforced by the *injunction* ... under the direction of the Attorney General of the United States [emphasis added]. 33 U.S.C. § 406 (1976).

[90] Every person and every corporation that shall violate ... the provisions of sections 407, 408, and 409 of this title shall be guilty of a misdemeanor and on conviction thereof shall be punished by (only) a fine not exceeding $2,500 nor less than $500, or imprisonment (in the case of a natural person) for not less than thirty days nor more than one year, or by both such fine and imprisonment, in the discretion of the court. 33 U.S.C. § 411 (1976).

navigable capacity of a waterway.[91] In addition, section 406 may require the restoration of an ecologically damaged area.[92] Both a private pollution claimant[93] and the federal government[94] can maintain a section 406 action. However, a section 411 action for a section 407 oil discharge specifically provides for a $2,500 penalty[95] but it does not provide injunctive relief.

In contradiction to a segment of an impressive dissent in *Republic Steel,*[96] the Court in *Wyandotte Transp. Co.*[97] permitted a section 411 civil action by the federal government to rectify the wrong to maritime commerce by a section 15 (33 USC 409) violation, an obstruction to navigation caused by a wreck. The Court was concerned that a denial of such a remedy to the United States would permit a wrongdoer to shift the responsibility for the consequences of his negligence on to the federal government. Subsequent lower court decisions have consistently held that the fines and penalties prescribed in section 411 are criminal in nature,[98] thereby precluding civil actions by private pollution claimants for restoration. This is primarily due

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[91] United States v. Republic Steel Corp., *supra* note 88, at 485; United States v. Kaiser Aetna, 408 F.Supp. 42, *aff'd,* Nos. 76-2400, 76-1968, slip. op. at 3367 (9th Cir. filed Aug. 11, 1978); United States v. Moretti, 331 F.Supp. 151, *vacated,* 478 F.2d 418 (5th Cir. 1973).

[92] United States v. Underwood, 344 F.Supp. 486 (M.D. Fla. 1972); United States v. Moretti, 423 F.Supp. 1197, 1202 (S.D. Fla. 1976).

[93] Sierra Club v. Morton, 400 F.Supp. 610, 623-4 (N.D. Cal. 1975).

[94] United States v. Underwood, *supra* note 92, at 493.

[95] United States v. Republic Steel Corp. *supra* note 88, at 491; United States v. Bigan, 274 F.2d 729, 732 (3rd Cir. 1960); *But see* United States v. Stoeco Homes, Inc., *supra* note 86, at 611, wherein the court recognized the availability of a section 407 injunction.

[96] Justice Harlan stated in his dissent in *Republic Steel, supra* note 88, at 507-8:

> One need go no further than the plain words of § 16 (411), which prescribes the penalties for violation of § 13 (407), to see that an injunction against violations of the latter section is not authorized. The provisions relating to violations not involving the erection of structures, such as discharge of refuse, unauthorized use of government navigational installations, and careless sinking of vessels, were gathered together in §§ 13 (407), 14 and 15 (409) and subjected to the penalties of § 16 (411). The last mentioned section is conspicuously lacking in any reference to injunctive relief.

[97] Wyandotte Transp. Co. v. United States, *supra* note 62, at 204.

[98] United States v. Commodore Club, Inc., 408 F.Supp. 311, 320 (E.D. Mich. 1976), indicates that a general intent to violate the Act must be established beyond a reasonable doubt as a prerequisite to criminal conviction under sections 403 and 406.

to section 413 which provides that the method of enforcement is vested *solely* in the U.S. Department of Justice.[99]

The second statute, The Coastal Zone Management Act, was enacted to foster the development by each state of those management practices and institutional reforms necessary for the management of its coastal zone.[100] This act does not modify federal regulations pursuant to FWPCA but rather incorporates the FWPCA into the state's coastal zone management program.[101] However, the Act does not provide for compensation of private property damage caused by an oil discharge.

Until Congress enacts legislation specifically providing relief to individual pollution claimants, the Federal Water Pollution Control Act will continue to constitute the sole national means other than common law remedies of containing oil discharges and restoring damaged natural resources. However, even this legislation does not have a comprehensive scheme of relief for private pollution claimants.

Relationship of Federal Water Pollution Control Act and the Limitation of Liability Act. Because the solution to the oil pollution problem, at least on the federal level, lies outside the framework of the Limitation of Liability Act, the United States enacted the FWPCA. The only recovery provided by the FWPCA is on behalf of the federal government or its subrogee for actual clean-up expenses incurred or on a state government claim for restoration or replacement of natural resources damaged or destroyed as a result of an oil discharge.[102] The FWPCA does not provide recovery by a private claimant for property damage, except in the case of damage to a natural resource such as clam or oyster beds, pursuant to a state action.

The two Acts conflict with each other with respect to the burden of proof and the specified ceiling amounts. In FWPCA actions, the federal government has the burden of proof whereas the LLA places the

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[99] Jacklovich v. Interlake, Inc., 458 F.2d 923 (7th Cir. 1972); Township of Long Beach v. City of New York, 445 F.Supp. 1203, 1211 (D.N.J. 1978); Parsel v. Shell Oil Co., 421 F.Supp. 1275, 1280 (D. Conn. 1976); Mitchell v. Tenneco Chemicals, Inc., 331 F.Supp. 1031 (D.S.C. 1971); Nat'l Sea Clammers Ass'n v. New York, *supra* note 33.

[100] M. BARAM, ENVIRONMENTAL LAW AND THE SITING OF FACILITIES at 121 (1976). *See* 43 Fed. Reg. 10510 (1978) (policies and procedures) and 43 Fed. Reg. 8378 (1978) (State Coastal Management Programs).

[101] 16 U.S.C. § 1456(f) (1976).

[102] 33 U.S.C.A. § 1321(g) & (f)(4) (1978). *See In re* Steuart Transp. Co., *supra* note 74, at 806.

burden of proof on the shipowner or operator after the claimant has properly established the vessel's fault. According to the FWPCA, the shipowner or operator is exonerated if he proves that the cause of the discharge was a listed exception.[103]

Of course, limitation is unnecessary if the shipowner or operator is absolved of fault. Nevertheless, liability is unlimited under both Acts when the federal government demonstrates the discharge was the result of willful misconduct or negligence within the privity or knowledge of the owner.[104] If the government fails to carry this burden, the shipowner or operator may limit his liability.

The ceiling amounts of the Limitation of Liability Fund and the FWPCA pollution fund may be different. If the federal government proves willful misconduct on the part of the shipowner or operator, liability is unlimited in a FWPCA action. Should the shipowner or operator fail to establish one of the specified *force majesture* or third party defenses and the federal government does not prove willful misconduct, the operator is liable for costs in an amount not to exceed $125 per gross ton for inland barges or $125,000, whichever is greater, and all other vessels, $150 per gross ton, or for vessels carrying oil or hazardous substances as cargo, $250,000 whichever is greater.[105] On the other hand, according to the Limitation Act, liability is unlimited if the vessel owner is chargeable with privity or knowledge. In an attempt to deal with these two statutes, the court in *Tug Ocean Prince Inc.*[106] stated:

> The statute is not a model of clarity. In the absence of clarifying case law or legislative history on point, one can only speculate as to the meaning of the "not with standing any other provisions of law" clause. With respect to federal clean-up costs it is uncertain whether Congress intended the FWPCA to supersede the Limitation of Liability Act or whether it intended both Acts to be read together so as to provide the greatest relief to the United States. Because the two statutes serve different purposes and differ substantially on crucial issues in all probability the United States is limited to recover under the Federal Water Pollution Control Act, which does not deny limitation for clean-up costs unless the discharge is the

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[103] Except where the owner or operator can prove that a discharge was caused solely by an act of God, an act of war, negligence on the part of the United States Government, or an act or omission of a third party . . . or any combination of the foregoing clauses, such owner . . . shall be liable to the United States Government for the amount of such (removal) costs. 33 U.S.C.A. § 1321(f)(1) (1978).

[104] *See In re* Tug Ocean Prince, Inc. 436, F.Supp. 907, *rev'd in part,* Nos. 77-6190, 77-6195, slip op. at 4237 (2nd Cir. filed Aug. 7, 1978).

[105] 33 U.S.C.A. § 1321(f)(1) (1978).

[106] *In re* Tug Ocean Prince, Inc., *supra* note 104, at 4237.

> result of willful negligence or willful misconduct within the privity and knowledge of the owner.

The FWPCA clearly allows the federal government to recover its clean-up expenses, but it does not provide such relief for the private claimant. Although the FWPCA does not specifically provide for private actions, it does not affect claims under general maritime law. Accordingly, the phrase "any provision of law," as found in the non-preemption subsection of the FWPCA,[107] would include the general maritime law. Claims for property loss by private pollution claimants would be recoverable under a general maritime action. If the shipowner or operator is not entitled to exoneration but is entitled to limitation, he will be liable up to the FWPCA ceilings for clean-up and restoration of natural resources costs. However, the shipowner will be liable up to the amount in the limitation fund in a general maritime action for property damage.

Finally, there is an obvious discrepancy if the maritime venture is a total loss (*i.e.*, the *Argo Merchant* and *Torrey Canyon* disasters.) In such a case, the limitation fund will be worthless and the private property owner will be precluded from an equitable recovery for property damage, but not for clean-up or restoration expenses.

Another area of major conflict is the applicable liability limit, the pollution of the limitation fund, when claims pursuant to both federal and state clean-up statutes are involved. Although the Supreme Court in *Askew* did not address this issue[108] it determined that the WQIA[109] would not preempt any state requirement or liability. However, the Court specifically refused to decide whether such liability imposed by a state would be subject to the limits of the WQIA or the Federal Limitation Act.[110]

Two recent district court decisions have disagreed on this issue. In *In re Steuart Transp. Co.*,[111] the court held that the more specific

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[107] Nothing in this section shall affect or modify in any way the obligation of any owner or operator of any vessel ... under any provision of law for damages to any publicly-owned or *privately-owned* property resulting from a discharge of any oil or from the removal of any such oil [emphasis added]. 33 U.S.C.A. § 1321(0)(1) (1978).

[108] "Whether the amount of costs (Florida) could recover from a wrongdoer is limited to those specified in the Federal Act and whether in turn this new Federal Act (WQIA) removes the pre-existing limitations of liability in the Limited Liability Act are questions we need not reach here." Askew, *supra* note 32, at 332.

[109] 33 U.S.C. § 1321(2) (Supp. II 1972).

[110] *See* K.H. Volk & N.H. Cobbs, *Limitation of Liability,* 51 TUL. L. REV. 953, 966 (1971).

[111] *See* note 74 *supra. But see* United States v. M/V Big Sam, *supra* note 9.

FWPCA supercedes the Federal Limitation Act and it permitted the State of Virginia to recover its clean-up costs in full, even though the combined federal and state claims exceeded the limits established in FWPCA.

However, in *In re Oswego Barge Corp.*,[112] the court held that a New York oil discharge strict liability statute conflicted with the "without privity and knowledge" clause of the Limitation of Liability Act. The court resolved this in favor of the Supremacy Clause by denying New York State's Motion for property damage and clean-up costs.[113] Accordingly, the court determined that the limitation provisions of the Limitation Act were applicable with respect to New York State's claims.

The *Steuart* decision conflicts with *Oswego,* which cited *In re Harbor Towing Corporation,*[114] as authority. Unfortunately, *Harbor Towing,* in addition to being a pre-*Askew* decision never considered the effect of the FWPCA on the Limitation of Liability Act. On the other hand, *Steuart* relied heavily on the only other reported decision on this issue, *Portland Pipe Line Company v. Environmental Improvement Commission.*[115] After a thorough analysis of *Askew* and the WQIA,[116] the Supreme Judicial Court of Maine determined that the $8 million limitation then applicable to discharges from on-shore and off-shore facilities under the WQIA, did not apply to state incurred clean-up costs and therefore the states were free to follow the advice of Justice Douglas in *Askew.*[117]

The *Steuart* court's analysis of the FWPCA, including the reference to *Portland Pipe Line,* suggests two lines of inquiry. First the FWPCA as amended by The Clean Water Act of 1977, allows joint action of federal and state government in the restoration or replacement of damaged natural resources subject to limitation.[118] Therefore, if the

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112 439 F.Supp. 312 (N.D.N.Y. 1977).

113 Congress did not intend that claims under (state) statutes of strict liability be excepted from limitation of liability. *In re* Oswego Barge Corp., *supra* note 112, at 318.

114 335 F.Supp. 1150 (D. Md. 1971).

115 307 A.2d 1, 44 (Me. 1973), *appeal dismissed,* 414 U.S. 1035, 94 S.Ct. 532, 38 L.Ed.2d 326 (1973).

116 33 U.S.C. § 1321 (2) (Supp. II 1972).

117 Justice Douglas said, "It is sufficient for this day to hold that there is room for state action in cleaning up the waters of a state and recouping, at least within federal limits, so far as vessels are concerned, her costs." Askew, *supra* note 32, at 332.

118 33 U.S.C.A. § 1321(f)(4) (1978).

Steuart decision stands[119] an anomally will be created. A vessel owner or operator will be able to limit his liability for state-incurred expenses of natural resources replacement, but the shipowner will not be able to limit his liability for state incurred oil discharge clean-up costs.

Second, although *Portland Pipe Line* was decided after the enactment of the 1972 Amendments to the FWPCA, it was apparently briefed before their enactment[120] as the federal act discussed by the court was the 1970 WQIA.[121] The issue in *Portland Pipe Line* was a recovery by a state for its clean-up expenses pursuant to a state strict liability statute. At that time, the WQIA did not provide for reimbursement of state incurred clean-up or restoration expenses as the FWPCA does now pursuant to the $35 million revolving fund.[122]

There has been much confusion about the alleged non-complementary nature of a Limitation Act fund and a FWPCA action for recovery of clean-up expenses and property damage, such as restoration or replacement of natural resources. At first glance, a worthless limitation fund would seem to preclude an adequate clean-up and property damage recovery. This is not the case. First, the FWPCA is primarily concerned with recovery of clean-up costs and it is not subject to the results of a limitation proceeding. Although a vessel owner or operator may limit his liability in a general maritime action for property damage, he may not do so in a clean-up recovery action. All vessels must acquire a "Certificate of Financial Responsibility" from the Federal Maritime Commission[123] as proof that the vessel will be able to meet any pollution contingency. This is particularly necessary in the event of a marine catastrophe where the vessel and cargo are worthless. Consequently, an action may be brought against the insurer pursuant to the standard liability scheme, for all clean-up costs and restoration expenses incurred by the federal government.[124]

Second, the revolving fund maintained by the federal government

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[119] *See* note 74 *supra.*

[120] Portland Pipe Line, *supra* note 115, was decided on June 4, 1973 and the Amendments to the FWPCA were enacted on October 18, 1972. Federal Water Pollution Control Act Amendments of 1972, 33 U.S.C. §§ 1251-1326 V, *reprinted in* (1972) U.S. CODE CONG. & AD. NEWS 3668.

[121] "Congress has, in the Water Quality Improvement Act, exercised Police Power but it has also specifically declared that it did not intend to preempt the field." Portland Pipe Line, *supra* note 115, at 40.

[122] 33 U.S.C.A. § 1321(k) (1978).

[123] *Id.* at § 1321(p)(1).

[124] *Id.* at § 1321(p)(3).

will finance all federal, state or private removal operations whenever the National Contingency Plan is implemented. This includes all cost incurred by the federal government for the removal of a "maritime disaster" which threatens any public or *private* shoreline.[125] However, neither the funds made available pursuant to the evidence of financial responsibility nor the revolving fund will compensate the private claimant for property damage.

The Oil Pollution and Compensation Act of 1977 and the Oil Spill Liability Fund and Compensation Act of 1978. On January 4, 1977, the Comprehensive Oil Pollution and Compensation Act of 1977[126] was referred jointly to the House Committee on Merchant Marine and Fisheries and Public Works and Transportation. The primary bill in the House, H.R. 6803, parallels much of the Carter Administration proposal.[127] It was passed by the House on September 12, 1977 and on the following day, the bill was received by the Senate where it has remained.

Until quite recently, the primary bill in the Senate was the Oil Pollution and Compensation Act of 1977.[128] This bill is no longer being seriously considered in light of the fact that on April 12, 1978 Senator Muskie's Committee on Environment and Public Works introduced a new liability scheme, the Oil Spill Liability Fund and Compensation Act of 1978.[129] In particular, the new Senate bill (S. 2900) is quite explicit. Although the new Senate bill and the House bills are fundamentally the same, the Senate bill differs from the House version by: (1) including liability for costs and damages of hazardous substances spills as well as oil spills; and (2) prohibiting federal preemption of state liability and compensation programs.

In particular, S.2900 is quite explicit in its explanation of the fund's implementation. Nine separate purposes are listed. S.2083, the original Senate bill, is not as clear as S.2900 especially with regard to state remedies.

Section 9 of S.2083 provides for an intricate claims procedure, complete with time tables, advertisement of the point-source and a three

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[125] *Id.* at § 1321(d).

[126] H.R. 47, 95th Cong., 1st Sess. (1977). *Also see* H.R. 776, 95th Cong., 1st Sess. (1977).

[127] S. 1187, 95th Cong., 1st Sess. (1977).

[128] S. 2083, 95th Cong., 1st Sess. (1977). This bill was reported out of the Com. on Commerce, Science and Transportation on September 9, 1977.

[129] S. 2900, 95th Cong., 2nd Sess. (1978). *See* 124 CONG. REC. No. 1 (1978).

member review panel to evaluate all property and economic loss claims. S.2900 does not provide for such a procedure. Furthermore, pursuant to section 12 (Consolidated Actions) of S.2083, a United States Attorney General must bring a class action suit[130] on behalf of a large group of claimants. He has 90 days after the discharge to maintain this action, after which time any member of the group may bring an individual action or one on behalf of the group. This "cooling off" period may have been a well intended provision to assist individual claimants in presenting their claims expeditiously. Unfortunately, it may be used to procure premature settlements from commercial interests such as fishermen and clammers who could not be expected to survive a 90 day inactive period as a result of a catastrophic oil discharge.

On September 16, 1978, H.R. 6803 cleared the last mark-up session and on October 5, 1978 it passed a House vote. The House bill originally had passed on September 23, 1977.[131] The Senate on October 5, 1978 received the House bill and approved S.2900 which included the hazardous substance provisions. The Senate never appointed conferees, and on October 15, 1978 when the second session of the ninety-fifth Congress concluded, the "superfund" legislation had died in conference.

Both S.2900 and H.R. 6803 serve the same purpose: the establishment of a comprehensive national liability and compensation scheme. By incorporating the discharge removal and restoration of damaged natural resource provisions of the FWPCA, but specifically providing private remedies for property damage and economic loss, either bill will correct the glaring fault of present federal laws. If either bill becomes law, the private pollution claimant will have a statutory remedy.

In addition to providing for the recovery of all removal costs incurred by the federal government, state government or "any person" pursuant to section 311(b) (3) section 3 of this bill, economic loss is:

(1) any injury to, destruction of, or loss of any real or personal property;

(2) any loss of use of real or personal property;

(3) any injury to, destruction of, or loss of natural resources;

(4) any loss of use of any natural resources, without regard to the ownership or management of such resources;

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[130] FED. R. CIV. P. 23(a).

[131] 9 E.R.C. 1129 (1978).

(5) any loss of income or profits[132] resulting from injury to or destruction of real or personal property or natural resources, without regard to the ownership of such property or resources; and

(6) any loss of tax or rental by the Federal Government or any state government.

Therefore, S.2900 is in accordance with similar FWPCA provisions concerning distruction or loss of natural resources. Only the federal or state government may recover for destruction of natural resources. An individual claimant is limited to recovery for the loss of use of any natural resource, such as reduction of income or impairment of earning capacity.

In H.R. 6803, the provisions for recovery of property damage are essentially the same as S.2900, except H.R. 6803 has two particular standing requirements not contained in the Senate bill. Due to its rather narrow definition of property, only an owner whose property is littoral, riparian, or marine in nature may maintain an action for recovery for the injury to, or destruction of, that property.[133] The House bill specifically excludes compensation for losses flowing from the injury to non-riparian or non-littoral property. This is in agreement with established nuisance law.[134] In addition, H.R. 6803 provides recovery for loss of earnings from the economic activity which utilizes the injured property or natural resource.[135] Consequently, an action for loss of earnings may be maintained by a non-property owner.

The major provision of both S.2900 and H.R. 6803 is the creation of the Comprehensive Oil Spill Liability Fund, by transferring the subsection K revolving fund of the FWPCA to the proposed Act. This fund or "superfund" as it is sometimes referred to, is the heart of the liability scheme.[136] Unlike the $35 million revolving fund of the FWPCA which is maintained to finance the removal of discharges and the restoration or replacement of damaged natural resources, the fund will compensate any claimant for all property and economic damage.

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[132] In accordance with a great deal of contract and tort law, loss of profits probably means loss of *net* profits which is gross profits minus the costs of doing business, *i.e.*, labor, depreciation, maintenance and repair.

[133] H.R. 6803 § 101(z).

[134] *See In re* New Jersey Barging Corp., *supra* note 25, at 937.

[135] H.R. 6803, *supra* note 133, at 103(a)(6).

[136] In addition to recovery of all fees collected pursuant to section 311(b)(2)(B) of the FWPCA, the $200,000,000 fund is maintained by a "not to exceed 3 cents per barrel" levy on all oil received into the United States.

In addition to incorporating the various clean-up provisions of the FWCPA, the S.2900 Fund carries out five significant services: (1) payment of any removal or damage claim which is in excess of the specified amount[137] for which the owner or operator of the point-source is liable; (2) payment of any claim for costs of removal or damages whether the point-source is known or unknown[138] (3) payment of all removal expenses incurred by anyone carrying out the National Contingency Plan pursuant to section 311(c) of the FWPCA; (4) the costs of assessing both short-term and long-term injury or loss of any natural resource and (5) in addition to supporting any federal or state government efforts in the restoration or replacement of any natural resources, the fund will reimburse any state for the payment of any removal or restoration claims which the state has paid with funds under its control.

Although H.R. 6803 does not detail the specific functions of the fund, the House bill would parallel all the Senate proposals, especially the one concerning a discharge from an unknown point-source. However, the last provision of S.2900 regarding the state pre-emption is in direct conflict with H.R. 6803. The Senate's failure to enact H.R. 6803 may be attributable to this distinction.

The House and Senate bills differ in two more significant respects. H.R. 6803 clearly preempts all other compensation funds, both federal[139] and state, for the claims that are specifically provided for in

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[137] "An amount not to exceed $300 per gross ton or $500,000, whichever is greater, of any vessel carrying oil or hazardous substances in bulk or in commercial quantities as cargo." S. 2900, *supra* note 129, at § 3(c)(1)(A).

[138] In granting an injunction against the Secretary of Interior from receiving bids for sale of Outer Continental Shelf tracts, the court in Massachusetts v. Andrus, No. 78-184 (D. Mass. filed Jan. 28, 1978), *rev'd in part,* Nos. 78-1036, 78-1037 (1st Cir. filed Feb. 20, 1979) considered the effect of this proposed bill "The effect of the... establishment of compensations funds would in effect compel the lessees of these tracts to pay for damages *even when their liability could not be established*" [emphasis added].

[139] Outer Continental Shelf Lands Act Amendments of 1978, 43 U.S.C.A. § 1812 (1978); Trans-Alaska Pipeline Authorization Act, 43 U.S.C.A. § 1653(c)(1) (1978); and Deepwater Port Act of 1974, 33 U.S.C. § 1517(f)(1) (1976).

this bill.[140] Whereas S.2900 permits the states to impose additional liability.[141]

On April 12, 1978 when S.2900 was first presented, it had a detailed description of state programs, e.g., purchase and repositing of clean-up and removal equipment; training of personnel in clean-up and removal techniques; payment of damages or losses resulting from such discharges in the same way as such claims would be paid under state law as it existed immediately prior to enactment of this bill all of which may be reimbursed from the fund. Subsequent to the June 10, 1978 markup session and the July 6, 1978 "Staff Working Paper"[142] publication, all of the above provisions for reimbursement of state expenses, including state administration costs for such programs were eliminated.

However, the initial subsection providing for state action, Section 7, remained intact. At this time, it is unclear whether or not the Committee on Environment and Public Works is redrafting its position on state preemption in light of the "uniform national scheme" approach.[143] Nevertheless, offshore and inland carriers will be observing all preemption provisions carefully.

Another major impasse causing the Senate's delay in acting upon H.R. 6803 has been the exclusion of hazardous substances. In light of the Clean Water Act Amendments to the FWPCA, the Senate bill clearly provides for accountability for hazardous substances, in addition to oil discharges. The House bill does not provide for hazardous substance removal. Due to the somewhat unclear FWPCA provisions concerning hazardous substance removal, identification of both removable and non-removable substances, and civil penalties based on toxicity, degradability, and dispersal characteristics, the House did not include hazardous substances in H.R. 6803. However, the House did intend to subsequently amend the Act and provide for hazardous substance removal and compensation, once the Senate had enacted the basic oil spill liability and compensation scheme.

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[140] H.R. 6803, *supra* note 133, at 110(a)(c) states in part, "Any damages listed in section 103(a) (removal expenses, property damage and economic loss) can be recovered *only* in Federal court, under this Act. Any other types of damages may be sought through means outside this Act, including through State courts."

[141] S. 2900, *supra* note 129, at 7 provides in part, "Nothing in this Act shall be construed or interpreted as preempting any state from imposing any additional liability or requirements with respect to the discharge of oil or hazardous substances within such state."

[142] This paper is available from the Senate Com. on Environment and Public Works.

[143] *See* 7 E.L.R. 1695 and 7 E.L.R. 1775 (1977). *But see* 8 E.L.R. 325 (1978).

As explained, S.2900 includes spills of hazardous substances in addition to oil discharges and H.R. 6803 clearly does not. However, neither bill imposes a fee for hazardous substance transfer.[144] Consequently, the fund would be available to all carriers of hazardous substances, at the expense of oil carriers who ship petroleum products by sea.

On June 8, 1978, the United States District Court for the Western District of Louisiana granted a preliminary injunction enjoining the Environmental Protection Agency (EPA) from enforcing its oil and hazardous material regulations.[145] Subsequently, on the plaintiffs motion for summary judgment, the court found that the "one pound" method of determining harmful quantities does not consider "times, locations, circumstances and conditions."[146] As a result the court determined that the EPA's final regulations of hazardous substances are arbitrary and capricious. Unfortunately, the hazardous substance provisions of S.2900 are directly tied to EPA's hazardous substance regulations. At this time, it is not known whether the committee on Environment and Public Works will delete the hazardous substance provisions in accordance with the House approach or wait until the issue related to harmful quantities is resolved.

In the final analysis, both bills would offer a much needed comprehensive national law governing oil pollution liability and compensation. A uniform scheme would be beneficial for the carriers, by enabling them to accurately allocate their resources on a national basis instead of the "patchwork" state by state approach. The insurance expenses required to satisfy each state's compensation and liability scheme and financial responsibility provisions would be burdensome. Nevertheless, the uniform regulation of oil spill compensation is the most effective means of combating oil pollution. The enactment of a comprehensive oil spill and liability act would fill the unfortunate void of the Federal Water Pollution Control Act and reduce the unequal bargaining positions of the petroleum industry and individual property owners.

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144 Sen. E. Muskie, Chairperson of the Committee on Environmental and Public Works, stated, at 124 CONG. REC. No. 51 (Apr. 12, 1978), that: "More than half of the designated hazardous substances are petroleum-based products, thereby making the oil fee-based fund a legitimate source for liability coverage for hazardous materials. Further, the penalties assessed for spills of non-removable hazardous substances will be deposited in the fund and more than cover any costs associated with hazardous materials spills."

145 Manufacturing Chemists Ass'n v. Costle, 451 F.Supp. 902 (W.D.La. 1978).

146 Manufacturing Chemists Ass'n v. Costle, 455 F.Supp. 968, 976 (W.D.La. 1978).

Conclusions

One may have the impression that the shipping industry, especially the flag of convenience sector, is primarily responsible for oil pollution. This is untrue. Including accidents but not terminal operations, dry docking and bilge pumping, shipping represents only 20% of the total point-source oil pollution. Land-based sources, on the other hand, account for over 60%. This is primarily due to river and urban run-off and atmospheric fallout in the form of rain from clouds formed over land, resulting in automobile and industrial pollution entering the meterological cycle. Consequently, the maritime industry has taken an unfair share of the blame as shown below.

Marine pollution by petroleum hydrocarbons 1974 (million metric tons)[147]

Natural seeps	0.6
Offshore industry	0.08
Tankers load on top	0.31
Tankers not using load on top	0.77
Dry docking	0.25
Terminals	0.003
Bilges and bunkering	0.5
Tanker accidents	0.2
Non tankers accidental	0.1
Coastal refineries	0.2
Atmospheric fall out	0.6
Coastal municipal waste	0.3
Coastal non refinery Industrial wastes	0.3
Urban run-off	0.3
River run-off	1.6
Total	6.113

As explained, operational, not catastrophic, incidents are primarily responsible for vessel point-source pollution. Pursuant to the pending IMCO Convention of 1978, the international community adopted operation and construction provisions to reduce operational discharges. The United States Congress enacted the Convention into law as the Port and Tanker Safety Act of 1978 (PTSA).[148] As a result, tanker

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147 M. Gunnerson, *Hydrocarbons in the Ocean,* SEA TRADES at 35, U.S. Dep't of Commerce, NOAH, Apr. 1976.

148 Act of Oct. 17, 1978, Pub L. No. 95-474, § 2, 92 Stat. 471 (to be codified in 33 U.S.C. § 1221 (1978).

construction, navigation and operations will be closely monitored by federal agencies to ensure protection of the marine environment. Hopefully, operational discharges will soon cease and catastrophic discharges will terminate as a result of offshore surveillance and traffic schemes.

The "Superfund" scheme with regard to elimination of vessel point source oil discharges is only an *ad hoc* approach. In theory, this legislation would provide a liability scheme to a private pollution claimant who could neither identify the point-source nor sufficiently prove his damages. Undoubtedly, the cost of maintaining the proposed Fund will be passed onto the consumer and the additional regulations will burden an already heavily regulated industry. Hopefully, the success of the PTSA will eliminate the need for a "Superfund" or at the very least, with increased offshore surveillance and further development of oil identification techniques, private pollution claimants could identify the point-source in order to sustain a common law action. In any event, with the PTSA, Congress has finally enacted uniform preventive measures (instead of remedial ones) for the benefit of private pollution claimants, the oil transportation industry and the marine environment.

Patent Cooperation Treaty: A Critique

S. Delvalle Goldsmith*

The article on the Patent Cooperation Treaty (PCT) in the "Look Ahead" section of the January 1978 issue of *Nation's Business* brings this important Treaty to the attention of the American businessman. However, further mention and explanation of some of the aspects of this Treaty may be helpful.

The PCT is probably not "the most important treaty in patents in nearly 100 years". It may be "the second most important treaty in nearly 100 years", the first being the European Patent Convention (EPC) which has become effective June 1, 1978. The EPC was first thought of as a "private club" for Europeans with no "accessibility" for United States or other non-Europeans so that, beginning on June 1st, U.S. inventors and companies have been able to file a single European patent application *in English* and, by a single prosecution *also in English,* obtain patent protection in most of the important European countries. (How the change from non-accessibility to accessibility came about is a story in itself — strangely enough involving maneuvers at the Diplomatic Congress at which the PCT was finalized.)

Incidentally, the reason for the caveat "in nearly 100 years" is because the most important patent treaty was the Paris Convention signed in 1883 which provided for national treatment, priority periods and other important aspects of international patent and trademark protection.

The PCT (contrary to the EPC) does not produce any patents by one application and one prosecution. In fact, if protection in three PCT

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countries, is desired, four applications must be filed: first a PCT international application and later three individual national applications with three individual national prosecutions. The PCT, it is true, provides additional time before the national applications must be filed and national fees paid, national patent agents employed, and translations made. This may be a mixed blessing. On the one hand there is the additional time for the U.S. inventor to make up his mind before incurring the expense of the individual foreign national filings and prosecutions. On the other hand, there is the same additional time in which a foreign inventor can file a PCT application in the United States and antedate previously filed applications by U.S. inventors.

The article refers to the PCT as providing a 20-month period from an initially filed PCT international application. However, the PCT international application need not (and probably would not) be the initially filed application. The inventor would probably start with a national application in his home country and file the PCT international application within 12 months, claiming Paris Convention priority from his original application. He would have 20 months from his original priority date to complete his PCT applications. This would probably be about 8 months from the PCT international application filed about a year later.

The basic advantage of the PCT, would seem to be the extra 8 months allowed before incurring the expense of individual foreign filing. (Without the PCT, the term for filing with priority from the original national application would be 12 not 20, months.) If the normal 12-month period elapses before a U.S. applicant decides to file foreign applications, or if he cannot decide even then, the PCT certainly presents an advantage over the EPC in that a PCT international application could be filed in the United States Patent and Trademark Office (USPTO) and the U.S. applicant need not rush to file foreign applications or to make a decision. The price to be paid for this advantage is indicated below.

A PCT international application can be filed in the USPTO as indicated above. Also, a PCT international search will be made by the USPTO. However, from there on, WIPO, an international organization situated in Geneva, becomes involved in almost every step with resultant "paper-shuffling," extra expense, and the burden on the applicant to ensure that all the prescribed steps are accomplished within the allowed terms. Thus, the USPTO must send a copy of the PCT international application to Geneva within 13 months of the original filing date. The applicant must watch for a notice from WIPO indicating WIPO's receipt of the copy. If no notice is received, the

applicant himself must obtain another copy from the USPTO and send it to WIPO to arrive not later than 14 months from the original filing date. If any one of these terms is not met, the international application (together with the opportunity to file later in the desired countries) lapses. Similar complications arise in getting the international application to the desired countries within the 20-month term, amending after receipt of the PCT search report, and in many other steps of the PCT procedure.

A second advantage of PCT is that a single international search is made on the basis of the international application, and the national Patent Offices can use this (to the extent they desire) as a basis for their national prosecution. This is more of an advantage for the "developing countries" which have poor or no searching facilities than it is for the United States which is able to make a careful search. In fact, the USPTO has announced that it will make an "international-type" search for *all* applications (so far without payment of a search fee for national applications corresponding to the $300.00 PCT search fee).

Fees and costs must necessarily be greater for the PCT than for the EPC as they involve maintenance of the "organization" in Geneva and, in addition, must compensate the national offices for their extra work in communicating with Geneva. Thus there is the "basic fee" for filing an international application, a "designation fee" for each country designated for ultimate filing, the aforementioned "search fee," and a "transmittal fee." All this is *in addition* to the usual national fees which must be paid in each designated country at the end of the 20-month period (with the possible exception that, in a country which has a search fee, this may be reduced if the respective Patent Office decides that it can utilize all or part of the previously made PCT search).

The PCT provides a uniform format for the international application and, presumably, for ultimate filing in non-translation countries based on the international application. Of course, this advantage, as far as the format of the specification is concerned, disappears for countries requiring translation and consequent retyping. Incidentally, we will have to get used to the PCT format which differs from the one to which we have become accustomed with respect to paper size, margins, page numbering and typing. (The paper size for PCT international applications must be 29.7 x 21 cm. — about 1¾ x 8¼ in. — and the typing must be 1½ spaced.) It should be noted that the USPTO will accept national applications in PCT format.

Thus, PCT involves the "good news and the bad" as does most everything else in this imperfect world. However, it is definitely important

and *Nation's Business* is to be complimented in bringing this rather technical treaty to the attention of the American businessman.

Announcement from the American Bar Association National Institute

Traditional concepts of intellectual property, licensing and technology transfer are being challenged and re-examined internationally in light of the pace of technical change and the burgeoning of conflicting ideologies. In the Paris Covention, and through the framing of international codes of conduct, the differing approaches to these issues by the industrialized and developing nations are being debated. Important changes have occurred in the governmental policies of the Soviet Union, China, and Mexico toward licensing and intellectual property rights. Significant developments have taken place in techniques for resolving disputes in agreements with Eastern Bloc countries and Japan. There have been important shifts in the antitrust policies of the United States and the European Economic Community concerning licensing. New problems and techniques have been encountered by the music, publishing and film industries in licensing copyrights abroad.

These and related topics will be the subject of a two-day American Bar Association National Institute to be held at The Hyatt Regency Hotel in Washington, D.C., on April 5 and 6, 1979.

Participants in this National Institute will receive written study materials on the subjects to be discussed and will have an opportunity to address questions to the faculty. The tuition fee covers attendance at the National Institute, the study materials, two luncheons and an informal reception on April 5.

For further information, contact the ABA National Institutes, American Bar Association, 1155 East 60 Street, Chicago, Illinois 60637 (telephone 312-947-3600).

ABANDONMENT UNDER § 102(c) AND FORFEITURE*

PAUL T. MEIKLEJOHN**

A person shall be entitled to a patent unless... he has abandoned the invention....[1]

The statutory defense of abandonment of an invention and the judicially-created doctrine of forfeiture of the right to a patent were construed recently in *Moore v. United States*.[2] Briefly, the trial judge concluded that more than a 13-year delay between Moore's actual reduction to practice of his invention and the filing of his patent application did not constitute an abandonment of the invention nor did it amount to a forfeiture of his patent rights. The court found that the defendant had not carried its burden of proving that Moore engaged

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[1] 35 U.S.C. § 102(c).

[2] 194 U.S.P.Q. 423 (Ct.Cl. 1977).

in acts which were proscribed by 35 U.S.C. § 102[3] (such as public use or sale) or that substantially the same invention was created by another working independently during the thirteen-year period of delay. Furthermore, the court believed that the public could still benefit from the patent disclosure, thus justifying an allowance of the patent.

Finally, the court held that Moore's filing of a series of continuation-in-part (CIP) applications to overcome objections raised by the United States Patent and Trademark Office (USPTO) and to increase patent coverage was not an abuse of USPTO practices and did not constitute a forfeiture of Moore's right to a patent.

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[3] 35 U.S.C. § 102 reads as follows:

> *Conditions for patentability; novelty and loss of right to patent.* A person shall be entitled to a patent unless —
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> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
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> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
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> (c) he has abandoned the invention, or
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> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
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> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or
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> (f) he did not himself invent the subject matter sought to be patented, or
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> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Moore v. United States

David Pelton Moore, a patent attorney,[4] sued the United States Government in the Court of Claims for infringing the claims of one of his patents.[5] To appreciate the legal issues involved in this case, some background information is necessary.

The patent in suit involved solid explosive compositions and solid propellant compositions.[6] The trial judge found that Mr. Moore conceived the idea of using rubber as a binder in an explosive composition as early as 1939.[7] The government stipulated that he actually reduced his explosive to practice not later than January 1942.[8]

Moore attempted to interest the Navy in his composition (which he called "Moorite") just after the outbreak of World War II, but the Navy required a disclosure of the formula as a prerequisite to testing. Moore did not supply the Navy with the requested information.

In 1948, Moore and Moldex Rubber & Plastics entered into a contract to develop Moore's patent whereby he was to receive a percentage of the returns. Moore and Moldex attempted to interest the Navy in Moorite as a propellant. That same year, twenty pounds of propellant were given to the Navy, without charge, for testing. The composition was tested at Picatinny Arsenal with Army and Navy personnel participating in the tests. The tests did not result in any orders or sales.

The court found that Moore never lost interest in his invention. On the contrary, he attempted, albeit unsuccessfully, to interest several corporations in producing his rubber explosives and propellants during the period from 1950 to 1955. In 1955, Moore interested John L. Lewis and the United Mine Workers in producing Moorite. As a result, Moore filed his first patent application on July 27, 1955. This application was placed under a secrecy order "which prohibited Moore

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[4] Mr. Moore received an LL.B. degree from Columbian College Law School (now the National Law Center of the George Washington University) in 1897 and a Master's Degree in Patent Law in 1899. He was registered to practice before the U.S.P.T.O. on March 2, 1899 and is currently a member in good standing.

[5] Mr. Moore is the sole or joint patentee on more than seventy United States patents ranging in subject matter from "Milk Jar Closure or Cap" (U.S. Patent No. 761,005, which issued on May 24, 1904) to "Spring Needle Knitting Machines" (U.S. Patent No. 3,407,630, which issued on October 29, 1968).

[6] Reissue Patent No. 26,108, entitled "Solid Explosive Composition and Method of Preparation Employing Vulcanized Rubber and a Solid Inorganic Oxidizing Salt", reissued on November 1, 1966.

[7] 194 U.S.P.Q. at 425.

[8] *Id.*

from disclosing the subject matter of the patent application to others not cognizant of the invention prior to the date of the secrecy order. The interest of the United Mine Workers ended shortly thereafter."[9] The secrecy order was lifted on April 2, 1957. Moore's original patent, U.S. Patent No. 3,135,634, issued following a series of CIP applications. The original patent was reissued as the patent in suit.

In December 1939, Moore had prepared and notarized a patent application directed to the explosive composition and method which he had conceived as early as 1939. This application was never filed with the USPTO. Moore also had prepared a second patent application concurrently with the delivery of the test sample to the Navy in 1948. This second application was the one which Moore filed in 1955.

The court found that from 1941 to 1955 Moore was "financially, physically, and mentally capable of filing an application on the invention in issue."[10]

The Government's Contentions

Although the government's position was that the patent in suit was invalid because of abandonment and/or forfeiture, its brief did not clearly distinguish between the two. It appeared to present three interrelated validity defenses. The first two stem from allegations that Moore "unduly delayed filing of an application for a patent on his invention." Consequently, Moore either abandoned his invention or forfeited his right to a patent. The third defense was that Moore, by filing several CIP applications, forfeited his right to a patent because he unduly delayed the issuance of his patent.

Opinion of the Trial Judge

At the outset, the trial judge noted that an analysis of the pertinent case law indicated that the "hoped-for line of demarcation between what has been characterized as acts of abandonment and/or forfeiture does not exist."[11] He then focused on the constitutional basis[12] for the patent laws and found that "the historical purpose for the granting of patents is to encourage a public disclosure of new scientific and tech-

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[9] *Id.* at 426.

[10] *Id.* The record shows that Moore filed and prosecuted several other patent applications in the period between 1941 and 1955.

[11] 194 U.S.P.Q. at 426.

[12] Art. I, § 8 of the Constitution of the United States states that "[t]he Congress shall have power . . . [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

nical developments."[13] He noted further that "the patent incentive need not be resorted to if inventors are willing to make a full, voluntary public disclosure of their inventions."[14] The trial judge then found that 35 U.S.C. § 102

> delineates the types of situations in which an inventor loses his right to a patent. Included among these, for example, are 35 U.S.C. § 102(b) which provides that an inventor shall be entitled to a patent unless he has previously described the invention in a printed publication, and 35 U.S.C. § 102(c) which provides that an inventor shall be entitled to a patent unless 'he has abandoned the invention.'[15]

The judge concluded that the constitutional goal of encouraging disclosure

> should be pursued regardless of when the invention was reduced to practice, and in the absence of any action proscribed by statute, or of instances where it can be shown that the public would have derived the benefit of the invention by the acts of another in due course. In the absence of such a showing, which includes the case presently before the court, a patent is in order because the public will be benefited by the invention's disclosure.[16]

The court distinguished many of the early abandonment/forfeiture cases, reasoning that they concerned "actions which are now proscribed by 35 U.S.C. § 102."[17] Furthermore, in every previous case in which abandonment and/or forfeiture were grounds for invalidity, "the public would have benefited by the public disclosure of the invention in due course even without the granting of the patent."[18] The trial judge concluded that the public would not so benefit absent Moore's patent application and therefore held that the abandonment/forfeiture defenses failed.

A. Burden of Proof. The burden of proving abandonment or forfeiture was on the Government by a showing of clear and convincing evidence.[19] The Government's proof of "mere delay" between the re-

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[13] 194 U.S.P.Q. at 426.

[14] *Id.* at 427.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.* The public would have benefited in these cases because either the inventor's own activities were sufficient to put the invention in the public domain or the activities of others were such that the invention eventually would have been disclosed.

[19] Petersen v. Fee Int'l, 381 F.Supp. 1071, 182 U.S.P.Q. 264 (W.D. Okla. 1974); Panaview Door & Window Co. v. Van Ness, 135 F.Supp. 253, 107 U.S.P.Q. 31 (S.D.Cal. 1955).

duction to practice and the filing of a patent application was inadequate to meet that burden for either defense.

B. Abandonment. The court held that Moore did not abandon his invention because he lacked the requisite intention to do so. That intent could be express or implicit, but in either case Moore's activities belied such an intent. Delay alone was not sufficient to constitute an express abandonment. Furthermore, Moore did not implicitly intend to abandon his invention because the intention to abandon had to be "the only reasonable explanation of [his] 'inaction'."[20] On the contrary, Moore's drafting and retaining of two patent applications and his attempt to interest the Navy and several corporations in his invention all contradict any implicit intent to abandon his invention.

C. Forfeiture By Delay in Filing a Patent Application. The court found that Moore did not forfeit his right to a patent. Unlike abandonment, "forfeiture appears to be grounded more on what Judge Learned Hand... characterized as '[T]he fiat of Congress that it is part of the consideration for a patent that the public shall as soon as possible begin to enjoy the disclosure'."[21] The court distinguished the factual situation in *Moore* from all other cases where forfeiture was found. In each of these other cases either "the invention was in the public domain because of acts by the inventor which are now proscribed by 35 U.S.C. § 102 or because during the inventor's delay others working independently made the same or substantially the same invention."[22]

The forfeiture doctrine has its roots in *Metallizing Engineering Co. v. Kenyon Bearing & A.P. Co.*[23] In that case, acts which today would constitute a 35 U.S.C. § 102(b) bar were found to constitute a forfeiture of the right to a patent. In dictum, however, Judge Hand stated that the § 102(b) activities might not even be necessary.

> But if he goes beyond that period of probation, he forfeits his right regardless of how little the public may have learned about the invention; *just as he can forfeit it by too long concealment, even without exploiting the invention at all.*
>
> It is indeed true that an inventor may continue for more than a year to practice his invention for his private purposes or his own enjoyment and later patent it. But that is, properly considered, not an exception to the doctrine, for he is not then making use of his secret to gain a competitive advantage over others; he does not thereby extend the period of his

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[20] 194 U.S.P.Q. at 428.

[21] *Id.*

[22] *Id.* at 433.

[23] 153 F.2d 516, 68 U.S.P.Q. 54 (2d Cir. 1946), *cert. denied,* 328 U.S. 840, 69 U.S.P.Q. 631.

> monopoly. *Besides, as we have seen, even that privilege has its limits, for he may conceal it so long that he will lose his right to a patent even though he does not use it at all. With that question we have not however any concern here.* [Emphasis in original.][24]

The trial judge in *Moore* found that the "cases cited by Judge Hand as support for the proposition that mere delay may work a forfeiture do not, upon close analysis, support such a conclusion."[25] These cases were *Woodbridge v. United States*[26] and *Macbeth-Evans Glass Co. v. General Electric Co.*[27]

In *Woodbridge,* the patent applicant had violated a special statutory provision which allowed him to place his application (which was ready for issuance as a patent) in the secret archives of the Patent Office for up to one year "for the sole purpose of providing time for the inventor to file a working model of the invention."[28] Nine and a half years later Woodbridge wanted to let the patent issue, but in such an amended form that the application would cover similar inventions patented by others during the nine and a half year interval. The facts in *Moore* were distinguished from those in *Woodbridge* in that

> (1) Moore did not have his allowed patent application held in a secret archive in a manner contradictory to a statutory provision; (2) although others were working in the same general field, defendant has not by the necessary clear and convincing evidence shown that others invented and patented the very same invention covered by the Moore patent in suit; and (3) it appears that but for Moore's filing for a patent, his invention would not have been brought to the attention of the public.[29]

Macbeth-Evans involved facts — secret use for profit for over nine years — which today would constitute a 35 U.S.C. § 102(b) bar to patentability. These facts were not present in *Moore.*

The trial judge next distinguished a recent case in which mere delay was found to be the basis for a forfeiture holding. In *Levinson v. Nordskog Co.,*[30] the district court held that "a person who, after conceiving and perfecting an invention, keeps it secret for five years until he thinks it will receive a more favorable market"[31] forfeits his right to a patent on that invention. The trial judge noted that, al-

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[24] *Id.* at 520, 68 U.S.P.Q. at 58-9.

[25] 194 U.S.P.Q. at 429.

[26] 263 U.S. 50 (1923).

[27] 246 F. 695 (6th Cir. 1917), *cert. denied,* 246 U.S. 659 (1918).

[28] Moore v. United States, *supra* note 2, at 429.

[29] *Id.* at 430.

[30] 301 F.Supp. 589, 163 U.S.P.Q. 52 (C.D.Cal. 1969).

[31] *Id.* at 590, 163 U.S.P.Q. at 53.

though the court's holding in *Levinson* mentions only the five year delay, more than mere delay was actually involved.

> After being advised in September 1962 of American Airlines' interest in his idea, plaintiff in September 1963 filed an application for a patent.
>
> It also appears, however, that in the meantime defendant by at least December 4, 1962, was seeking to sell a device which plaintiff contends infringes his patent.[32]

The court then carefully analyzed each of the cases cited by the *Levinson* court in arriving at its conclusion that a mere delay of five years constitutes forfeiture. Judge Colaianni found that "none of the cases cited indicate that it has been applied to a situation which involves pure and simple delay — regardless of the length or duration of the delay — between the time that an inventor reduces his invention to practice and the time that he files for a patent application."[33] Furthermore, he cited *Bates v. Coe*[34] for the proposition that mere delay is not sufficient per se for forfeiture to occur.

> Inventors may, if they can, keep their invention secret; and if they do for any length of time, they do not forfeit their right to apply for a patent, unless another in the meantime has made the invention, and secured by patent the exclusive right to make, use and vend the patented improvement. Within that rule and subject to that condition, inventors may delay to apply for a patent....[35]

A more recent commentary on the effect of mere delay on an inventor's right to a patent states:

> Furthermore, the patent laws do not require that an application be filed within a reasonable time after the completion [actual reduction to practice] of the subject invention. Instead, a patent application may be filed on a secret invention at any time as long as it is filed within a year after the invention has been placed in commercial use.[36]

Judge Colaianni then looked to *Young v. Dworkin*,[37] a case involving 35 U.S.C. § 102(g) where Judge Rich, in a concurring opinion, distinguished forfeiture of the right to a patent and forfeiture of the right to rely on an actual reduction to practice in a priority dispute.

> I cannot agree with the board that the question in this case is whether Young 'forfeited his *right to a patent*.' But for Dworkin's conflicting claim,

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[32] Moore v. United States, *supra* note 2, at 431.

[33] *Id.* at 432.

[34] 98 U.S. 31 (1878).

[35] *Id.* at 46.

[36] Adelman, *Trade Secrets and Federal Preemption – The Aftermath of Sears and Compco*, 49 J. PAT. OFF. SOC'Y 713, 727 (1967).

[37] 489 F.2d 1277, 180 U.S.P.Q. 388 (C.C.P.A. 1974).

> Young forfeited nothing and would get a patent. All he *forfeited,* as I tried to point in *Brokaw v. Vogel, supra,* last paragraph of the opinion, was the right to rely on his prior actual reduction to practice in a priority dispute. Considering what Robinson said, quoted above, another, and perhaps better, way to have stated it would have been that Young was estopped by his conduct to rely on his reduction to practice in a priority dispute. [Emphasis in original.][38]

D. Forfeiture By Delaying the Issuance of a Patent. The Government relied on three cases — *Ex parte Hull,*[39] *Vitamin Technologists v. Wisconsin Alumni Research Foundation,*[40] and *Wirebounds Patents Co. v. Saranac Automatic Mach. Corp.*[41] — to support its contention that Moore forfeited his right to a patent by filing a series of CIP applications.

In *Hull,* claims were allowed in the application filed initially but, instead of allowing the patent to issue, the applicant filed a CIP application which added refinements to the original invention. When these claims were found to be allowable, he carried all of them into a second CIP application, adding further refinements. Six CIP applications were eventually filed. Hull admitted that he filed them in order to "prevent others from seeing his invention and improving on it."[42] Although the Board of Appeals held that Hull's actions did not bar his right to a patent, they questioned whether a court would enforce such a patent and warned Hull that if he filed another CIP application without allowing the present one to issue, there could be "a rejection based on conduct that is contrary to the purpose of the Constitution and patent laws."[43]

In *Vitamin Technologists,* the Ninth Circuit Court of Appeals concluded that the inventor was using CIP applications to hide the invention. The court dealt with an unconscionable scheme involving manipulation of the patent laws to deny the benefits of the invention (Vitamin D irradiation for rickets) to the margarine industry and the poorer segments of the public. The court found that during a period of extensive commercial use in the natural dairy products industry, an application was filed which contained claims which were allowed. However, by filing a continuing application, the inventor purposely delayed the issuance of allowed claims which were of the same scope as those which eventuated in the patent.

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[38] *Id.* at 1286, 180 U.S.P.Q. at 395-6. [Rich, J. concurring.]

[39] 191 U.S.P.Q. 157 (Bd.App. 1975).

[40] 146 F.2d 941, 63 U.S.P.Q. 262 (9th Cir. 1944).

[41] 65 F.2d 904, 18 U.S.P.Q. 171 (6th Cir. 1933).

[42] Moore v. United States, *supra* note 2, at 435.

[43] *Id.*

In *Wirebounds,* the inventor filed a continuing application to obtain claims which were broader than those already contained in an issued patent. The court concluded that since he could legitimately obtain these claims only by filing a reissue application, the delay of more than two years after issuance of the patent constituted laches. As a result, the applicant lost whatever rights he might otherwise have had.

In *Moore,* the court found that the first four CIP applications were needed to overcome the examiner's objections. Only in the fourth CIP application did Moore receive any "indication that his application contained allowable claims."[44]

Moore then attempted to add claims directed to an embodiment using flowable rubber.

> The Patent Office not only refused to allow the new claims in this application, but, as well, rejected the six claims that had previously been allowed. Finally, Moore failed yet another continuation-in-part application, Serial No. 165,456, on January 10, 1962.
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> In Serial No. 165,456, the Patent Office allowed the six claims previously allowed in Serial No. 818,254, plus two additional claims. No claims to the flowable rubber embodiment were, however, allowed. This application issued as Patent No. 3,135,634.
>
> Moore, however, persisted in his attempts to patent his flowable rubber embodiment and, therefore, before allowance of the 3,135,634 patent and, specifically, on May 20, 1963, he filed continuation-in-part application 281,748. The continuation-in-part application 281,748 was directed to the flowable rubber embodiment as well as others. When the Patent Office refused to allow claims in this continuation-in-part, Moore filed still another continuation-in-part application, No. 422,056, eventually was abandoned with no claims indicated as being patentable, and the chain of continuity terminated. In the meantime, on May 19, 1965, Moore filed an application to reissue his 3,135,634 patent. That application not only included the eight claims of his patent, but also added the additional claims.[45]

The court thus found that Moore's conduct was different from that found objectionable in *Vitamin Technologists, supra, Wirebounds, supra,* and *Hull, supra.* Accordingly, it held that Moore had not forfeited his right to a patent by delaying the issuance of his patent.

Analysis

The clear result of the *Moore* decision is that the United States Supreme Court decision in *Bates v. Coe*[46] is still the law of the land,

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[44] *Id.* at 434.

[45] *Id.*

[46] *See* note 34, *supra.*

i.e., mere delay, without more,[47] will result in neither abandonment nor forfeiture. The implications of the court's opinion will be treated separately below with respect to the abandonment and forfeiture defenses; the forfeiture defense will be treated separately with respect to pre-filing and post-filing activities.

A. Abandonment. Proof of abandonment requires that one *intend* to abandon.[48] This intention may be either express or implied.[49] Factual situations in which abandonment is express are somewhat exceptional. In such situations, clear and convincing evidence would have to be produced[50] that the inventor either orally or in writing stated, in effect, "I hereby abandon this invention." Such factual situations are quite rare as evidenced by the paucity of cases in which a court has held that there was an express abandonment.

An intention to abandon the invention may also be implied. The quantum of evidence needed to imply such an intention depends upon the standard applied by a particular court. The court in *Marvin Glass*[51] required that the implication be the necessary one, while the court in *Moore* required that the intention to abandon be merely "the only *reasonable* explanation of [the inventor's] 'inaction'."[52]

Under the stricter "necessary implication" test, the inventor must not have engaged in any activities which would be inconsistent with the intention to abandon. For example, in *Levinson*,[53] the inventor left the device shut up in his basement laboratory (and later in his

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[47] For a discussion of the issue of whether "mere delay, without more" is redundant, *see* Peeler v. Miller, 535 F.2d 647, 190 U.S.P.Q. 117 (C.C.P.A. 1976), where Judge Rich stated, "The addition of 'without more' to 'mere' seems to be a redundancy of the kind to which lawyers are peculiarly prone." 535 F.2d at 654, 190 U.S.P.Q. at 123n.10. Judge Miller, concurring, replied,

> The error of the superflous comment in footnote 10 of the majority opinion is demonstrated by the statement of the obvious in the opinion itself: 'Surely, the word mere does not imply a total absence of a limit on the duration of the delay.' The language in Young v. Dworkin was taken from Gallagher v. Smith, 41 C.C.P.A. 734, 743, 206 F.2d 939, 946, 99 U.S.P.Q. 132, 138 (1953).

535 F.2d at 655, 190 U.S.P.Q. at 124n.1.

[48] Marvin Glass & Assoc. v. Sears, Roebuck & Co., 318 F.Supp. 1089, 1102, 167 U.S.P.Q. 33, 44 (S.D.Tex. 1970).

[49] *Id.*

[50] Petersen v. Fee Int'l, *supra* note 19: Panaview Door & Window Co. v. Van Ness, *supra* note 19.

[51] Marvin Glass & Assoc. v. Sears, Roebuck & Co., *supra* note 48.

[52] Moore v. United States, *supra* note 2, at 428.

[53] Levinson v. Nordskog Co., *supra* note 30.

garage), told his attorney that he wanted to patent it if a market should develop, but otherwise forgot about it.[54] These activities did not prove an implicit intent to abandon.

Even if an inventor were to put his invention aside for a very long period of time, forget about it, and then several years later be spurred into activity by the activities of others, this would not *necessarily* imply abandonment since the mere fact that he did not destroy or give away his invention is inconsistent with and thereby rebuts any such implication.

An intention to abandon an invention is likely to be implied only in the following kind of factual situation: After an invention is made, including a conception of "utility" in a patent law sense, the inventor ("Inventor A") concludes that it is nevertheless worthless (for example, a notebook entry reads "not worthwhile" or "no good"). Accordingly, he destroys or throws away virtually everything associated with the invention, *e.g.*, physical embodiments of the invention, drawings associated with its conception, etc. He never expressly states that he is abandoning the invention, however.

Later, another inventor ("Inventor B") either conceives or reduces to practice substantially the same invention and, unlike Inventor A, realizes its value. After learning of Inventor B's activity, Inventor A recalls the details of his invention and files a patent application on it.

If Inventor B also files a patent application, then Inventor A's rights will be determined in a priority contest with Inventor B.[55] Under these facts, Inventor A would have some difficulty in proving that he neither "abandoned, suppressed, or concealed"[56] his invention. Thus he may be deprived of the benefit of his early reduction to practice.

If Inventor B does not file a patent application, then the question is whether Inventor A abandoned his invention within the meaning of 35 U.S.C. § 102(c). Whether B files or not, however, the issue of A's abandonment would arise only *after* A filed a patent application.[57]

If Inventor B does not file a patent application and the issue of A's abandonment arises in a validity context, a court is likely to find that A implicitly intended to abandon his invention. That abandonment

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[54] Levinson v. Nordskog Co., *supra* note 30, at 589, 163 U.S.P.Q. at 53.

[55] 35 U.S.C. § 102(g).

[56] *Id.*

[57] It should be noted that abandonment of a patent application does not necessarily imply abandonment of the invention under 35 U.S.C. § 102(c). A patent applicant who is very interested in his invention may find that he does not have the financial ability to continue the prosecution of his patent application.

took place at the time A decided his invention was worthless and destroyed the tangible embodiments of it.

It should be noted that A's patent could be rejected in an *ex parte* context or found invalid in infringement litigation under both 35 U.S.C. §§ 102(c) and 102(g). The § 102(g) defense would apply if there were a prior invention of another "who had not abandoned, suppressed, or concealed."[58] The difference between the § 102(c) and § 102(g) defenses is that under § 102(g), Inventor A has a chance to prove that Inventor B also "abandoned, suppressed, or concealed"; thus B cannot rely on his reduction to practice which precedes A's filing date. Inventor A might prevail over Inventor B even though both "abandoned, suppressed, or concealed" if either A had renewed his interest in the invention while B never did, or if A had renewed his interest in the invention at a point in time prior to when B renewed his interest.[59]

A factual situation in which a § 102(c) defense might apply, but a § 102(g) defense would not, is as follows: An inventor demonstrates his intent to abandon his invention by making a notebook entry which might read "not worthwhile", and then destroying the physical embodiments of the invention. Later the inventor realizes the value of his invention and applies for a patent. No "invention by another" is involved so § 102(g) is inapplicable. However, under these facts a court may find an implication to be necessary that the inventor abandoned his invention. If so, he would be absolutely barred under § 102(c). However, the inventor may be successful in arguing that his renewed interest in this invention, as evidenced by his patent application, represents the "recapture" or rediscovery of his invention.[60]

A question which may be raised is whether filing a patent application would ever be sufficient to rebut an inference that the inventor abandoned his invention. In this connection, it should be remembered

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[58] 35 U.S.C. § 102(g). These issues may arise in the context of an *ex parte* rejection by a Patent Examiner, *In re* Bass, 474 F.2d 1276, 177 U.S.P.Q. 178 (C.C.P.A. 1973); or as a validity defense in infringement litigation, Sutter Products Co. v. Pettibone Mulliken Corp., 428 F.2d 639, 166 U.S.P.Q. 100 (7th Cir. 1970); and Grinnell Corp. v. Virginia Electric & Power Co., 277 F.Supp. 507, 156 U.S.P.Q. 443 (E.D.Va. 1967).

[59] *See* Steierman v. Connelly, 192 U.S.P.Q. 433 (Bd. Pat. Int. 1975), where the board indicated that an inventor who had once abandoned, suppressed or concealed his invention could renew his interest in the same for priority purposes.

[60] Some have suggested that, by analogy to personal property, it may be possible for an inventor to recapture or rediscover an abandoned invention. *See* 1 PATENT PREPARATION AND PROSECUTION PRACTICE, Chap. 4 at 4-11 (Kayton ed. 1976). Certainly it is in the public interest not to bar the inventor who rediscovered his invention if the public would benefit from the disclosure.

that the § 102(c) issue *always* arises *after* a patent application has been filed. If an inventor were able to "recapture" or rediscover an abandoned invention merely by showing his interest in the invention by filing a patent application, the abandonment issue would almost *never* arise.[61]

However, a court may look at the reasons why an inventor filed his patent application. If he was "spurred" into action by the activities of another, then the first inventor would probably be held to have abandoned his invention. Since he filed a patent application only because of the influence of the activities of another, then it could be said that he did not possess the invention himself if possession, *i.e.,* lack of abandonment, is defined as including the realization of the value or worth of the invention. However, if the first inventor reduced to practice his invention, discarded it, then several years later discovered on his own the real value of his invention, and filed a patent application, a court may consider this evidence as competent to show that he never really abandoned his invention in the first place. In this latter situation, the inventor himself not only possessed the inventive concept but also appreciated the value of the invention, albeit several years after his reduction to practice. Thus, courts might weigh the inventor's new-found interest along with the evidence of his initial disillusionment and conclude that he never actually abandoned the invention.

B. Forfeiture By Delay in Filing a Patent Application. As a defense, forfeiture, like abandonment, is rarely applicable, although more frequently raised. Although it has been raised in the past when the activity in question would be sufficient to constitute a § 102 bar,[62] it is clearly not needed in such a situation.

Judge Rich even attempted to sound the death knell for the forfeiture doctrine in his concurring opinion in *Young v. Dworkin, supra,* when he stated in a § 102(g) interference context:

> The issue is, therefore, not forfeiture or estoppel or anything other than whether Young suppressed or concealed, since no question of abandonment has been raised. The only reason we have to look to prior cases is to

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[61] Another kind of abandonment may result if a patent applicant allows a patent to issue when that patent discloses an invention which is not claimed. Upon the issuance of the patent, the unclaimed subject matter is presumed by the USPTO to be dedicated to the public. This presumption may be rebutted, however, by the patentee filing a reissue application claiming that subject matter when the reissue application is filed within one year of the issue date of the original patent. *In re* Gibbs, 437 F.2d 486, 168 U.S.P.Q. 578 (C.C.P.A. 1971).

[62] *See* Macbeth-Evans, *supra* note 27, and Metallizing Engineering, *supra* note 23.

> gain an understanding of the meaning of 'suppressed' and 'concealed,' which concepts have been codified in § 102(g). *Case law 'doctrines' are no more; the question is now simply one of statutory construction.*
>
> I may say that this approach to the law is one which has just occurred to me in the study of this case and I present it in the hope of making the law simpler and clearer in the future by the exclusion from opinions of *unnecessary legal theories like forfeiture.* [Emphasis added.][63]

In *Moore,* a delay of more than thirteen years between reduction to practice and filing a patent application was not sufficient, in itself, to constitute forfeiture of the right to a patent. The question, then, is what is left of the forfeiture doctrine after *Moore.* To answer this question, it is necessary to distinguish forfeiture from abandonment. As noted above, abandonment generally involves some act or acts which indicate that an inventor no longer believes in his invention coupled with the absence of indicia inconsistent with an intent to abandon.[64]

The trial judge concluded that Moore did not forfeit his invention because (1) the Government failed to prove by clear and convincing evidence that his invention was in the public domain, through acts which are proscribed by § 102,[65] and (2) the Government failed to prove by clear and convincing evidence that the public would eventually receive the benefits of Moore's invention because others working independently had made substantially the same invention.[66] If the invention were in the public domain because of acts which are proscribed by § 102, there would be no need for a forfeiture defense. The statute is determinative.

To the extent any non-statutory defense like forfeiture exists, however, it may be successfully rebutted even after years of delay between reduction to practice and filing, by showing that (1) others working independently were not making substantially the same invention during the time when the first inventor delayed, or (2) even if others were making substantially the same invention, the public would not eventually receive the benefits of the invention through the diligent acts of these other inventors. The forfeiture defense would be stronger if it could be proven that the first inventor was spurred into filing by the activities of the subsequent inventor, but

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[63] 489 F.2d at 1286, 180 U.S.P.Q. at 395-96 [Rich, J. concurring].

[64] One could forfeit his invention, however, while constantly retaining his interest in it. In many of the cases in which forfeiture was concluded, the inventor was "too interested" in his invention — *i.e.,* his interest was such that it amounted to a statutory bar under 35 U.S.C. § 102(b).

[65] *See* note 29, *supra.*

[66] *See* text accompanying note 16, *supra.*

even under those facts, a court might find that any inference of forfeiture would be rebutted by a showing that the public would still benefit from the issuance of the patent.[67]

If the second inventor were to file a patent application, the rights of the first inventor would be determined in a priority dispute with the second inventor.[68] Forfeiture would not be applicable as such since the rights of the inventors in this situation would be determined by statute.[69]

C. Forfeiture By Delaying the Issuance of a Patent. A rather extreme factual situation is needed for a court to find that an inventor has forfeited his right to a patent by delaying its issuance. In the CCPA, at least Judge Rich believes that "[c]ase law 'doctrines' are no more."[70] Only in cases like *Ex parte Hull, supra, Wirebounds, supra,* and *Vitamin Technologists, supra,* where the applicant was either (1) abusing USPTO practice by filing a continuing application to obtain patent claims which he would only obtain by way of reissue,[71] or (2) positively attempting to conceal the invention within the USPTO by filing one or more continuing applications,[72] would a court be likely to find forfeiture.

The case for a forfeiture conclusion obviously improves as the number of unjustified continuing applications increases. However, if each continuing application could be justified on the basis of (1) the presentation of new arguments or evidence to rebut USPTO rejections, or (2) an attempt to obtain greater claim protection, it would appear that the applicant is merely doing what he is statutorily permitted to do. Case law doctrines should not interfere with these statutory rights.

The theory underlying the forfeiture doctrine in the context of deliberate delaying of the issuance of a patent is apparently that the applicant should not be allowed to "have his cake and eat it too" by securing an early filing date for the purpose of avoiding § 102 bars, yet delaying the issuance of the patent for the sole purpose of developing a better market for the invention. It is doubtful whether such a theory is correct, however. The patent system which is, in part, based

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[67] Moore v. United States, *supra* note 2, at 427.

[68] *See* note 3, *supra.*

[69] *See* text accompany note 63, *supra.*

[70] *Id.*

[71] *See* Wirebounds Patents Co. v. Saranac Automatic Mach. Corp., *supra* note 41. *See also* Moore v. United States, *supra* note 2, at 435.

[72] *See* Vitamin Technologists, *supra* note 40; *Ex parte* Hull, *supra* note 39. *See also* Moore v. United States, *supra* note 2, at 435.

on the inventor's tendency to be greedy, should not punish him if he lawfully attempts to delay the issuance of his patent, regardless of his reason for doing so.[73]

The Commissioner has been given, by statute, the power to "establish regulations".[74] Such a regulation may be needed to deal with some of the problems discussed in this section. In the absence of such a regulation, courts should not interfere as long as the applicant does not violate any statute.

Conclusions

Although the statutory defense of abandonment and the judicially-created doctrine of forfeiture are often mistakenly applied to activities which are already proscribed by other parts of § 102, they rarely are truly in issue in real life situations. Mere delay, even for more than thirteen years, is not enough to constitute abandonment or forfeiture. Abandonment requires proof by clear and convincing evidence of an intent, either express or implicit, to abandon the invention. An intent is not to be inferred if acts inconsistent with such an intent are shown. Forfeiture, if ever a viable defense, requires proof by clear and convincing evidence that while the first inventor delayed filing his patent application, others working independently made substantially the same invention and the public would no longer benefit from the issuance of the first inventor's patent. Finally, if forfeiture may result from the deliberate delaying of the issuance of a patent, the mere filing of one or more continuing applications will not amount to a forfeiture. To support a conclusion of forfeiture because of a delay in the issuance of a patent, a court at least would have to find that the applicant either abused USPTO practices or intended to delay issuance for the sole purpose of keeping the invention from the public.

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[73] *Cf.* Overland Motors Co. v. Packard Car Co., 274 U.S. 417 (1927); and Woodbury Patent Planing-Mach. Co. v. Keith, 101 U.S. 479 (1879). It should be noted that every paper filed by an attorney or agent representing an applicant or party to a proceeding in the Patent and Trademark Office must be signed by that attorney or agent, except for papers which are required to be signed by the applicant or party in person. That signature constitutes a certificate that, *inter alia,* the paper "is not interposed for delay." 37 C.F.R. § 1.346. Thus, an attorney or agent could not *lawfully* attempt to delay the issuance of a patent.

[74] 35 U.S.C. § 6, in pertinent part, reads as follows: "(a) The Commissioner ... may ... establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office."

Identifying and Regulating Environmental Carcinogens: Living with Uncertainty*

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The identification and regulation of environmental carcinogens presents major public policy problems. The growing list of identified carcinogens is not the only issue. Consistent relationships between the current knowledge of environmental carcinogens and their regulation are difficult to attain because of changing laboratory standards for determining carcinogenicity, the hypothetical nature of extrapolating laboratory data to potential human risk, and the numerous federal agencies responsible for regulating carcinogens.

The federal system for regulating carcinogens needs revision because of rapid advances in cancer-testing techniques and the add-on approach that has been characteristic of regulatory legislation in this area. However, for reform to have meaning, the underlying problems must be understood, a precondition that is largely absent and further

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confused by the seeming ubiquitousness of carcinogens in every facet of our lives.

In this paper, the authors describe cancer testing technology, the federal authorities that regulate environmental carcinogens, and the links between the two processes in which uncertainties are inherent. The authors' primary purpose is to identify these areas of uncertainty so that policymakers have a common basis for developing future approaches on (1) how to be more consistent in evaluating the scientific evidence for carcinogenicity and framing it in a way useful for regulation, (2) specific methods of coordination between the scientific and regulatory communities, and (3) how the regulatory process should be reorganized.

Current public policy largely delegates decisions on what to do about environmental carcinogens to the scientific community and the regulatory agencies. Our purpose is not to examine the wisdom of this placement of responsibilities, but rather to openly discuss the problems this placement poses, the uncertainties that cannot be avoided, and the value judgments that must continue to be made. Our hope is that an open discussion of these issues will lead to better understanding by the public and its representatives and a more ordered approach by scientists and regulators in dealing with these uncertainties.

Determining Carcinogenicity

The problem is to identify the carcinogenic potential of substances before they have been shown to cause cancer in humans. This task is primarily one of estimating the degree of risk to humans through indirect methods. In addition to validating the carcinogenic effects that have been shown in experimental conditions, relationships must be established between these effects and the potential for causing cancer in humans.

In determining whether a substance is a potential carcinogen the conditions under which a substance acts are as important as its molecular structure. Whether a particular substance causes cancer in humans is a separate question from whether or not it causes cancer under experimental conditions.

General criteria for assessing the evidence of carcinogenicity can be classified according to the source of data: (1) data from human studies, (2) data from animal experiments, (3) data from short-term tests.

The rationale behind short-term tests is the assumption that the observed effect is related to carcinogenesis. Such tests include an array of procedures ranging from the observation of chromosomal

aberrations in mammalian cell lines, to the determination of mutation rates in bacterial or cell cultures or in fruit flies.[1] Little is known about the predictive value of the relationship among these tests.

The Ames test, the most widely known short-term test, uses mutants of the bacterium *Salmonella typhimurium.* It presumes that cancers and mutations stem from cellular DNA alternations, and that the demonstration of a chemical's mutagenicity shows it is potentially carcinogenic. The mutants used in the Ames test do not have the ability to synthesize the amino acid histidine. In a histidine-free culture, growth does not occur. When a mutagenic substance is added, mutations occur, including those which repair the histidine production defect. Bacteria able to grow in the absence of histidine are counted. Strong mutagens result in larger numbers of bacteria being able to grow in the absence of the amino acid.

This is relatively a shotgun approach wherein site specific DNA effects are related to carcinogensis. Ninety percent of known carcinogens tested are mutagenic in the Ames test[2] and, conversely, Ames claims that almost every mutagen that has been given an adequate cancer test has been found to be a carcinogen.[3]

The utility of short-term tests is in the screening of large numbers of chemicals. Animal experiments are expensive and time consuming. Accepted protocols for rat experiments now require expenditures of $100,000 to $200,000 per test and three years to perform. Short-term tests can be done for a few hundred dollars and be completed in weeks to months.

Animal experiments provide stronger evidence that a chemical is carcinogenic in humans. Of the known human carcinogens, nearly all are carcinogens in animal tests.[4] Because no clear distinctions exist between chemicals which are carcinogenic in laboratory animals and chemicals which are carcinogenic in humans, most scientists regard all chemicals which have been shown to be carcinogenic in animals to

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[1] Congress of the United States, Office of Technology Assessment, *Cancer Testing Technology and Saccharin,* Washington, D.C.; U.S. Government Printing Office, 1977.

[2] McCann & Ames, *Detection of Carcinogens as Mutagens in the Salmonella/ microsome test: Assay of 300 Chemicals, Discussion,* 73 Proc. Nat'l Acad. Sci. 950 (1976).

[3] Ames, McCann & Sawyer, *Mutagens and Carcinogens,* 194 SCIENCE 132 (1976).

[4] National Academy of Sciences, *Pest Control: An Assessment of Present and Alternative Technologies,* Vol. 1: *Contemporary Pest Control Practices and Prospects: The Report of the Executive Committee,* Washington, D.C.: National Academy of Sciences, 1975).

be potentially carcinogenic in humans. In practical terms this means that chemicals known to cause cancer in animals remain suspect no matter how many studies are conducted on other animals or humans with negative results.

Current National Cancer Institute guidelines for animal testing are as follows:[5]

> (1) Groups of 50 animals of one sex and one strain should be started on the experiment at 6 weeks after birth or at weaning. Control groups should also contain 50 animals. (In practice 100 animals (50 M, 50 F) should be used at each dose.)
>
> (2) The chemical should be administered by a route that mimics human exposure.[6]
>
> (3) At least two doses, MTD (maximum tolerated dose) and MTD/2 or MTD/4 should be administered.
>
> (4) Treatment should be continued long enough (in practice generally 24 months) to produce a maximum response.
>
> (5) Animals should be sacrificed (usually at 24 months) and necropsied according to detailed pathology procedures.
>
> (6) Tests should be conducted in two species, and the results of the more sensitive one given greater consideration.

Additionally, a subcommittee of the National Academy of Sciences has recommended that:[7] "(7) Exposure to the chemical for two generations should be considered. (This procedure exposes the animals of the second generation to the substance *in utero,* which may represent the most sensitive stage of the animal's life.)"

These guidelines provide criteria for deciding whether or not the experimental conditions were valid. They do not provide a basis for standardizing the interpretation of the results of any particular experiments, *i.e.,* whether or not the experiment shows cancer induction.

Human studies, which, for ethical reasons, cannot be controlled as animal experiments, always contain an element of speculation. Epidemiologic studies presume that there are multiple causes for a specific type of cancer. The problem is to isolate one cause. This can be done only if a population which is exposed to a particular chemical shows an increase of cancer over that which is present in a

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[5] National Cancer Institute, *Guidelines for Carcinogen Bioassay in Small Rodents,* DHEW (NIH) Publ. No. 76-801 (Feb. 1976).

[6] This criterion is a little anomalous, because it really addresses the issue of applicability to human experience, not the integrity of the conditions of the specific experiment.

[7] National Academy of Sciences, *supra* note 5.

non-exposed population. Moreover, chemicals to which humans are actually exposed may be at such a low dose that the impact may not be detected by epidemiologic tools.

If a chemical has been shown to be carcinogenic in animals (what might be termed the "qualitative" proof of carcinogenicity in humans), a quantitative estimate is made on its effect in humans. Because high doses are used in animals, a mathematical model is constructed for the dose-response relationship. Since extrapolation to the low dose levels is the issue, the choice of the mathematical model may be crucial. Usually, the results of the most sensitive animal experiments are used to extrapolate to the potential carcinogenic effect in humans[8] because the safest assumption is that humans are the most sensitive animal species.

Rodent experiments in which groups of 50 rodents are tested at different dose levels would not detect an incidence of less than 1 to 50 and if doses comparable to human exposure were used, the results of these experiments would almost always be negative for low-potency carcinogens. Hence, the results of high dose levels in animal experiments are used to calculate the expected response at lower dose levels. Epidemiologic studies can confirm or contradict the animal test evidence for cancinogens that produce a strong response in animal tests and which can be expected to produce a large increase over the prevailing rate of cancer in humans. For weak carcinogens, the expected increase as predicted by the animal test data might still be less than that which could be detected by epidemiologic studies. Although the epidemiologic studies in these cases show no effect, they would not contradict the results of positive animal experiments.

Problems Interpreting Experimental Evidence

Many uncertainties complicate the relationships between short-term tests, animal experiments, and human epidemiologic studies. The reliance that should be placed upon them as proof of cancer causation in humans is also unclear. These uncertainties can be separated into three concerns:

- Are the experimental conditions acceptable?
- Are the conclusions reached from each experimental result valid?
- How are the results of different experiments to be reconciled when some are positive and some negative?

The experimental condition sought is the isolation of one variable so

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[8] Ames, *supra* note 3.

that a causal relationship can be shown between it and the effect observed. The problem is that the chemical to be tested may itself alter the experimental environment especially when living systems (cell cultures, animals) are used and doses are increased. Thus, efforts must be made to prove that these secondary changes are themselves not responsible for the observed effect.

The test animal selected is crucial, and at least two species must be tested.[9] Test animals are very specialized and in-bred. In addition, even species of the same ancestry might have very different characteristics. Test results are often difficult to compare because the animals may not be from the same source across experiments, and because certain animal strains have a propensity to develop tumors.[10] Although these tumors might be of a certain type and limited to specific body sites, tumor site and type in test animals are not necessarily correlated to similar types and sites in humans.[11] Additionally, for some sites such as the bladder, certain test animals harbor parasites which in turn are known to cause tumors.[12]

The use of high doses in current procedures assumes that there is no threshold for the carcinogenicity of a particular chemical. If a carcinogenic effect is shown with very high doses, then a carcinogenic effect is assumed even at very low doses, the difference being in the number of cancer cases to expect.

High doses are also used to compensate for (1) the strength of the carcinogen, (2) the exposure level or dose, and (3) the number of animals exposed.[13] But high doses, resulting in "metabolic overload," can affect the metabolism of the chemical and the physiological state of the test animal which in turn are possible cancer causes.[14]

The diet of test animals is usually a standardized formula. However, consumption cannot be standardized because of the varying effects on appetite by different chemicals, and the individual appetite variations among animals. Amount of diet can be standardized by

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[9] National Cancer Institute, *supra* note 6.

[10] National Cancer Institute, General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances, Report of the Subcommittee on Environmental Carcinogenesis, Typescript, June 2, 1976.

[11] National Academy of Sciences, *supra* note 5.

[12] Chapman, *Infection with Trichosomoides crassicauda as a Factor in the Induction of Bladder Tumors in Rats Fed 2-Acetylaminofluore,* 7 INVEST. UROL. 154 (1969).

[13] See *supra* note 7.

[14] National Cancer Institute, *supra* note 11.

involuntary feeding but the route of administration may also affect cancer causation.[15] Therefore, while there may be little problem in concluding that a chemical causes cancer in test animals, if the route of administration is not identical to that of humans, the connection between animal test results and human experience remains questionable.

The definition of "tumor" is crucial for three reasons. First, benign tumors do not necessarily mean that a chemical does not cause cancer. Benign tumors are not without risk and may be an early state of malignant tumor genesis.[16] Indeed, chemicals which induce benign tumors often induce malignant ones. Second, tumors and their different manifestations (benign, pre-cancerous hyperplasia, invasive malignancy, etc.) are ultimately determined by individual pathologists using essentially morphological criteria (they look at gross and microscopic preparations and make expert judgments), thus, differences in interpretation always remain.

Finally, rapid advances in cancer testing technology almost guarantee that animal experiments undertaken according to current guidelines will not conform exactly to guidelines existing at the end of the experimental period. Thus, even with recommended guidelines for experimental protocols, subjective, albeit expert, judgments are unavoidable.

The method of interpreting the results of technically acceptable experiments is the second area of uncertainty. Statistically significant increases in cancer formation in exposed, versus control groups of animals show that the chemical tested is carcinogenic. However, there is some controversy as to whether this statistical test must be met before carcinogenesis is proven. Many researchers accept findings of tumors in unexpected sites or of unusual type as proof of carcinogenesis even though their rates may not be statistically significant. Benign versus malignant tumor formation raises similar issues and becomes especially troublesome when statistical significance depends on the inclusion or exclusion of benign tumors.

The third area of uncertainty appears when attempting to *reconcile positive with negative test results.* Positive test results almost always carry more weight than negative test results when comparing tests of the same general classification, *i.e.,* short-term tests, animal tests, or human epidemiologic studies. For example, cyclamates were taken off

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[15] *Id.*

[16] *Id.*

the market because of positive carcinogenic tests in rats fed a mixture of cyclamate and saccharin, the predominant mode of use of these artificial sweeteners at the time. Despite the fact that these results were not repeated when testing only cyclamates, and despite the subsequent evidence that saccharin is a carcinogen,[17] scientific reviews of the potential of cyclamate as a carcinogen have called for more studies and have not overruled this questionable positive test in light of the subsequent negative tests.[18] Consequently, petitions to remarket cyclamate are being carefully examined. The issue will probably be ultimately decided by the courts and not by reliance on the conclusive findings of a body of scientific experts.

Disagreements concerning the significance of positive results in one test classification and negative results in another have been mainly between positive animal tests and negative epidemiologic studies. The initial basis for the disagreement was the belief that carcinogenicity in animals was irrelevant to carcinogenicity in humans. This skepticism has now largely dissipated. However, additional confusion has occurred because of the failure to distinguish those situations described above in which the animal tests predict a human response lower than that which could be detected by epidemiologic studies. The controversy is now shifting towards the relationship between short-term tests and animal experiments, *i.e.*, how to interpret positive short-term tests and negative animal tests. Investigators are presently accumulating empirical evidence to show a relationship between dose levels in short-term tests and expected carcinogenic response in test animals. This is being done to ultimately demonstrate a relationship between short-term tests and human exposure.[19]

The Clearinghouse on Environmental Carcinogens

The National Cancer Institute (NCI) has established a Clearinghouse on Environmental Carcinogens to provide direction to the Institute on its testing of suspected chemical and physical carcinogens. The Clearinghouse receives nominations of suspect agents, ranks them on a priority scale for testing, selects the most important, has them tested, and evaluates the tests to determine what human risks were shown.

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[17] Congress of the United States, *supra* note 1.

[18] National Cancer Institute, Report of the Temporary Committee for the Review of Data on Carcinogenicity of Cyclamate, Washington, D.C.: National Cancer Institute, February 1976.

[19] Meselson, & Russel, *Comparisons of Carcinogenic and Mutagenic Potency* in ORIGINS OF HUMAN CANCER (H. Hiatt, J. Watson, J. Winston eds. 1977).

The organization of the Clearinghouse is described in its charter:[20]

> There shall be four standing Subgroups of the Committee. Each shall have not more than fifteen members, all of whom shall be members of the parent Committee. The Subgroups shall be: (1) the Subgroup on Chemical Selection to review, to nominate, and to rank chemicals that require carcinogenicity testing, (2) the Subgroup on Experimental Design to advise on appropriate experimental designs for routine tests and to develop protocols for studies intended to improve the state-of-the-art, (3) the Subgroup on Data Evaluation and Risk Assessment to assess the carcinogenicity of chemicals based on the adequacy of bioassay studies and data and to estimate the human risk posed by chemicals adjudged to be carcinogens, and (4) the Executive Subgroup to coordinate and to direct the activities of the Committee and to advise on matters not within the charge of one of the other Subgroups.

The Subgroup on Chemical Selection advises the head of the carcinogenesis program about which chemicals should be tested by the NCI in animal experiments. This advice ranges from "the appropriateness of testing specific chemicals in the near-term to a systematic approach for identifying representatives of large, environmentally important chemical classes for evaluation in the long-term."[21]

In practice many of the advisory activities of the Sub-group begin with nominations of chemicals by the Chemical Selection Working Group. This latter group is composed of federal employees of various agencies. Federal Health, the Subgroup, advises the Associate Director for Carcinogenesis whether a nominated chemical should or should not be tested. The final decision rests with the Associate Director.

In addition to receiving nominations from the Chemical Selection Working Group, the Subgroup itself may nominate chemicals suggested from other sources, including its own members. The Subgroup members recognize that the chemical-by-chemical approach is slow and that it does not assure that more important chemicals will be considered at an early time. Currently, the Subgroup is considering two methods for establishing priorities. The first of these is grouping chemicals on the basis of human exposure levels. For example, chemicals could be grouped into those encountered in the workplace, in food, in the air, in water, etc., generally reflecting existing Federal regulatory authority. From each of these groups, the chemicals that are most frequently encountered or that are most suspect could be

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[20] National Cancer Institute, Amended charter, Clearinghouse on Environmental Carcinogens, (typescript) May 5, 1977.

[21] National Cancer Institute, Objectives of the Clearinghouse on Environmental Carcinogens, (draft) August 31, 1977.

tested first. The second method is grouping chemicals according to structure. All chemicals can be divided into approximately 18 subgroups. Within each subgroup chemicals judged more dangerous would be tested first. An advantage to this approach is that the proportion of each subgroup already tested or being tested could be readily ascertained. As of January 1978 the Subgroup on Chemical Selection was actively considering both methods as well as a combination of the two.

The Subgroup on Data Evaluation and Risk Assessment analyzes and evaluates the results of completed tests, including some 300 to 400 tests of chemicals already performed at or for the NCI. The evaluation of this "backlog" of tests is expected to be completed by early 1978.

As final reports are received, they are assigned to a member of the Data Evaluation Subgroup for primary review. After discussion, the Subgroup votes on whether or not to accept the report. Each accepted report contains a conclusion that the tested chemical is or is not a carcinogen under the test conditions. Acceptance of the report does not mean that the subject is closed, however. The mandate of the Subgroup does not include evaluation of all animal experiments on the chemical tested, only those performed by or for NCI. Thus, the Subgroup makes a judgment on whether or not specific experiments show carcinogenic effects and whether or not those experiments demonstrate human risk. And, as the following description of a meeting of the Subgroup on Data Evaluation and Risk Assessment shows, acceptance of a report does not necessarily mean that the acceptance is conclusive.

Eight reports were evaluated at a recent meeting of the Subgroup.[22] One chemical was declared a human risk; another was declared to be non-carcinogenic without reservations. In two cases the results were declared equivocal. The unusual nature of the tumors precluded a decision about human risk in another case. Another decision was made to ignore admittedly treatment-related tumors because doubt was expressed that a human risk assessment could be made on the basis of a carcinogenic response in only one strain and one sex. Finally, in two decisions, reports with admittedly weak test protocols were accepted as demonstrating no carcinogenic response. A brief description follows of the discussion on one of these latter reports, that on the insecticide dichlorvos.

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[22] National Cancer Institute, Minutes, Fourth Meeting of the Data Evaluation/Risk Assessment Subgroups of the Clearinghouse on Environmental Carcinogens, (typescript) July 25, 1977.

The chemical dichlorvos was fed at two dose levels for 80 weeks to rats and mice in separate experiments. The animals were then sacrificed at the end of two years. A number of lesions found in test animals were absent in controls. In treated mice, 2 squamous-cell carcinomas, 1 squamous-cell papilloma, and areas of focal hyperplasia were found in esophageal epithelium. None of these conditions was found in control animals, but it was pointed out that such conditions occur spontaneously. No tumors were found in rats, but non-neoplastic, proliferative lesions were seen in the upper gastrointestional tract in 2 rats and an epithelial hyperplasia of the esophagus was observed in another. A number of treated rats developed fibrous tumor-like nodules of the skin, but these were not considered significant. The staff concluded that there was insufficient evidence to support the carcinogenicity of dichlorvos under the conditions of the tests. The primary reviewer was critical of the small number of control animals. He noted other pathologies (not mentioned in the staff presentation) which he said he had been produced in two other comparable studies, and stated that dichlorvos was a mutagen in microbial systems.

Following the discussion, the Subgroup voted to accept the report with two dissents. The primary reviewer argued that if inadequate control data made it impossible to decide that the chemical was a carcinogen, the same deficiency made it impossible to decide that it was not. The other dissenter stated that the rarity of epithelial tumors of the esophagus convinced him that they were treatment-related. Another discussion followed, and it was decided to recommend dichlorvos to the Subgroup on Chemical Selection for possible retest. The motion to refer was passed unanimously.

In this case a report cited by the primary reviewer as inadequate was accepted by the Subgroup. The conclusion was that the chemical was not carcinogenic. Having accepted the report as negative, with a conclusion based on admittedly inadequate data, the Subgroup then voted to consider the chemical for retest.

Federal Regulation of Environmental Carcinogens

Regulation in the United States is usually organized according to where or how people are exposed to danger, rather than according to the type of substance encountered. Thus, a single carcinogen may be regulated by a maze of sometimes conflicting and often inconsistent and uncoordinated statues and programs depending, for example, on whether it is found in the workplace, in foods, drugs, or cosmetics, in the air or water, or in "consumer products."

This regulatory inconsistency is heightened by the fact that it is

often difficult to tell exactly where one agency's responsibility ends and another's begins. The result is that no one agency has the responsibility or resources to serve as a focus for action. The Commissioner of the Food and Drug Administration (FDA) has recognized this problem and has initiated efforts to consolidate the procedures of the different federal regulatory agencies in developing (1) compatible testing standards and guidelines, (2) a common approach to assessing health risks from chemicals, (3) better coordination of compliance and enforcement efforts, (4) coordination of public education programs on chemicals, and (5) review of all mutual research efforts.[23]

The current federal regulatory 'framework" for controlling exposure to carcinogenic substances consists of nine primary statutes administered by four agencies, with technical advice from at least three other agencies. The statutory provisions under which carcinogens are regulated are usually contained within statutes covering toxicity in general. Except for the Federal Food, Drug, and Cosmetic Act[24] and the Toxic Substances Control Act,[25] the relevant statutes do not explicitly discuss carcinogenicity.

The FDCA generally takes precedence over other laws in the regulation of substances that may be ingested. Health hazards in the workplace (implicitly including carcinogenic substances) are covered by the Occupational Safety and Health Act,[26] which is administered by the Occupational Safety and Health Administration of the Department of Labor. Those substances to which consumers are likely to be exposed (other than foods, drugs, cosmetics, and other excluded substances regulated under different authorities) are regulated by the Consumer Product Safety Act[27] and the Federal Hazardous Substances Act.[28] The Environment Protection Agency (EPA) administers four relevant statutes covering specific areas of the physical environment: The Clean Air Act;[29] the Water Pollution Control Act;[30] the Safe Drinking Water Act;[31] and the Federal Insecticide, Fungicide, and Rodenticide Act.[32] EPA also administers the

[23] Greogory, *Washington Scene,* 5 LEGAL ASPECTS OF MED. PRAC. 54 (1977).

[24] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301.

[25] Toxic Substances Control Act, 15 U.S.C. § 2601 *et seq.* (1976).

[26] Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*

[27] Consumer Product Safety Act of 1972, 15 U.S.C. § 2051 *et seq.*

[28] Federal Hazardous Substances Act, 15 U.S.C. § 1261 *et seq.*

[29] Clean Air Act, 42 U.S.C. § 300 (1963).

[30] Federal Water Pollution Control Act, 33 U.S.C. § 1251 (1952).

[31] Safe Drinking Water Act, 42 U.S.C. § 300 (1977).

[32] Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 (1975).

Toxic Substances Control Act of 1976 (TSCA),[33] which is sometimes thought of as an attempt to introduce rational and comprehensive regulation of toxic substances (including carcinogens). However, TSCA does not mandate a comprehensive and coordinated regulatory program for carcinogens and other toxic substances. It is more accurately described as a program to "fill in the cracks" in regulatory coverage, since substances covered by other acts are still to be regulated by those acts whenever possible.

These statutes and selected relevant characteristics of their regulatory coverage are summarized in Table I. Also, the Department of Agriculture (not shown on the Table) administers legislation, such as the Federal Meat Inspection Act,[34] which can be (but rarely has been) used to regulate carcinogenic substances.

Specific versus general risk. As mentioned above, only two of the relevant statutes contain specific procedures for regulating carcinogenicity as opposed to toxicity in general. Although most of the regulatory provisions of the Food, Drug, and Cosmetic Act apply to general risks, three sections of that Act contain directives for regulating the specific risk of cancer. Substances that are ingested as food additives, color additives, and residues of animal drugs in food products are subject to very specific and explicit action if they are shown to be carcinogenic. Unlike carcinogenic substances in other areas, no allowable exposure levels may be set. Once carcinogenicity has been demonstrated to the FDA's satisfaction, there is no regulatory discretion. No risk-benefit analyses may be considered; the substance must be totally banned from foods.

The wording of the three sections dealing with the specific risk of carcinogenicity is similar. The most well-known is the "Delaney Clause," applicable to food additives, under which the proposed ban on saccharin was issued: "[N]o additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals."[35]

The Toxic Substances Control Act (TSCA) indicates that chemical substances suspected of presenting an unreasonable risk of carcinogenesis, mutagenesis, or teratogenesis, should be given priority regulatory attention by the EPA.[36] Action is to be taken against such sub-

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[33] *See supra* note 24.

[34] Federal Meat Inspection Act, 19 U.S.C. § 1306 (1967) (*as amended* 1970).

[35] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 34B(c) (3) (A). This is § 409(c) (3) (A) of the separately bound Public Law.

[36] *See supra* note 24, at § 4(f).

TABLE I: FEDERAL REGULAT

	(a) Administered By:	(b) Type of Substances Regulated	(c) Specific Procedures for Regulating Carcinogens?	(d) If "c" Does Not Apply, How are Carcinogens Regulated?
1(a) Federal Food, Drug, and Cosmetic Act — food provisions	Food and Drug Administration, DHEW	Foods, food additives, other substances or residues in food	Yes, in several sections (food additives, color additives, residues of animal drugs)	For other sections, general safety is the criterion
1(b) Federal Food, Drug, and Cosmetic Act — drug provisions	Food and Drug Administration, DHEW	Drugs and substances in drugs	No	Carcinogenicity is considered as a risk of the drug; used in weighing safety against usefulness
1(c) Federal Food, Drug, and Cosmetic Act — cosmetic provisions	Food and Drug Administration, DHEW	Cosmetics and substances in cosmetics	No	Action is taken on the basis of adulteration (unsafe or injurious)
2. Toxic Substances Control Act	Environmental Protection Agency	Substances such as foods, drugs, cosmetics, tobacco are not covered; all non-excluded substances are covered but if other Acts cover such substances those Acts take precedence	Carcinogenic and certain other substances are to receive priority attention; a ruling must be made on carcinogens within a specified time; but regulatory action is based on toxicity	Toxicity; cancer regarded as a priority class of toxicity
3-6 Clean Air Act; Water Pollution Control Act; Safe Drinking Water Act; Federal Insecticide, Fungicide, and Rodenticide Act	Environmental Protection Agency	Pollutants in the respective areas of the environment	No	As environmental pollutants posing danger to public health; toxicity
7. Consumer Product Safety Act	Consumer Product Safety Commission	Substances used by consumers (at home, in recreation, etc.)	No	As hazardous products, or imminent hazards
8. Federal Hazardous Substances Act	Consumer Product Safety Commission	Hazardous substances (in effect, it primarily covers household products)	No	As hazardous substances; toxicity is criterion
9. Occupational Safety and Health Act	Occupational Safety and Health Admin., Dept. of Labor	Hazardous substances in the workplace	No	As toxic substances; there are proposed implementing regulations dealing specifically with carcinogens

*There is some judicial opinion that for animal drug residues, *if regulated under general safety* some risk/benefit analysis must be m even if carcinogenicity is indicated.

Source: Congress of the United States, Office of Technology Assessment. *Cancer Testing Technology and Saccharin.* Washington, D.C.: U.S. Government Printing Office, 1977.

CARCINOGENIC SUBSTANCES

(e) Benefit-Risk Analysis or Consideration of Factors Other Than Safety	(f) Discretion in Regulating	(g) Relationship to Other Federal Statutes
Risks dominate; no such analysis permitted if color or food additives or residues from animal drugs are carcinogenic; if a naturally-occurring substance in food is carcinogenic, technological feasibility of removing it may be weighed against the health risk.	Carcinogenic food and color additives, and foods with carcinogenic residues of animal drugs,* must be banned; otherwise discretion is not prohibited	The Act takes precedence in areas of foods and related substances; for residues from pesticides there is an interagency memorandum of agreement between FDA and EPA.
Explicitly required; the benefits and the risks (safety) of a drug must be considered in regulating.	Yes, FDA may permit carcinogenic drugs or substances in drugs to be marketed if the benefits outweigh the risks	Takes precedence in the area of foods
No benefits to health are presumed; risks predominate in analysis; those "cosmetics" claiming positive health benefits are treated as drugs.	Banning takes place based on the discretion allowed by the adulteration sections of the Act; public health is only criterion	Takes precedence in the area of cosmetics
Explicitly required by the Act.	All regulatory actions are at the discretion of EPA	See Column "b"
Permitted	All regulatory actions are at the discretion of the Commission	At the discretion of the EPA, these Acts take precedence over the Toxic Substances Control Act
Explicitly required by the Act	All regulatory actions are at the discretion of the Commission	Not applicable to substances covered by Food and Drug Act; close relationship to Hazardous Substances Act
Not explicitly mentioned; has been interpreted as allowing it, and the Commission uses such analyses	Banning is at the discretion of the Commission; certain labeling requirements are non-discretionary	Not applicable to substances covered by Food and Drug Act
Permitted by the Act; required by the implementing regulations	Yes	Takes action when other Federal agencies have not, for workplace hazards

stances, however, under the same rule-making authorities of the TSCA as are applicable to toxic chemicals in general.

Thus, with the exception of the provisions of the FDCA and the TSCA, all major federal statutes applicable to control of carcinogenicity derive from the regulation of general risks to health from toxic substances. Only the FDCA contains provisions which explicitly direct a mandatory action, a total ban.

New versus established substances. The statutes vary greatly on whether a new[37] substance is to be regulated differently from an established one. The key distinction is whether an agency can require pre-market testing to determine if the substance is to be allowed on the market.

A peculiar case is the Consumer Product Safety Act (CPSA)[38] which permits the Consumer Product Safety Commission to require that information on the health dangers of new products be provided to the Commission before marketing. That agency, however, does not have the authority to take action until the product is on the market![39] However, those chemical products regulated by the CPSA after they are on the market, might be regulated under the TSCA which has pre-market regulatory powers.[40] TSCA could cover such substances if they were not covered by CPSA; and since they are not covered by CPSA *until* they reach the market, the TSCA may apply.

The EPA has authority to require submission of data on the safety of new and established chemical substances.[41] If such data proves insufficient for a determination of the chemical's safety, the EPA may then require further testing. Sidney Wolfe of the Ralph Nader-affiliated Health Research Group believes that the EPA's authority to require pre-market testing is discretionary rather than mandatory. According to Wolfe, when that fact is added to the Act's complicated procedures for requiring testing, the result is likely to be that adequate pre-market testing is the exception rather than the rule.[42] A differing view is held by Devra Davis of EPA's Office of Toxic Sub-

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[37] A "new" substance for our purposes will mean both a substance which has not yet been significantly used, a substance which has had substantial use but which is to be used for a different purpose, under different conditions or exposures, etc.

[38] *See supra* note 27 at § 13 (a).

[39] R. Brown, Consumer Product Safety Commission; Personal Communication, 1977.

[40] *Id.*

[41] *Id.*

[42] Wolfe, *Standards for Carcinogens: Science Affronted by Politics,* in ORIGINS OF HUMAN CANCER.

stances, who stated that the EPA *must* require premarket testing.[43] The statutory language itself is not definitive, but seems to back the discretionary view in its use of such phrases as "the Administrator *may* require..." (emphasis added). Whether pre-market testing is discretionary or mandatory, the EPA does have authority to prohibit manufacturing, processing, and marketing before and after the substance is allowed on the market.[44]

In theory, the standards of safety and of benefits from use, which the EPA utilizes in making regulatory decisions, do not differ between new and established substances. In practice, it may be more difficult to develop information on new substances, since so much of it will be based on projections of possible effects. Conversely, taking action on established substances is more difficult despite better information, because it is usually harder to remove a substance from the market than it is to prevent its entry.

The Food, Drug and Cosmetic Act (FDCA) does make some distinctions between new and established substances. If substances were in use before passage of the FDCA and if they pass a lenient screening test, even though added to food, they are not considered to be "food additives" and are therefore not subject to the sections of the FDCA relevant to food additives, unless significant questions about their safety are raised by the Food and Drug Administration (FDA).[45] On the other hand, new food additives must be given pre-market clearance by the FDA.[46] Standards are the same for new and established food additives. The FDA's refusal of a petition to market a new food additive, its removal of an established food additive from the market, and its reclassification of a substance added to food as a formal "food additive," thereby requiring it to meet food additive safety standards, are all made on the basis of the approach used to interpret evidence on safety. There is a difference, however, in which party has the legal responsibility to demonstrate the safety or danger to health of a food additive. For new food additives, the sponsor of the petition (usually a manufacturer) must show its safety.[47] But once a substance is in use, it is up to the FDA to make a case for its potential dangers.[48] This burden of going forward with the evidence is also true for color addi-

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[43] D. Davis, Environmental Protection Agency; Personal Communication, 1977.

[44] *See supra* note 33, at § 6.

[45] *See supra* note 35, at § 321(s).

[46] *Id.* at § 348(a).

[47] *Id.* at § 348(b).

[48] E. Allera, Food and Drug Administration; Personal Communication, 1977.

tives, drugs and cosmetics. Thus, the scientific criteria will vary according to the substance and the type of evidence available rather than according to whether the substance is new or established.

Assessment of risks and benefits. Three of the most perplexing aspects of the regulation of carcinogenic substances are: (1) The assessment of the risks to health care due to exposure; (2) The assessment of the benefits to health, the economy, the environment, etc., due to continuing use of the substance; and (3) The comparison of the results of the above assessments to reach a decision on whether the risks outweigh the benefits or vice versa.

Not all the applicable statutes require or even permit this type of analysis. The Delaney Clause for food additives and the Delaney-like clauses for color additives and residues of animal drugs found in foods, do not allow balancing of risks and benefits. The provisions on cosmetics in effect presume that no benefit to health will accrue as a result of their use and do not allow assessment of economic or other benefits either. Therefore when a cosmetic, or an ingredient in a cosmetic, is shown to present a danger to human health, the substance is not allowed on the market.[49] The drug sections of the FDCA, however, *require* that risk-benefit analyses be conducted.[50]

Risk-benefit analysis is *permitted* by the Clean Air Act, the Water Pollution Control Act, the Safe Drinking Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Federal Hazardous Substances Act, and the Occupational Safety and Health Act.

Such analyses *must* be performed under the Consumer Product Safety Act,[51] the Toxic Substances Control Act,[52] and the sections of the FDCA mentioned above. Implementing regulations for the Occupational Safety and Health Act also make risk-benefit analysis mandatory. Thus, most of the statutes either require or permit the balancing of risks and benefits. However, Congress has given the agencies little guidance on how to perform the assessments or the balancing.

Some of the problems in assessing risks to health from use of or exposure to carcinogenic substances have been discussed above. Two of the primary underlying problems are deciding how much weight to give to results of the often numerous tests performed on a substance, and how to interpret what the test results mean in terms of human

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[49] *See supra* note 35, at § 361; and T. Quinn, Food and Drug Administration; Personal Communication, 1977.

[50] *See supra* note 1 and T. Byers, Food and Drug Administration; Personal Communication, 1977.

[51] *See supra* note 27, at § 9.

[52] *See supra* note 24, at § 6(c).

risks. The NCI guidelines are used by most of the agencies either implicitly or as a starting point. However, the agencies prefer to judge the quality of evidence on a case-by-case basis, and few agencies have developed standard criteria to be used for these judgments. The Occupational Safety and Health Administration has, however, abandoned the case-by-case method in favor of classifying carcinogens in terms of the types of test results providing the evidence of carcinogenicity.[53] It feels this may eliminate some of the problems related to judging the strength of results and to interpreting what the results may mean to human health. It should also somewhat streamline the regulatory process.

EPA's Cancer Assessment Group is responsible for assessing risks. This group makes its own judgments about the reliability of the evidence and the weight to be assigned to those tests considered most reliable. The National Institute of Occupational Safety and Health (NIOSH), a scientific agency within the United States Department of Health, Education and Welfare, was created to provide scientific support and resources for the OSHA's programs, and for related programs throughout the government. NIOSH often performs the assessments of risks for OSHA. It bases its judgments on NCI advice to a degree, but prefers to be flexible and to make its own judgments.[54] NIOSH is also involved in the benefits side of the analysis when it estimates the technical feasability (including the cost) of eliminating or reducing exposure to a carcinogen in the workplace. As will be discussed below, the cost of removing something is, in effect, an economic benefit of keeping it.

The second underlying problem, that of interpreting the significance of test results in terms of the possible human health impact, has caused agencies much consternation. When a risk-benefit analysis is performed, it is not enough to identify a threat to health; the threat must be quantified in order to balance it against the benefits. All the agencies assume that animal results are applicable to humans. The agencies differ in their methods of extrapolation. The authors were not able to develop statements detailing how they differ because the individual agencies vary their methods, often on a case-by-case basis. A common method, however, is the use of a straight-

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[53] Occupational Safety and Health Administration, Department of Labor, Regulation of Certain Toxic Materials: Identification, Classification, and Regulation of Toxic Materials Posing a Potential Occupational Cancer Risk to Workers; Draft Regulation, 42 Fed. Reg. 192 (January 21, 1977).

[54] R. Boggs, National Institute of Occupational Safety and Health, Department of Health, Education, and Welfare, Personal Communication, 1977.

line extrapolation model, using the no-threshold assumption. Most agencies reported great interest in the use of short-term tests and expressed a desire to have the methodology and validation of such tests given attention.

Although there are problems associated with the assessment of risks, such assessment is an advanced science when compared to benefits assessments. All of the regulatory agencies and their supporting scientific agencies have expressed dissatisfaction with the methodologies used in the second half of the risk-benefit equation. Benefits of a substance include positive benefits due to use and the avoidance of costs which would accrue if the substance were not available. The most common "benefit" to be measured and weighed against risk, according to the statutes, is economic impact. How the agencies perform these assessments is something of a mystery, often to the agencies themselves. By that is meant that the analysis conducted on one substance may be entirely different from the analysis conducted on another. No published guidelines are used systematically in regulating carcinogens.

In short, assessment of benefits by the regulatory agencies is largely an ad hoc process. Although agencies are not satisfied with the product of these analyses, they cite methodological problems, lack of guidance from Congress, and the basic difficulties involved in quantifying measures of social value or utility in defense of their processes.

Although both benefits and risks must be quantified in order to conduct a risk-benefit analysis, regulatory decisions are not usually made by merely choosing the course (banning, setting allowable exposures, etc.) indicated by the numbers. The EPA, for example, has risk analysis conducted by its Cancer Assessment Group and the benefit assessment by an economic analysis unit.[55] The two groups submit their individual results in the case of action being considered under the TSCA to the Office of Toxic Substances. That Office then makes a recommendation to the EPA Administrator based on a balancing of the risks versus the benefits. By the office's own admission, this is not a straightforward mathematical decision. It is a subjective weighing of assessments which, for all their attempts to use common measures, are not equivalent in terms to those measures. For example, x thousand lives lost or to be lost may be balanced against y million dollars in economic impact, and a decision made as to which is more important to society. The decision is not based on x

[55] *See supra* note 42.

versus *y*, but rather on a subjective social judgment about the *idea* of lives versus dollars.

Living With Uncertainty

Regulation of environmental carcinogens is now approached in one of two ways: (1) Substances under the Delaney Clause *must* be banned once a scientific conclusion is reached that a carcinogenic effect has been shown; or (2) Other substances *may* be banned or placed under restricted production and use once a carcinogenic effect has been shown *and* the benefits of their use have been taken into account. This has led to inconsistent interpretations of the relevance of test results to human risk. The former approach allows no regulatory discretion once carcinogenesis is shown. Under the Delaney Clause induction of cancer by means other than voluntary consumption, including involuntary feeding, would not be accepted as conclusive. Thus, the saccharin ban was proposed only after repeated experiments in which animals ingesting the artificial sweetener developed cancer.[56]

The contrast between the Delaney Clause and other federal regulatory authorities does not reflect a fundamental difference in outlook between carcinogens that are ingested and carcinogens to which one is exposed in other ways. Such differences in regulatory discretion have the effect of forcing the scientific community to use inconsistent standards for determining carcinogenicity. Public access to substances under the Delaney Clause depends wholly on the scientific determination of carcinogens, whereas public access to substances not under the Delaney Clause depends on several factors only one of which is the scientific evidence of carcinogenesis. Faced with these circumstances, the scientific community can be expected to demand more rigorous proof under the Delaney Clause than under other regulatory authorities.

It is harder to understand why the scientific community has not developed criteria by which the relative merits of individual experiments can be judged and through which more consistent conclusions can be reached. Some of the issues in test standardization and interpretation are not readily amenable to agreement, such as the inevitable criticisms that individual experiments have not ruled out certain extraneous factors, the problems associated with benign versus malignant tumors, and the numerous pathological changes that are related but not equivalent to tumor formation. But so many of the

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[56] *See supra* note 1.

conclusions on experimental findings rest on subjective, quasi-scientific beliefs. One reviewer believes that rare but statistically insignificant tumors are proof of carcinogenicity. Another believes that they were spontaneous and are insignificant. One reviewer believes that positive short-term tests tip the finding of equivocal results in a particular animal experiment toward proof of carcinogenicity. Another will find that the two types of tests are not related. What emerges is the lack of consistency in interpretation of test results from the same data source (short-term tests, animal tests, and epidemiologic studies), and in the relationships between data sources.

Systematic attempts are of course being undertaken. The effort of the OSHA to classify carcinogens in terms of the types of test results is one example. OSHA's proposal would place each carcinogen or suspected carcinogen into one of three categories, allowable exposure levels correlating to these classifications. For example, a "confirmed" carcinogen would be based on evidence in any of the following categories:[57] (1) humans; (2) two mamallian test species; (3) one mammalian species, if the results are replicated in the same species in a separate study; and (4) a single mammalian species, if the results are supported by multitest evidence of mutagenicity.

Similar systematic attempts should be undertaken to judge the reliability of the experiments themselves. The NCI guidelines for animal testing set forth criteria for judging whether or not a particular test was properly conducted. Even these guidelines, however, are a little confused. One of the criteria listed is that the chemical should be administered by a route that mimics human exposure. This criterion is not related to the validity of test conditions, but rather to the applicability of test results to human exposure. Cancers in test animals, if the other conditions were met, would be taken as proof that carcinogenicity was shown. There would still be a question of whether the chemical would produce cancer in humans if the route of exposure were different from the test conditions. This latter question would not have bearing on the validity of the animal tests, only on their relevance to human risk.

Recommended animal test protocols now take three years to perform and the guidelines are constantly being revised. Some practical solution must be found if we are to avoid either the rigid stance of ignoring tests that do not meet current guidelines or the current approach where reviewers of completed tests often abide by their own rules of what is significant and what is not. Weighting scales could be

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[57] *See supra* note 52.

developed for the integrity of individual tests in similar fashion to OSHA's attempt to classify carcinogens on the basis of the kinds of test results. For example, final conclusions from animal tests might be limited to findings that are statistically valid. Findings of tumors that are not statistically significant or which are questionably related to carcinogenesis should not be ignored, but they also should not be given the same weight as statistically validated tumors, which is presently done by some test reviewers. In other words, some review structure should be developed for judging the validity of individual tests.

Human epidemiologic studies can be misleading. When the surveyed population consists of easily identifiable exposed groups such as workers in chemical plants, the data are quite reliable. But suspected substances to which large populations are exposed make it exceedingly difficult to isolate the effect of the substance under scrutiny from all other possible causes of the type of cancer under observation.

These epidemiologic studies usually provide probabilities on the statistical significance of their findings; *i.e.,* the degree of statistical confidence that the effect shown or not shown was not due to chance and would be replicated in similar studies. These studies usually are not explicit in stating how much of a difference from the prevailing rate of the type of cancer under observation they would be able to detect. This is particularly important for suspected carcinogens that are relatively weak. In such situations, animal tests might show a definite though low-potency effect. The failure of human epidemiologic studies to detect a carcinogenic effect may not contradict the animal data at all. Extrapolations from the animal data might result in predicted human cancer rates that were below the rates that the epidemiologic studies were capable of detecting, and it could be equally argued that the epidemiologic studies do not contradict, and might even support, the animal findings.

For regulatory purposes, animal tests and human epidemiologic studies are inadequate tools. Animal tests take too long; epidemiologic studies come after the fact. Short-term tests may offer the most promise. But the field is still in the early stages of development and, despite the conviction of some scientists that they are capable of predicting carcinogenicity, a more accurate statement would be that they are currently testing the hypothesis that short-term tests can predict carcinogenicity. Furthermore, short-term tests yield little information on the potential *quantifiable* effect in humans, a significant shortcoming for regulatory purposes.

Conclusion

Uncertainties are inherent in identifying as well as in regulating environmental carcinogens. However, regulatory decisions will continue to be made on the basis of imperfect evidence. The best hope is that such regulatory decisions are made in a consistent way, on the best available evidence and with the regulatory discretion to overturn a decision as scientific and economic analyses improve. Present procedures rely too much on the ability of scientists and economists to quantify risks and benefits. Policymakers should recognize this fact, open up the process to public discussion, and spread the responsibility for making decisions on issues with increasing impact on our technology-oriented society.

Aflatoxin Contamination in Milk

MARY LOUISE DUFAULT*

Aflatoxin B_1 is one of the most potent chemical carcinogens known.[1] Recently it has been found in milk supplies in the United States. Aflatoxin B_1 is a by-product of a common mold growth found on grains and other feed supplies.[2] It is now well established that carcinogenic aflatoxin metabolites, ingested from feed by dairy cattle, are secreted in cows' milk. A real concern exists over permitting even low levels of aflatoxin in cows' feed because of the possible risk to human consumers.[3]

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[1] Present knowledge of the aflatoxins dates from 1960 when more than 100,000 turkey poults died in England after eating peanut meal imported from Africa and South America. From the poisonous feed were isolated *Aspergillus flavus* and a toxin produced by this organism that was named aflatoxin *(Aspergillus flavus* toxin — A-fla-toxin). J. JAY, MODERN FOOD MICROBIOLOGY at 401 (2d ed. 1977) [hereinafter JAY].

[2] *See generally* Hesseltine, *Natural Occurrence of Mycotoxins in Cereals,* 53 MYCOPATHOLOGIA ET MYCOLOGIA APPLICATA 141, 148 (1974); Maggon, *Biosynthesis of Aflatoxins,* 41 BACTERIOLOGICAL REVS. 822 (1977); Rodricks, *The Occurrence and Control of Mycotoxins and Mycotoxicoses,* 2 (1) F.A.O. FOOD AND NUTRITION 9 (1976); and C. EMMONS, MEDICAL MYCOLOGY 52 (3rd ed. 1977).

[3] Carcinogenicity can vary greatly with only minor changes in structure. However, when one hydroxy group is added between furane rings of B_1 to form M_1, toxicity is not altered. This directly contradicts information in Aflatoxin Contamination of Milk, 42 Fed.Reg. 61630 (Dec. 6, 1977), which states, "M_1 though less potent than B_1 . . ." *See* Hesseltine, *supra* note 2, at 148.

The relatively recent discovery of the existence of the problem in this country gives rise to a multitude of policy questions, particularly for the Food and Drug Administration (FDA) as the chief governmental guardian against unfit food. Although the highest levels and incidence of alflatoxin contamination are in tropical or semitropical regions, where the climate favors the growth of the producing fungi, it has also been found in foods produced in more temperate zones as far north as Canada. There is probably no populated region of the earth where some aflatoxin contamination of food does not take place. In this country, aflatoxin contamination in milk is considered a potentially serious public health problem in at least four southeastern states.[4] Its presence in meat and eggs as well as in milk is likely to be even more common than limited studies have determined.

The Delaney Amendment to Section 409 of the Food, Drug and Cosmetic Act bans "food additives" found to be carcinogenic irrespective of the amount of carcinogen present.[5] However, with aflatoxin the question arises whether it is a "food additive." Notwithstanding the carcinogenic danger, the FDA has held aflatoxin in milk is not a food additive. Instead, the FDA has treated aflatoxin as a "poisonous ingredient" for which a tolerance level can be established under certain circumstances and to which the Delaney Amendment does not apply. Thus the label attached to aflatoxin determines whether food containing it is proscribed or permitted. The FDA has set a tolerance level, referred to as an "action level," below which aflatoxin-contaminated milk can be and is sold.

This treatment is indefensible both in policy and according to legal precedent. The sale of contaminated milk should not be permitted where control or elimination of the source of the carcinogen, feed ingested by dairy cattle, is feasible. (The wiser policy would turn attention to the source of the health danger, cattle feed, and to the scientific data base for ending it.) Moreover, the Court of Appeals for the Seventh Circuit, in a case concerning fish contaminated with DDT, has ruled that even where the food source for fish cannot be controlled or avoided, DDT in such processed fish is to be considered a food additive and the fish to be adulterated as a matter of law.[6] If DDT in processed fish is a food additive, then aflatoxin in processed milk must be so considered.

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[4] *See generally* Human Health and the Environment — Some Research Needs, 77 DEP'T OF HEALTH, EDUCATION AND WELFARE PUB. 83, 84 (1977); and JAY, *supra* note 1, at 401; Rodricks, *supra* note 2, at 13; and Hesseltine, *supra* note 2, at 148.

[5] Section 409, 21 U.S.C. § 348.

[6] United States v. Ewig Bros. Co. Inc., 502 F.2d 715, 718 (7th Cir. 1974).

Possible Solutions – Technological Innovations

Cereal grains, the basis of cattle feed, are the most important food source contaminated with aflatoxins.[7] Aflatoxins are produced on cereals both in the field and in storage. The most important factors controlling aflatoxin formation in the field and in storage are relative humidity, moisture and temperature.[8] One practical solution to acute or sub-chronic toxicoses is to avoid moldy food or feed. Avoidance means either prevention by the use of good harvest and storage techniques and hybrid grains resistant to aflatoxin, fungicides and pesticides, or removal by examination of food or feed and removal of moldy lots. Current technology is directed to storage. Little is known about how to avoid contamination during the growth of grain, and little progress has been made in developing resistant strains of grains.[9]

Avoidance by Prevention and Removal. Research has indicated that prevention would be the most effective and profitable way to avoid aflatoxin contamination in the long run. Prevention would necessitate improvements in harvest and storage practices. Aflatoxin mold is most likely to develop immediately following harvest while the crop is still at high moisture content. Prevention would include drying the crop quickly to safe moisture levels before storage. For some crops mold growth appears most rapidly when outer layers are damaged or broken. Insect or rodent damage increases incidence. Preventative measures to diminish risk of aflatoxin contamination should therefore include rapid post-harvest drying procedures, which may need to be done artificially, protection against rodents and insect damage, and storage at low moisture content.[10] The risk of using fungicides

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[7] Other foodstuffs found to contain aflatoxins are peanuts, cottonseed, soybeans, peas, beans, cornpeas, cassava and sweet potatoes. The grains include corn, rice, wheat, millet, sorghum, sesame and barley. Wogan, *Aflatoxin Risks and Control Measures*, 27 FED. PROC. 932, 935 (1968).

[8] Temperatures ranging from 24-30°C. produce optimal aflatoxin yields: 11-45°C. is the usual range supporting growth. Products with moisture levels above 16% are capable of supporting growth. Light was found to inhibit formation. *See* JAY, *supra* note 1, at 402. *See also* Hesseltine, *supra* note 2, at 141-53; and Maggon, *supra* note 2, at 829.

[9] *See* Rodricks, *supra* note 2, at 12 & 13. Some think that plant breeding is not the solution but that pesticides are. A 1977 study is cited showing that *Aspergillus flavus* was found only in insect damaged corn. Hollis, *The Realism of Integrated Pest Management as a Concept and in Practice – with Social Overtones*, 1977 ANN. MEETING OF ENTOMOLOGICAL SOC'Y OF AMERICA SYMP. 1.

[10] Rodricks, *supra* note 2, at 12; and Wogan, *supra* note 7, at 935-6.

and pesticides may have to be balanced against the risk of aflatoxin contamination.[11]

Aflatoxins can be found in food that is obviously moldy. More importantly, they can be found in food taken from stocks which, upon visual inspection, seem to be sufficiently high in quality to be used directly as human food. Therefore, removal, the second technique of avoidance, has limited practical value. It can provide protection only against acute aflatoxicoses. Acute human aflatoxicosis is unlikely in a country like the United States because most people here can afford to avoid moldy food. In countries where widespread food shortages exist, consumption of moldy food is not uncommon.

More likely sources of aflatoxin contamination for this country are outbreaks of veterinary mycotoxicoses which continue to be reported in agriculturally advanced nations. Animals tend to reject feeds severely contaminated with aflatoxin mold unless sweetened, but the ingestion of less heavily contaminated feeds probably lies behind the reports of aflatoxin-contaminated milk in four southern states.[12]

Processing Methods of Detoxification and Removal. In addition to prevention and removal, processing methods that detoxify or remove aflatoxins in contaminated raw foods have been utilized with varying degrees of success. Several methods have successfully inactivated or removed aflatoxin from peanuts and cottonseed. Solvent extraction is one such method. Detoxifying agents, including oxidizing agents (5% NaOCl, 10% Cl_2), alkalies (NaOH, Na_2CO_3), ammonia, and heat plus moisture have at least partially inactivated aflatoxin in oilseed meals. Although aflatoxins are relatively stable to heat under anhydrous conditions, a reduction has been achieved in peanut meal using steam pressure, *i.e.,* autoclaving for four hours.

Some procedures offer promise for other protein sources such as grains. To date, however, there have been no major breakthroughs. It is important to note that while several of these studies have resulted in apparent aflatoxin inactivation, few have been concerned with nutritive value which would be a definite concern with milk.[13]

Aflatoxins in milk are apparently not destroyed by boiling or by any other simple means. Studies on aflatoxin recovery from pas-

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[11] Hollis, *supra* note 9, at 4. Hollis considers the production of food in a hungry world the first goal of "pest management," minimizing hazards to humans and the environment as the second.

[12] Campbell & Stoloff, *Implications of Mycotoxins for Human Health,* 22 (6) J. AGR. & FOOD CHEMISTRY 1006 (1974); *See also* Rodricks, *supra* note 2, at 12 & 13; and Wogan, *supra* note 7, at 936.

[13] Wogan, *supra* note 7, at 937.

teurized or stored milk have given conflicting results. Stoloff reported complete aflatoxin recovery from pasteurized and stored raw milk. Freezing for 120 days resulted in approximately a 45% loss. Previous studies had showed losses of up to 87% after freezing for 120 days, but the 45% figure would appear to be the more reliable.[14] While a 45% reduction by freezing is certainly significant, freezing milk supplies for four months is manifestly an economic impracticability. Milk inactivation studies would, of course, not be necessary if aflatoxin could be eliminated from dairy cattle feed.

Implications for Technological Innovation. The health risk associated with low dietary intake of aflatoxins is not known with certainty. That there is some risk seems likely. Aflatoxins have been shown to produce extreme cases of cancer in some experimental animals. In specific, stable human population groups there seems to be an association between aflatoxin consumption and the incidence of human liver cancer.[15] Both factors have convinced most public health scientists that exposure to aflatoxins should be reduced to the lowest levels technologically feasible.[16]

Primate studies, which give the most accurate animal correlation of risks to humans, have demonstrated that the difference between "no apparent effect" and liver damage levels from the organospecific aflatoxin is smaller than anticipated by researchers. Epidemiological studies are lacking, but several deaths of children have been linked to aflatoxin-contaminated rice and cassava.[17] For reasons not yet fully known, in all species studied, young animals and male animals have been found to be more susceptible to acute and subacute toxicity than have adult animals or female animals, respectively.[18] Children under

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[14] Stoloff, *Stability of Aflatoxin M in Milk,* 58 (12) J. DAIRY SCI. 1789 (1975). Three plausible explanations were offered giving credence to the 45% figure rather than a figure almost double that.

[15] Rodricks, *supra* note 2, at 12.

[16] *Id.* at 12.

[17] Campbell & Stoloff, *supra* note 12, at 1010-16. There are contributory nutritional factors as well, such as protein malnutrition, which make it difficult to say with absolute certainty that aflatoxin intake alone caused death. Contaminated cassava at the rate of 1.7 mg/kg of child's weight for a short time may have caused death of one child. Wogan, *supra* note 7, at 932. For most animal species, the LD_{50} value is in the range of 0.5-10 mg/kg body weight. Lethal dietary aflatoxin levels in the duckling were 0.3 ppm and in the rat they were 3-4 ppm. While acute lethality data of this sort are useful as an index of species susceptibility, they do not give information on effects of prolonged consumption. Since modern research on this problem has only been underway since 1960, more information will doubtless come in.

[18] Wogan, *supra* note 7, at 932-4.

the age of three years, a group consuming a high percentage of milk, are the most vulnerable, but adults having longer exposure time may also be in jeopardy.[19]

Human milk can become contaminated as well. It has been found that fetal tissue may be much more sensitive to the effects of carcinogens than adult tissue; in some cases, only 1% of the doses necessary to produce cancer in adults has produced cancer in fetuses.[20] Even though some products in the United States, including milk, are contaminated at very low levels (most often 1 part per billion), human health risks may still exist particularly for infants.[21]

To reliably prevent contamination of milk requires the ability to detect even minute quantities of aflatoxin in grains consumed by dairy cattle. The presence of aflatoxin cannot be determined with certainty except by analysis for the toxins. Although cereal grains are known to be the most important food source naturally contaminated, little data on the natural occurrence of aflatoxin in cereals exists because of the lack of precise chemical assays. Two methods now used in the United States have serious limitations. The "CB" method has a sensitivity of 1-3 ppb, but the difficulty of obtaining a truly representative sample of an entire lot makes the method problematic. The other method, thin layer chromatography, provides another analytical approach, but it must always be backed by a confirmatory test since fluorescence is not always indicative of aflatoxins.[22] One of the most pressing practical needs in aflatoxin research is for a rapid screening method for detection at grain elevators and mills.[23]

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[19] Campbell & Stoloff, *supra* note 12, at 1006-15.

[20] J. CORBETT, CANCER AND CHEMICALS 19 (1977). Carcinogens can interact with the fetus and produce cancer later in life as in the DES cases.

[21] Rodricks, *supra* note 2, at 13. The number of human carcinogens known is becoming larger as more research is being done in this area. For example, stilbestrol in 1971, methyl chloromethyl ether in 1973 and vinyl chloride in 1974. The incubation time requires for chemical carcinogenesis in humans is relatively long. An induction period of 10, 20 or even 30 years is not uncommon. It is a scientific fact that many chemical carcinogens become chemically (covalently) bound to DNA, RNA and proteins of the cells in certain susceptible tissues. It has become common knowledge that cancer is induced by these chemical carcinogens as a result of this binding to these macromolecules. Aflatoxin is one of those chemicals that induce cancer by this mechanism. It has also become axiomatic that most chemical carcinogens must be metabolized (changed chemically) by the body before they become carcinogenic. Aflatoxin is not an exception. Heidelberger, *Chemical Carcinogenesis,* 44 ANN. REVS. OF BIOCHEMISTRY 79-126 (1975).

[22] Hesseltine, *supra* note 2, at 142-6.

[23] *Id.* at 146. Chromatography involves fluorescence under U.V. light; "CB" utilizes a mini column technique.

The United States needs a policy to deal with the problem of how much aflatoxin, if any, can safety be ingested. Incentives for improved techniques must be provided which will not wipe out the dairy industry or small farmers. Aflatoxin B_1 is not just a carcinogen; it is one of the most potent carcinogens known. Aflatoxin at high levels presents risks to the health of livestock thereby precipitating an economic problem. Contamination by aflatoxin M_1 at even less than acute levels may well present the problem of cancer development for humans, particularly for the young.

Epidemiological studies are badly needed to complement studies in experimental animals. More technological development is necessary for the prevention of aflatoxin, utilizing natural methods where effective, with backup of pesticides and fungicides where necessary. Differences in varietal susceptibility need close examination. Suitable drying and storage techniques need to be developed. Detoxification methods need greater attention. Sampling and analysis procedures need refinement. Much more research on an effective aflatoxin elimination or inactivation method of milk processing is crucial. Even the United States in the past few years has experienced the effects of having specific foods in short supply. This country is not wealthy enough to lose milk and grain through aflatoxin contamination or unsophisticated enough technologically to justify not coming up with a knowledgeable answer.

Implications for Public or Regulatory Law

The implications for public or regulatory law are clear. Congress through appropriate agencies must decide how the aflatoxin problem is to be handled from a legal perspective. Elimination or inactivation of aflatoxin in milk is proving complex and, at present, are goals which have not been achieved. The next question then is what is to be done with contaminated milk. The Food and Drug Administration (FDA) is authorized by statute to regulate this type of problem. Possible solutions range from outright restriction on sales of contaminated milk to establishing tolerance levels below which aflatoxin contaminated milk may be sold. Incongruous as it might seem, what is done turns on the label applied to aflatoxin, *not* on the scientific data base available.

FDA Classifications – Tolerance Levels. FDA classifications for various substances in foods are not necessarily mutually exclusive; there can be overlap or the possibility of uncertainty as to the category under which a food is best defined. For example, Section 409 of the

Food, Drug and Cosmetic Act (FDCA) governs food additives.[24] Section 402 governs adulterated food including naturally occurring poisonous ingredients; Section 408 governs tolerance for poisonous ingredients in food; and Section 408(a) governs tolerances for pesticide chemicals in or on raw agricultural commodities. "What's in a name" has determined the fate of a number of foods marketed in this country in the past few years. Depending on the category used, either tolerance levels have been accepted or the equivalent of a ban has been imposed.

If aflatoxin in milk is labeled a "food additive" under Section 409 of the FDCA, that milk must be restricted from interstate sale.[25] Aflatoxin is a known carcinogen. Under the Delaney Clause to Section 409 there is *no* acceptable level of carcinogenic contamination.[26] The milk would be held adulterated as a matter of law under Section 402.[27]

If, on the other hand, aflatoxin-contaminated milk is held to the standard for "poisonous ingredients" under Section 408[28] or to the standard for "naturally occurring poisonous ingredients" under Section 402(1)(a),[29] it may be permissible for it to be sold. Section 408 indicates, with respect to added substances, that if the poisonous substance cannot be avoided by following good techniques of processing, tolerance levels may be established. If there are no tolerance levels established, the substance *may* be held adulterated under Section 402.[30] Section 408 turns on the avoidability of the poisonous substance.

At present there are no tolerance levels established under Section 408 for aflatoxin contamination in food, but the FDA could promulgate a tolerance level if it so desired.[31] The FDA's avoidance of the issue is evidenced by its December 1977 ruling that since there were no tolerances established under Section 408 for aflatoxins, it was establishing something called an "action level" of 0.5 ppb for aflatoxin M_1 contamination of milk.[32] This could be taken as good news or as

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[24] Food additives are defined in § 201(s); 21 U.S.C. § 321(s).

[25] Sec. 409; 21 U.S.C. § 348.

[26] Sec. 409(c) (3) (A); 21 U.S.C. § 348 (c) (3) (A).

[27] Sec. 402; 21 U.S.C. § 342.

[28] Sec. 408; 21 U.S.C. § 346.

[29] Sec. 402 (1) (a); 21 U.S.C. § 342 (1) (a).

[30] Sec. 408; 21 U.S.C. § 346.

[31] *Id.*

[32] *See* Aflatoxin Contamination of Milk, *supra* note 3.

bad news. It is good that at least some low level has been set above which aflatoxin-contaminated milk cannot be sold. However, there is still some question as to the safety of such milk even at 0.5 ppb particularly for the very young. By setting what is called an "action level," the FDA has temporarily legalized the sale of milk contaminated with aflatoxin up to 0.5 ppb and it is not known if this is reasonably devoid of hazard. Not classifying aflatoxin as a "food additive" has made it possible to sell contaminated milk legally with the FDA's approval. The rationale seems questionable at best in light of the potent carcinogenic capabilities of aflatoxin.

At first glance it would seem that since aflatoxin is a "poisonous ingredient" in milk it should be governed by Section 408. However, it is also a "naturally occurring toxin" under Section 402(1)(a) as it is not put into milk as an additive in the sense that, for example, color is added to margarine. Section 408 covers poisonous or deleterious substances *added* to food. It might also be expected that Section 408 would prohibit *poisonous* foods per se. Such, however, is not the case. Under Section 408 the FDA may exercise its discretion for the "protection of the public health" and set tolerance levels for poisonous ingredients which "cannot be avoided by good manufacturing practice."[33] Only when those limits are exceeded would Section 402(a)(2)(A) apply, which designates a food as adulterated and therefore unsafe.[34]

Section 402 does apply to "naturally occurring poisons." Like Section 408, it gives the FDA discretion in determining whether a food such as aflatoxin contaminated milk is or is not adulterated. Section 402(a)(1) states that "in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health."[35] A lower standard therefore applies for naturally-occurring poisons than for *added* poisonous, unsanitary or deleterious substances. No statutory authorization exists at present to set official standards for natural poisonous and deleterious substances comparable to the authority to set standards for some food additives and pesticide chemicals.[36]

It should be noted that the effect of some poisons on the body varies

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[33] Sec. 408; 21 U.S.C. § 346.

[34] Sec. 402 (a) (2) (A); 21 U.S.C. § 346 (a) (1) (A).

[35] Sec. 402 (a) (2); 21 U.S.C. § 346 (a) (2).

[36] Note, *Health Regulations of Naturally Hazardous Foods: The FDA Ban on Swordfish,* 85 HARV. L. REV. 1025, 1034 (1971-72) [hereinafter *The FDA Ban on Swordfish*].

directly with the extent of their presence. The effect can be plotted on a continuum in relation to concentration of the substance and degree of exposure to it, considering attendant variables such as whether the substance is degraded or metabolized, stored or excreted, etc. The body can tolerate some amounts of some poisons, such as methol-mercury, the substance found in swordfish,[37] with no apparent ill effects. The body excretes methylmercury at a rate which eliminates one half the amount present in about 70 days, the substance's biological half life. At low levels of consumption, intake and elimination balance to maintain an equilibrium of low toxic levels in the body. The equilibrium level is the scientific basis for calculating safe rates of consumption.[38] It is on this basis that tolerance levels are set "limiting the quantity as necessary to protect the public health."[39] In a similar situation, that of pesticide chemical levels (DDT), the court in *United States v. Ewig Bros. Co.*,[40] said, "Scientists seem to agree that if the DDT level is high enough, the food should not be consumed by [hu]man[s] and, conversely, if the amount is sufficiently small, ingestion of DDT may be harmless." The level set should be generally recognized among qualified experts as safe.[41]

It should be kept in mind that some may consider arbitrary the tolerance levels selected in ppm or ppb. Ideally, the levels are to be based on the best available scientific information and not merely on economic or political motivations or fragmentary data. The ideal, unfortunately, is not always achieved. Because rapid progress has been made in measuring techniques in the past ten to twenty years, it is now possible to detect the presence or substances at increasingly minute levels. That the presence of a poison is detectable in many cases does not per se indicate a food is not safe. "A thing is safe if the risks are judged to be acceptable," not if it is completely "free from risk."[42]

Aflatoxin-contaminated milk presents a special problem because aflatoxin is a carcinogen. As explained above, if aflatoxin were to be considered a "food additive" under Section 409 of the FDCA instead of a "poisonous ingredient" under Section 408 or a "naturally occurring poison" under Section 402, aflatoxin contaminated milk would be au-

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[37] An Article of Food Consisting of Cartons of Swordfish, 395 F.Supp. 1184 (D.C.N.Y. 1975).

[38] *See* page 5 in text and *The FDA Ban on Swordfish, supra* note 36, at 1027.

[39] Sec. 408; 21 U.S.C. § 346.

[40] 502 F.2d 715 (7th Cir. 1974).

[41] *Id.* at 718.

[42] W. LOWRANCE, OF ACCEPTABLE RISK at 8 (1976).

tomatically prohibited from sale at any measurable amount, no matter how minute. Aflatoxin is clearly not "added" as that term is generally used. However, Section 201(a) defines "food additive" to mean "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[43] Clearly, aflatoxin found in milk could come within this definition.

The term "food additive" does not usually include "pesticide chemicals" on raw agricultural commodities, which are covered by Section 408(a). Subsection (a), "[T]olerance for pesticide chemicals in or on raw agricultural commodities," states that any pesticide chemical not generally recognized as safe shall be considered unsafe unless a tolerance in or on the raw agricultural commodity has been prescribed or it has been exempted from the requirement for a tolerance, all at the discretion of the FDA. If tolerances or exemptions have been made, the food is not considered adulterated within Section 402 (1) (a). If there is no residue, registration of the pestidice is also granted.[44]

Case Law. The definitions discussed above were interpreted in 1974 by the Court of Appeals for the Seventh Circuit in *Ewig Bros., supra,* a case concerned with fish contaminated with DDT. The court held that *before* the contaminated fish are processed DDT is a "pesticide chemical" on a raw product, while *after* processing the presence of DDT causes the fish to be adulterated as a matter of law without any proof that it is actually unfit as food.[45] If DDT in processed fish is considered a food additive, then certainly aflatoxin in processed milk must be considered a food additive.

Precedent or legal basis for the acceptability of aflatoxin in milk can also be drawn from *United States v. An Article of Food Consisting of Cartons of Swordfish,*[46] wherein mercury in swordfish was held to be a pollutant and therefore an "added substance" within the meaning of Section 402 (a) (1) notwithstanding the claimant's argument that mercury could not be an "added substance." The claimant contended that mercury, found in fish for centuries, is not naturally pro-

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[43] Sec. 201 (s); 21 U.S.C. § 321 (s).

[44] Sec. 408a (1); 21 U.S.C. § 346a (1).

[45] *See* United States v. Ewig Bros., *supra* note 6, at 722.

[46] *See* note 38, *supra.*

duced by fish but is acquired through the external food supply of the fish.[47]

The analogy between mercury-contaminated fish and aflatoxin contaminated milk is clear. Both contaminants have existed for centuries. Both are in the food source of the contaminated substance or, in the case of aflatoxin-contaminated milk, in its product. The analogy breaks down insofar as there is no control over what chubs and swordfish eat, but there is control over what cows producing contaminated milk eat. The argument for banning aflatoxin-contaminated milk is even stronger because cows' feed can be controlled, while that of swordfish cannot be controlled.

Milk, although denominated as a raw agricultural commodity by the FDA, after processing could be held to the standard for processed foods, *i.e.*, pesticide residues in manufactured dairy products come within the definition of "food additives" and are subject to food additive regulations. There are no tolerances or exemptions from tolerances for pesticides in milk or dairy products. Thus, when they contain pesticide residues in any amount, they are defined by statute as unsafe and therefore adulterated.[48]

It seems incongruous that chemical pesticides should be subject to zero tolerance in milk while a known carcinogen should be permitted at an "action level." There has been criticism of the FDA's concepts of "no residue" and "zero tolerance" by, among others, the National Academy of Science, which finds those concepts untenable in light of finer measurements. The Academy suggests the use of terms like "permissible residue" or "negligible residue," a "safe" use or a "no effect" level. However, with respect to carcinogens, the Academy says that to approve such a compound for use when it might leave a residue on food would require the "most extraordinary" justification. It considers insufficient data on a safe tolerance a reason for using zero tolerance.[49] It could be argued that there is insufficient data on a safe tolerance level for aflatoxin in milk.

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[47] An earlier ruling in *Vita Food* was in direct contradiction to the later ruling in the *Swordfish* case. The court in *Vita Food* held that while fish were adulterated within § 402(a) (2) (C) by additives of DDT and Dieldrin, the company did not actually "add" these to their product. They therefore were accidental and not "food additives" under the Act. United States v. Vita Food Products, Inc., 356 F.Supp. 1213 (D.C.Ill. 1973), 21 ALR Fed. 302, *rev'd on other grounds,* 502 F.2d 715.

[48] Fistere, *Pesticide Residues – Legal Aspects,* 20 FOOD DRUG & COSM. L.J. 684, 685 (1965).

[49] National Academy of Science, *No Residue and Zero Tolerance,* 20 FOOD DRUG & COSM. L.J. 608, 614-22 (1965).

Case law suggests that aflatoxin in milk could be considered a food additive under Section 409. The sole criterion for identifying a food additive is whether a substance which may become a component of, or affect the characteristics of, any food is generally recognized among qualified experts as having been shown to be safe.[50] The now famous Delaney Amendment, Section 409(c)(3)(A), specifically provides that "no additive shall be deemed to be safe if it is found to induce cancer when intested by [hu]man or animal."[51] The additives need not be intentional. The definition includes incidental additives as well; accidental ones are excluded.

The FDA has no discretion but must prohibit the contaminated food if a carcinogen is present as a food additive at any amount. The purpose of the 1958 Delaney leigslation, as explained in 1972 in *Continental Chemiste Corp. v. Ruckelshaus*, was to prohibit the use of food additives which had not been adequately tested to establish their safety.[52] Prior to such testing, new additives are to be banned by a statutory concept of per se adulteration.

Burden of Proof. The purpose of Congress in approving the Food Additives provisions of 1958 for Sections 402 and 409 was to prevent injury to the public health by sale and transportation in interstate commerce of misbranded and adulterated foods. The burden of proof was shifted. Prior to 1958 the Government had to prove a substance was harmful. Now the burden is on the processor to prove a substance is safe. Satisfaction of the criterion of safety requires proof of a reasonable certainty that no harm will result from the additive, but it does not require proof beyond any possible doubt.[53]

The Delaney Amendment to the Food Additives Amendment of 1958 indicates the magnitude of Congressional concern about hazards created by carcinogenic chemicals.[54] Since its passage, the Delaney Amendment has met with the scathing criticism that it was the result of technical naivete and scientific advocacy rather than scientific objectivity.[55] The major criticism has to do with the Amendment's

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[50] United States v. 41 Cases, 420 F.2d 1126 (5th Cir. 1970).

[51] *See* note 27, *supra.*

[52] Continental Chemiste Corp. v. Ruckelshaus, 461 F.2d 331 (1972).

[53] Myers, *Construction and Application of Food Additive Provisions of FDCA* (21 U.S.C.S. § 321(s), 321(u), 342(a) (2) (c), and 348), 21 AM. L. REP. FED. 314, 321-7 (1974).

[54] *Id.* at 345.

[55] Blank, *The Delaney Clause: Technical Naivete and Scientific Advocacy in the Formulation of Public Health Policies,* 62 CAL. L. REV. 1084, 1120 (1974); Hall, *Safe at the Plate,* 12 NUTRITION TODAY 6 (1977).

prevention of agency discrimination in controlling carcinogens. Critics cite the great improvements since 1958 in the detection of increasingly minute amounts of such substances in food as a reason for the desirability of discretion. The argument frequently degenerates into the contentions that setting tolerance levels for carcinogens is no different from setting them for acute poisons, that not all encounters with carcinogens are equally harmful and that the tolerance levels chosen for carcinogens should be set so as to create no more than an acceptable risk to human life.[56] The problem with the rationale, whether applied to aflatoxins in milk or to additives in convenience foods (a burgeoning market of the industrial food giants who are most upset by the Delaney Amendment), is the difference between acute poisons and carcinogens. For the former, the harm of an over-the-threshhold dose is limited to harm to certain categories of persons under certain conditions. For the latter, harm also clearly increases with potency, but whether there is any threshold dose below which the harm is acceptable is not known.[57]

The FDA's decision to set an "action level" of 0.5 ppb for aflatoxin contamination was a judgment of risk that a low dosage would be safe and therefore acceptable. The action raises many questions. What would be the cost of no action level at all, that is, of banning contaminated milk from interstate commerce and spreading the cost over the remaining milk to be sold. Dairies face a similar problem now in relation to pesticide residues in milk. The model for controlling pesticide residues may be relevant for controlling aflatoxin-contaminated grain. If shipped, milk with pesticide residues can be labeled "adulterated," dairies can be prosecuted, and the milk subject to seizure. If the milk is not shipped, but destroyed, the dairies may suffer severe financial loss. However, there may be no prosecution of the dairy if, under a "good faith" provision, the dairy has received grain containing pesticide residues from second parties. The dairy can establish a guarantee signed by the person providing the grain. (This does not apply to grain produced by the dairy for its own cattle's feed.) With the guarantee, the dairy can get an indemnity payment for dumping pesticide-contaminated milk. The entire provision is cited as an improving technological experience which has been used much

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[56] Blank, *id.*

[57] Environmental Defense Fund, Inc. v. United States Dep't of Health, Education and Welfare, 428 F.2d 1083 (1970), included testimony to the effect that scientifically there was no way to determine a "safe" level for a substance known to produce cancer in animals.

less than expected.[58] The same plan would seem to have potential value for aflatoxin-contaminated grain as it would increase the incentive to eliminate the hazard at its source. A plan should be developed at the state level, too, which would include all milk, not just that involved in interstate commerce.

Conclusions

In the United States, formal policy procedure, not informal rulemaking, is needed to deal with the aflatoxin problem realistically. The FDA in particular, of all the federal agencies, has seen the value of the former with the opportunity for the presentation of opposing viewpoints, cross examination, etc. Informal standards are effective only to the extent that suits are won in court. A private litigant's chance of prevailing over a government agency like the FDA over a technical standard, however informal, is especially slim.[59] Grave problems of inference would be present relating cause with effect, and legal cause with actual cause. An individual's chances of recovery against a milk company would be remote.

In some parts of the world the threat of cancer is remote when compared with the immediate reality of hunger, but in the United States we can afford to be concerned with even a slight risk of cancer.[60] Ultimate cost may actually be less if costs are internalized by the industry than if aflatoxin-contaminated milk carries a high social overhead. On a global scale, no fully satisfactory risk-benefit equation has been established for aflatoxin or for any toxicant which is to some extent unavoidable in food (where the only benefits are economic and the conservation of food supplies).[61] Evaluation of risk takes on a new dimension where food is the only fundamental life support system for which there is no choice. Where the ultimate hazard is starvation, not risk-benefit, risk v. risk would have to apply.[62]

It would seem that, in light of the best available information, there is no safe level of aflatoxin consumption. Steps should be taken quickly to insure better avoidance of aflatoxin formation for the good of consumers and the economics of the dairy industry. Unless there is some greater risk in not so doing, aflatoxin should be considered a

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[58] Fistere, *supra* note 48, at 692 (in reference to 21 U.S.C. § 303(c)).

[59] LOWRANCE, *supra* note 42, at 9.

[60] Rodricks, *supra* note 2, at 14.

[61] *The FDA Ban on Swordfish, supra* note 36, at 1035-8.

[62] Hollis, *supra* note 9, at 11.

"food additive" under the Delaney Amendment and subject to a zero level tolerance.

The rate of cancer is highest in developed countries. With this in mind, the United States would be wise to be exceptionally careful in minimizing the incidence of carcinogens in our food.

An Assessment of the Use of Cost-Benefit Analysis in Regulatory Agency Decision Making*

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CONSIDERABLE dissatisfaction has been expressed with the process and results of regulatory agency decision making. Recommendations have been made that the Federal agencies employ rational, "balancing" approaches such as cost-benefit analysis in conducting their standard-setting and adjudicatory functions.

This paper examines some current uses of cost-benefit analysis by several agencies in their decision-making processes, and identifies and discusses apparent limitations.

Statutory and Judicial Requirements

Statutes enacted by the U.S. Congress provide the frameworks for regulatory decision making by the Federal agencies and prescribe, usually in general terms, several criteria and considerations to be employed by the agencies in carrying out their discretionary and mandatory functions. Such statutes commonly impose on an agency the requirement *simultaneously* to consider technical and economic feasibility charac-

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teristics and health and environmental effects in their decision-making processes to establish standards, issue licenses, or take other agency action. This responsibility to consider such diverse factors simultaneously may be imposed by a single statute on an agency, or by a set of statutes enacted over time, all of which may apply to a single agency.

Comprehensive statutes to control externalities, such as the Federal Water Pollution Control Act Amendments of 1972, the Consumer Protection Act, the Noise Pollution Control Act, and the National Environmental Policy Act of 1970 (NEPA) are examples of Congressional enactments that call for agency consideration of such factors in decision making. Statutes governing resource development and management by Federal agencies, such as the Outer Continental Shelf and the Submerged Lands Acts, the Reclamation and the Water Resource Acts, and the Atomic Energy Act of 1954 (as amended) also impose similar requirements for decision making on the Federal departments and independent agencies.

Judicial review of agency decision making under these statutes has been particularly rigorous and has had the effect of insuring that Federal agencies comply with such multiple-criteria requirements in their decision processes. For example, NEPA and the Administrative Procedure Act,[1] which apply to all agencies, have been judicially interpreted as requiring agency use of "balancing analysis" *(Calvert Cliffs v. AEC)*[2] and "substantial inquiry" *(Citizens to Preserve Overton Park v. Volpe)*[3] by agencies in their decision-making processes, thereby requiring that all relevant factors such as economic and technical feasibility, and health and environmental effects, must be simultaneously considered.

The agencies have therefore sought to develop and apply new techniques for decision making that can satisfy these statutory and judicial requirements for balancing multiple factors, such as cost-benefit analysis.

Agency Implementation

Agencies are now turning to cost-benefit analysis in an effort to comply with statutory and judicial requirements. Cost-benefit is a relatively

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[1] NEPA (42 U.S.C. 4321-4361) and APA (5 U.S.C. 500-576) are generically applicable to all agencies of the Federal government, and similar statutes have been enacted in many states for applicability to state agency regulatory activities.

[2] In *Calvert Cliffs,* the D.C. Court of Appeals required that agencies use the results of their environmental impact assessments under NEPA in "balancing analyses" to reach their final determinations. [449 F.2d 1109 (1971).]

[3] In *Overton Park,* the U.S. Supreme Court dealt with the need for compiling a full, adequate record to support agency decisions. [401 U.S. 402 (1971).]

simple technique for decision making, and has been extensively used by the Corps of Engineers, the Bureau of Reclamation, and other departments and agencies in the design of water-resource programs, dams, and flood-control and other projects. Engineers and economists are therefore experienced in the application of the technique to developmental purposes. Congress has promoted its use in water-resource programs through the creation and activation of the Water Resources Council.[4] Further, the courts have not objected to the use of the technique per se as a method of reaching balanced decisions in such developmental programs, have generally been unwilling to substitute their judgment for that of the agency on developmental matters which involved the application of the technique, and have usually stated that alleged deficiencies in such uses of cost-benefit is a matter for Congressional review in annual authorization and appropriation hearings held by several Congressional committees on the sequential elements of these long-term developmental programs.[5]

Quite recently, use of cost-benefit has been undertaken by *regulatory* agencies as well, in their decision making to set standards, issue licenses, and reach siting and other regulatory and nondevelopmental decisions. These agencies include, for example, the Environmental Protection Agency and the Nuclear Regulatory Commission.

Several committees of the National Academy of Sciences, the Academy itself, and other advisory and professional associations have recommended further use of the technique by these and other regulatory agencies as the most feasible method for bringing about rational decision making. Social scientists and economists have worked on further development of the technique to enable its users to accommodate qualitative or not readily quantifiable considerations.

Chief among the several regulatory agencies to adopt the technique, provide in their regulations for its use, and employ it as a matter of course in their decision making is the Nuclear Regulatory Commission (NRC). NRC now employs cost-benefit in setting radiation standards "as low as practicable," and in its licensing of nuclear facility construction

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[4] The Water Resources Planning Act, 43 U.S.C. 1962, created the Council. *See generally,* U.S. Water Resources Council, *Summary and Analyses of Public Response to Proposed Principles and Standards for Planning Water and Related Land Resources and Draft Environmental Statement,* July 1972.

[5] *See,* for example, EDF v. Corps of Engineers, 325 F. Supp. 728 (1971); Conservation Council of North Carolina v. Froehle, 340 F. Supp. 222 (1972); and discussion in Hillhouse, *Federal law of water resources development* in FEDERAL ENVIRONMENTAL Law (E. Dolgin & T. Guilbert eds. 1974) at 872-873.

and operation.[6] The Environmental Protection Agency has also promulgated regulations requiring that the technique be used for the establishment of other radiation standards and for the setting of emission standards for toxic chemicals under the Water Pollution Control Act Amendments of 1972. The Consumer Product Safety Commission and several other agencies have not formally acknowledged use of the technique, but recognize that the technique or a rough equivalent is used in its decision processes.[7] Implementation of the National Environmental Policy Act by various agencies, in accordance with the *Guidelines* of the Council on Environmental Quality,[8] has brought about further adoption and use of the technique in certain agency decision-processes (Table 1).

Use of a new technique on this scale for national decision making on matters involving the management of risks may have unforeseen and undesirable implications. The time is ripe to directly address the implications of using cost-benefit in regulatory decision making, before such implications become manifest.

Issues for Evaluation

The use of cost-benefit analysis by regulatory agencies raises several issues that deserve study, so that appropriate corrective measures may be taken in time to avoid undesirable societal consequences. Discussion of these issues is briefly presented here. Note that most of these issues are inherent in any regulatory decision process, but are most urgently and clearly raised when regulation is based on cost-benefit.

a. *Identification of Costs and Benefits.* The identification of costs and benefits may appear to be a relatively simple task, but in reality is an immature art. The Leopold, Sorenson, and GSA matrices[9] are of some use as checklists of some possible effects that may attend the construction of discrete projects, but are inadequate to the task of identifying the effects of a standard (for radiation, for example) that may have national and global consequences over long time frames. To what extent will agency regulatory processes provide adequate notice to potentially af-

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[6] *See generally,* 10 C.F.R. 20, 10 C.F.R. 50, and other sections of NRC's regulations, particularly Appendix 1 to 10 C.F.R. issued in 1975. For discussion, *see Consideration of Health Benefit-cost Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives,* Washington, D.C.: National Academy of Sciences (BEIR Committee), 1977.

[7] Findings based on interviews with personnel of various agencies.

[8] CEQ Guidelines, 40 C.F.R. 1500 (1973).

[9] For discussion of matrix methods, *see Review of Decision Methodologies for Evaluating Regulatory Actions Affecting Public Health and Safety,* Chap. 6, Battelle Northwest Laboratories, Report BNWL-2158 (1976).

TABLE 1
ECONOMIC BENEFIT/COST ANALYSIS IN ENVIRONMENTAL IMPACT STATEMENTS *

	Prepared	Included
Agriculture		
Forest Service	Generally	Yes
Soil Conservation Service	Yes	Summarized
Commerce	Yes	Yes
Defense	Sometimes	Yes
Air Force	Yes	No
Army	Sometimes	Sometimes
Navy	Yes	Summarized
Corps of Engineers	Yes	Yes
Health, Education, and Welfare	No	No
Food and Drug Administration	Yes	Yes
Housing and Urban Development	No	No
Interior		
Bureau of Indian Affairs	Yes	No
Bureau of Land Management	Often	No
Bureau of Outdoor Recreation	Occasionally	No
Bureau of Reclamation	Yes	No
Fish and Wildlife Service	No	No
National Park Service	No	No
Geological Survey	No	No
Justice		
Law Enforcement Assistance Administration	Yes	Yes
Labor	No	No
State	No	No
Transportation	Not usually	When prepared
Federal Aviation Administration	Not usually	When prepared
Federal Highway Administration	Not usually	When prepared
Treasury	Not usually	
Energy Research and Development Administration	Yes	Yes
Environmental Protection Agency	No	No
Federal Energy Administration	No	No
Federal Power Commission**	Yes	Yes
General Services Administration†	Yes	No
Nuclear Regulatory Commission	Yes	Yes

*Source: Council on Environmental Quality, *Environmental Impact Statements: An Analysis of Six Years Experience by Seventy Federal Agencies*, Washington, D.C., 1976.

**FPC prepares comparative economic-analysis and cost-effectiveness studies on proposed actions but does not conduct classic benefit-cost studies.

†GSA does a cost evaluation, but an "economic benefit/cost" analysis is not always included or attached to the EIS.

fected interests and enable them to play a role in the identification process?

To what extent will it be possible to identify significant long-term effects by means of the various assessment techniques we now possess or can develop? To what extent will the characterization of effects as costs or benefits reflect establishment values and the status quo and ignore changing values and behavior (e.g., the NRC's characterization of increased energy supply as of virtually unlimited benefit at a time of increased concern about the need to conserve energy and fuel resources and move to small technologies)?

b. *Measurement and Quantification of Costs and Benefits.* Similar uncertainties arise regarding the capacity of regulatory agencies adequately to measure and value costs and benefits, particularly those which cannot be properly valued by the marketplace or economic processes. Can we measure or value such effects as carcinogenicity, mutagenicity, teratogenicity, consumer convenience, or the perpetuation of certain aspects of certain lifestyles such as mobility? Are we ready to accept the valuation of $1000 per man-rem promulgated in 1975 by the Nuclear Regulatory Commission in order to conduct its cost-benefit analyses and set standards for ionizing radiation?[10] Should such values be commonly adopted by all agencies with regulatory jurisdiction over different aspects of the same problem, such as EPA and FDA, which share with NRC to some extent control over ionizing radiation? By what legal procedure shall we set such values? To what extent shall we enable various interests to play a role in the objective measurement and subjective valuation processes? Who will represent the unborn (future generations) in the valuation of mutagenic and other future effects, which arise from standards established by NRC and EPA for radiation and toxic materials?

c. *Consideration of Distributional Effects.* Closely associated with the foregoing issues is the need to consider adequately distributional effects of agency decision making based on cost-benefit. Clearly the adverse effects of radiation emitted from nuclear power plants in accordance with NRC standards will fall most heavily on those living in the environs of the power plants, but this distributional effect pattern is not adequately recognized in the NRC's use of cost-benefit analysis. How shall we safeguard the interests of these impacted groups and others such as the poor, the primitive, and the unborn?

d. *Determination of Appropriate Weighting Factors.* A facile solution to the issues of quantification and distributional effects is the

[10] *See* NRC's Appendix I, *supra* note 6.

use of weighting factors in cost-benefit analysis. How shall we set and determine the adequacy of such factors, in light of conflicting values and varying attitudes about the distributional patterns, and citizen willingness to accept certain probabilities of risks?

e. *Post-hoc Considerations and Enforcement.* After using cost-benefit to establish regulatory actions, it can be assumed that unintentional and intentional violations of the prescribed regulations will occur. The Nuclear Regulatory Commission has learned that despite its application of radiation standards (developed by use of cost-benefit) to utilities, violations occur, such as excessive accidental releases of radioactive effluents. How to enforce or otherwise act on the basis of such violations when, despite the unforeseen increased costs, the economic viability of the regulated party and the needs of dependent consumers are at stake: plant shutdown, the imposition of new safeguards (retrofitting), or waiver of requirements? In other words, is the cost-benefit basis for designing and regulating power plants, in this case, enforceable once the plants have been built and are in operation?[11]

f. *Structural-political Considerations.* In light of the foregoing issues, what structural-political considerations should be addressed? Again, to consider the experience of the Nuclear Regulatory Commission, the cost-benefit analysis used to approve the construction and operation of a new facility is premised on a specific population dose of radiation and its valuation.[12] Yet the Commission lacks the authority to control population density and migration in regions off-site from the plant, and the States are reluctant and/or incapable of maintaining the population subject to exposure at the density levels used in the calculations for initial approval of the facility. Will such structural-political developments proceed concurrently with the use of cost-benefit to assure its efficacy and enforceability over time? Further, in light of the valuation and distributional issues noted earlier, what political developments will be necessary and achievable to enable meaningful participation or representation of various constituencies including the unborn?

g. *Technology-forcing Considerations.* If the emitted substance to be controlled to some degree by cost-benefit regulation is always going to be harmful to some, such as is the case for radiation and for toxic chemicals with linear dose-response relationships, the objective of regulation is to force the development and application of new tech-

[11] *See* discussion in Chap. 4 of NAS-BEIR report, *supra* note 6.

[12] *See supra* note 6.

nologies to provide more effective limitation of releases on the sources of such pollutants, over time. To what extent will the use of cost-benefit for establishing regulations and prescribing control technologies retard the technology-forcing function? Information on control technologies is more available to industry than to government; in the past, industry has presented pessimistic data on the feasibility and costs of new technological developments to government agencies (e.g., auto emission technologies).[13] How shall we assure the adequacy of the data and opinion on such technological developments, so that cost-benefit does not become a tool for conveniently maintaining the status quo on control technology, nor be used to stultify the forcing of new control developments?

h. *Ethical Limitations.* What constitutional and ethical limitations will be applicable to the use of cost-benefit? How will due process, equal protection and other legal and ethical concepts apply to the conduct of regulation by cost-benefit? Is it ethical to use an economic method which requires valuation in order to establish the quality of life of this and future generations?

In another hazard or safety context, that of vehicular safety regulation, it has been noted that:

> If... the principal benefits anticipated are the savings in lives and/or reductions in the frequency or severity of injuries which cannot be reasonably quantified in monetary units, serious theoretical and conceptual difficulties arise.... Virtually all cost-benefit studies involving the loss of life or limb have assigned fixed monetary values... typically obtained either by computing the discounted future income of individuals or by computing the discounted differences between future earnings and personal consumption. These concepts and approaches have been criticized on a number of grounds....
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> National Highway Traffic Safety Administration (NHTSA) has expressed a similar [critical] view. In its recent notice of proposed rule-making concerning school bus crashworthiness, the agency stated that it 'has conducted conventional cost-benefit studies on school bus safety, but the normal valuation techniques evidently do not adequately reflect general public opinion on the importance of protecting children from death or injury. *It is obvious from the voluminous mail and Congressional interest that society places a higher value on the safety of its children than a conventional cost-benefit analysis would indicate...*' [B]ecause of the major conceptual and methodological difficulties in the valuation of life and limb, cost-benefit studies will be appropriate only in the decision-making processes involving standards *not* primarily intended to save lives and reduce injuries — that is... standards to reduce property damage.
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> Congress recognized this distinction. Under Title I of the *Motor Vehicle Information and Cost Savings Act* (P.L. 92-513, 1972) — principally intended to reduce property damage losses resulting from low-speed crashes — it included a mandatory requirement for the Department of Trans-

[13] *See* discussion in Chap. 4 of NAS-BEIR report, *supra* note 6.

> portation (DOT) to consider both the costs and benefits.... However, in considering the National Traffic and Motor Vehicle Safety Act, (P.L. 89-563, 1966) which empowered DOT to set motor vehicle safety standards aimed at reducing deaths and injuries, Congress rejected draft language requiring such studies for safety standards. (Hearings Before Committee on Interstate and Foreign Commerce, U.S.H. Rep., 89th Congress, 2d Session, on HR 13228, "Part 2, Traffic Safety", p. 1203).

Similar Congressional rejection of cost-benefit for setting standards and for other features of regulatory decision making, in favor of the determination of health parameters and other ambient effect-oriented approaches, is found in the legislative history and enactments on Clean Air and on Water Pollution Control. The Federal courts, in reviewing regulatory agency decisions on pollutants with considerable health implications, have also demanded that health factors be given a high priority in the thinking and nature of such decisions, indicating that cost-benefit alone would be inappropriate.[14]

j. *Accountability.* To what extent will the use of cost-benefit analysis promote the accountability of government decision makers to the courts, the affected interests, and the public at large? Will the jargon and arcane nature of the methodology retard lay understanding of agency decision processes? The cost-benefit approach of the Nuclear Regulatory Commission is complex and not easily comprehensible. The courts and other accountability mechanisms must be evaluated in terms of their ability to cope with the advent of regulation based on cost-benefit. For example, the following balancing analyses are all now potentially applicable to the NRC process of approving an application by a utility for a license to operate a nuclear power facility:

(a) Use of cost-benefit by the NRC in promulgating agency standards and other rules of general applicability to power plant performance.

(b) Use of cost-benefit by the NRC in promulgating limitations for a specific power plant for design approval.

(c) Use of balancing analyses in determining whether or not the separate construction and operating licenses should be issued for a specific plant.

For the first two steps, use of cost-benefit is mandated by the NRC's *Appendix I* and other regulations.[15] Alternately, the use of a "balanc-

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[14] *See,* for example, EDF v. Ruckelshaus 439 F.2d 584 (D.C. Cir. 1971).

[15] *See supra* note 6.

ing analysis" is mandated by NEPA for all three steps when such steps constitute "major actions" of environmental significance.

For the dual licensing procedures of the third step, the NEPA mandate for "balancing analyses" is clear; and a Federal court has recently cautioned that the NEPA requirement applicable to the issuance of an operating license may not be short circuited — that a facility which meets NRC regulations does not concurrently and automatically qualify for licensing without the required weighing of risks and benefits under NEPA. Nevertheless, for the specific case before it, the court concluded that:

> Apart from the requirements of NEPA or similar ones already implicit under AEA [Atomic Energy Act], it would be pointless, and a waste of agency resources, to require the AEC [Atomic Energy Commission] to reapply efforts that have already gone into its basic health and safety regulations, in individual licensing proceeding, in the absence of some evidence that a particular facility presents risks outside the parameters of the original rule making. And in evaluating the sufficiency of agency determinations in particular cases it would be stultifying formalism to disregard the whole record and test AEC compliance by only the evidence received at so-called "health and safety" hearings; or NEPA compliance only on the basis of so-called "environmental" hearings.[16]

This judicial decision promotes administrative efficiency by eschewing duplication of balancing analyses, and seems to make good sense. But it is clear that such efficiency is justified only when the risks and benefits appropriate for the facility-licensing balancing task under NEPA have been adequately considered in the prior balancing undertaken by the agency under its own regulations (e.g., NRC *Appendix I).* Determination of these justifying circumstances is a complex task which rests ultimately with the courts. The extent to which the courts can handle this difficult task responsibly will therefore depend on judicial willingness to examine the substantive features of agency decision processes, and the development of judicial expertise on cost-benefit.

k. *Modification and Alternatives to Cost-benefit.* Finally, what modification or alternatives to cost-benefit should be considered, so that the issues identified can be diminished? Will use of screening models, multi-attribute analysis, and other progeny of cost-benefit reduce some of the problems of valuation? Does cost-effectiveness analysis provide a better method of simultaneously considering diverse factors in regulatory decision making and also insuring that various social-well being parameters are not breached by the regulated activities?

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[16] Citizens for Safe Power v. Nuclear Regulatory Commission, 6 E.L.R. 20095 (D.C. Cir. 1975).

This inventory of issues attending the use of cost-benefit analysis in regulatory decision making indicates that research and public discussion on the subject at this time is a responsible and necessary course of action, if future decision making is to be both rational and humane.

Special Considerations in the Regulation of Environmental Carcinogens

a. *Regulatory Patchwork.* Responsibility for the regulation of environmental carcinogens is scattered throughout many U.S. government agencies today. So, as a toxic metal such as cadmium, or an herbicide, or any other carcinogenic chemical wends its way through the environment and food chain to its human receptors, it passes through the jurisdiction of many agencies. But despite the many watchdogs, the same carcinogen may elude certain critical controls because of serious regulatory omissions or gaps in legislated authority enacted by Congress.

The Federal agencies with primary regulatory responsibilities for the control of environmental carcinogens are the Environmental Protection Agency, the Nuclear Regulatory Commission, the Food and Drug Administration, and the Occupational Safety and Health Administration. However, other agencies, ranging from the U.S. Army Corps of Engineers to the Department of Transportation, also play roles in the regulation of carcinogens. Each of these agencies has statutory authority to regulate the use and emission of *some* of the substances, from *some* of the sources, in *some* of the pathways, for the purposes of protecting *some* of the population under *some* circumstances.

Each agency has its own objectives, analytical approaches, databases, and control criteria, but often no agency has adequate authority or motivation to control at certain critical points. Substances such as polychlorinated biphenyls (PCBs), implicated in cancer of the liver, have therefore eluded coherent systematic control. To some extent, this gap may be the result of the agencies' failure to coordinate or implement their functions properly. However, the primary problem seems to be inadequate Congressional legislation, which has established agency functions in this inefficient and uncoordinated manner.

This regulatory patchwork results mainly from uncertainty as to what constitutes cancer, the diversity of suspect substances and their pathways to their victims, the many possible but difficult-to-test synergistic factors, and the varied susceptibility of the affected population.

Environmental carcinogens fall into several classes, traceable to specific sources. The major classes of environmental carcinogens include the trace metals (beryllium, cadmium, etc.), synthetic and organic chemicals (DDT, PCBs, etc.), combustion products (aromatic hydrocarbons), other chemical products (nitrites, asbestos, etc.), and ionizing radiation from medical, industrial, and energy activities.

Each presumed carcinogen has its own environmental and commercial pathway from source to human receptor. Common pathways include air, water, soil, the food chain, drug use, and the direct application of medical and other services. Some human receptors are "voluntarily" exposed as consumers and workers, some are "bystanders" who have not voluntarily subjected themselves to exposure, and some fall into both categories. The human receptors vary in their susceptibility to cancer; the most susceptible include the very young, the pregnant, and those who smoke cigarettes. The unborn are also extremely vulnerable to these substances and create a relatively new and difficult class of receptors for the agencies to try to protect.

The specific contribution to human cancer of each substance and each source, each pathway and causal relationship, the intervention of exogenous and synergistic factors, and the adequacy of laboratory and animal data and their extrapolation to humans are among the myriad issues besetting government regulatory agencies. As a result, the Federal agencies must grapple with the serious problems of legal proof in their attempts to set standards. The same uncertainties confront the Federal courts when they review agency rule-making on standards and other agency decisions.

b. *The Analytical Pattern.* At the heart of the regulatory confusion in dealing with environmental cancer is the analytical method used by the separate regulatory authorities. Many agencies employ a "balancing process," in which the costs of establishing and maintaining any levels of emission and human exposure to a carcinogen are balanced against the economic or social benefits accrued by the production and use of the substance. In some cases, agencies use a highly formalized cost-benefit analysis. In other cases, the weighing of the benefits and risks to society which would be incurred from the various levels of emissions and exposure is more informal. In either case, the net risk or cost and the net benefit is estimated, valued, and quantified before the agency determines which of several possible levels of emission and exposure it should allow, in light of available control techniques.

This balancing approach leads each agency to impose a limitation or level of control on the source of an environmental carcinogen at the

general point where costs or risks are equivalent to benefits. Some agencies add margins of safety or weighting factors to their analysis, either by choice or to satisfy statutory requirements.

The problems of such "balancing" approaches have been discussed earlier in this paper, and include:

- What value should be placed on human life, illness, or suffering?
- Who should decide on such values?
- How should such values be determined?
- How are cases judged where benefits accrue to some but risks accrue to others? How does one judge the distributional and equity issues?
- How should we value the lives of the unborn?
- How reliable and objective are the designated costs of new control equipment, which are largely based on information from the industry to be regulated?
- How accurate is the agency's assessment of benefits to society from the activity in question?

These are significant problems for the balancing process, and at the least, new techniques are badly needed to elicit public attitudes and apply ethical safeguards to protect minorities and the unborn. For example, when the Corps of Engineers proposes to use a chemical herbicide to clear duckweed from navigational channels, and the EPA approves the action (and thus approves the subsequent contamination of the water, environment, and food chain), some relatively arbitrary judgments have been made by the two agencies as to the probability of human illness or death to be sanctioned, possibly resulting from the originally beneficially intended use of the herbicide.

c. *The Costs Add Up.* Today's fragmented use of "balancing" by individual regulators has a pernicious, cumulative effect over many agencies' decisions. Each decision by each separate agency inevitably rationalizes an additional contribution of carcinogens and risks to the human environment. So each decision effectively increases the total amount of environmental cancer. Such regulatory decisions occur daily. These "justifiably" allowable risks could conceivably accumulate to the point where an entire present or future population could be at substantial risk. Although each regulatory body is concerned only with its own incremental contribution to future cases of environmental cancer, each incremental contribution adds to the number of people whose lives will be affected.

One may differ with this conclusion. The results of such incremental decisions may not be additive; there may be safe thresholds of exposure within which no harm occurs; the analysis possibly assumes an erroneous linear relationship between dose and response; perhaps only the same, particularly susceptible human receptors will be at risk, although their risk will be increasing. Nevertheless, some sort of cumulative effect can be expected. Over time it will be substantial.

Taken to its logical extreme, our present fragmented uses of "balancing" in regulation present an even more absurd scenario:

Each agency justifies its own small contribution to environmental cancer on the ground that it constitutes only a minute fraction of all cancer. (Some agencies, such as the Nuclear Regulatory Commission, have already adopted this logic.) But all agency regulations together will create an environment in which the number of cancer cases has increased. So, the Catch 22: as the number of victims of environmentally induced cancer grows ever larger, the significance of each agency's contribution actually diminishes.

Therefore, an agency could conceivably justify an even greater contribution to environmental cancer in the future, and set even less effective controls on the toxic substances it is required to regulate. This scenario, though not yet realized, can be anticipated, given the fragmentation of regulatory authority and the use of balancing in the many small decisions made by the regulators.[17]

Conclusions and Recommendations

The implications of using cost-benefit in regulation deserve analysis far beyond the scope of this review, primarily because of our increasing reliance on the technique to justify decisions which put the health and safety of present and future generations at risk. Assuming that this reliance will continue, we must rigorously review the capabilities of Congress, the administrative agencies, and courts for insuring that uses of the technique are socially appropriate on legal and ethical grounds. We must reinforce the features of administrative practice and judicial review that promote the accountability of those employing the technique, and develop measures for evaluating uses of the technique on specific regulatory matters. The central issue is our capacity for social control of science and technology. We are learning that our problems lie not with stereotypes of agencies and industries, nor with "bad" technologies, but with our analytical and regulatory

[17] For discussion of the issues raised in this section, *see* M. Baram, *Regulation of Environmental Carcinogens,* 78 TECH. REV. (No. 8) at 40-42 (1976) and Chap. 4 of NAS-Beir report, *supra* note 6.

capabilities, which must somehow provide the "felicific calculus" to integrate rationality and humanism in decision making.

The regulatory context in which cost-benefit is now being used is a relatively intangible one for most citizens. It is remote in spatial and emotional terms, more complicated and less amenable to citizen understanding and participation, than the developmental context which is usually set at the local level and which usually involves issues which can be appropriately resolved by a balancing of local interests — which are more readily identifiable and measurable.

The questions about uses of cost-benefit in the regulatory context raised in this paper are significant in that they relate to societal capacity to protect human health and welfare for this and the succeeding generations which will bear the risks of contemporary decisions on radioactivity and other harmful substances.

Serious consideration should be given to the adoption of alternatives to cost-benefit for such regulatory decision making, in light of the questions which have been raised. It is unlikely and unacceptable that alternatives be chosen which do not balance various factors in some systemic and structured process. Therefore, the choice of an alternative is limited, and *cost-effectiveness* analysis becomes an obvious candidate.

Cost-effectiveness analysis requires the articulation of objectives, the weighing of the alternative means to achieve the various articulated objectives, and the selection of the least cost approach. For regulation of nuclear energy sources of radioactivity, use of the cost-effectiveness approach would mean the establishment of societal health objectives and risk parameters (e.g., carcinogenic risks) by Congressional or other institutional processes that are acceptable as being socially representative.

The task of making such decisions on health objectives would certainly be a difficult one, but once accomplished, the results could serve to insure that regulatory decision making on energy and other activities involving harmful externalities is accountable to articulated societal objectives for environmental health. This process would also force consideration of our role in providing stewardship for future generations. Consideration of alternatives to cost-benefit for regulatory decision making, such as cost-effectiveness analysis, is perhaps the most critical need of the times from the standpoint of human health and survival.

Group Exemptions (1978 Draft) for Licensing Restrictions in the EEC (A Forensic View)

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Parturient montes, nascetur ridiculus mus.
(The mighty mountains in labor give birth
to a mere mouse.) *Horace, Ars Poetica*

The latest draft Regulation for providing a group or block exemption for licensing restrictions has surfaced from the EEC Commission. This latest draft, which differs only slightly from a number of earlier drafts, shows the rather inflexible attitudes of its drafters. Numerous comments have been published about the earlier versions, but it was thought better to wait until now to see if the strong criticism leveled at the Commission from various quarters would result in salutary changes showing up in the later drafts. Regretfully, this is so only to a very small extent.

In all fairness, in criticizing the Commission draft, one must also look at the practices prevailing in the Common Market countries before the Commission started to regulate in this surprisingly drastic, unusual fashion.

We in the United States have lived under, and have become used to, various antitrust laws which have existed since the last part of the nineteenth century. On the other hand, except for some limited type

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cartel laws, no such contraints existed in Europe. This accounts for the rapacious licensing tendencies and restrictions demanded by European licensors, particularly those in France, Germany and Switzerland. It was the survival quite late into the twentieth century of such European rapacity which has led quite a number of non-European countries, mostly South American countries, to introduce quite stringent restrictions to protect domestic licensees. We have heard again and again from South American regulators that their restrictions were aimed primarily not at American but at European licensor practices.

Before the establishment of the EEC, European licensing partners were generally puzzled by the United States antitrust laws. Initially, they had to be persuaded to refrain from the insistence on certain clauses, especially if they were in the position of licensor, when they negotiated with a licensing partner from the United States. As their experience with United States licensees increased, they have gradually become used to that "strange phonomenon," the United States antitrust laws. However, in their licensing activities in other countries, they continue to use clauses which are not acceptable to United States partners.

It was in this licensing atmosphere that the Rome Treaty, with its regulatory bureaucracy, was established. The extreme licensing restriction practices have brought about more extreme kinds of regulatory tendencies by the Commission. Therefore, what we in the United States may perceive as an excess of zeal in the regulatory proposals of the Commission, is really only a return to the more extreme licensing practices of European licensors.

United States antitrust laws have been developing gradually in the courts and through legislation since the end of the last century. Europe, on the other hand, was thrown suddenly into the sea of antitrust regulation and had to learn to swim right away. Even with the gradual development of antitrust laws in the United States, antitrust enforcers in the United States continue to manifest a bias against the legally sanctioned restrictions inherent in patents. It is small wonder then that the European antitrust enforcers who did not have the tempering effect of time are manifesting an even greater anti-patent bias. One might have been less surprised to see such a document issue from a group of developing countries than from the EEC.

The correct premise is that a businessperson should be free to do anything he desires unless it is prohibited by law. Under normal circumstances, regulation should not be directed towards permitting certain licensing restrictions, but towards deciding whether any

should be prohibited. The Rome Treaty, on the other hand, in Article 85(3) contains a system of exemptions for innocuous restrictions which may nevertheless appear to have an anti-competitive effect under Article 85(1). Thus it became a *fait accompli* in the EEC that the point of departure is "all is wrong" except that which is permitted.

Under these circumstances, a properly conceived project for indicating kinds of licensing restrictions which would generally appear to be "clean," should merely aim at compiling a list of licensing restrictions which would have *no detrimental effect.* Instead, the Commission, in Article 1 of the draft, chose to concentrate on clearing those restrictions the use of which, as the EEC points out in its introduction, would have, in its opinion, a *salutary* effect. The Commission was looking at such factors as whether a restriction improves the production of goods; whether it promotes technical progress by increasing the number of production facilities; the quantity of goods produced in the Common Market; whether they make it possible for entities other than the patentee to manufacture goods using the latest technology and to develop such technology further by making patent holders more willing to grant licenses and by making it easier for other enterprises to decide to run the risks involved in investing capital. This is the wrong approach. Licensing restrictions should not be judged on the basis of whether they bring about a desirable result but rather whether there is any reason for prohibiting them. The only proper time one might look at possible desirable results occurs when desirable and undesirable results have to be balanced against each other in order to determine whether a restriction should be cleared or not.

The premise of the Commission's regulation effort is not only wrong but it is also poor politics. This accounts for the extremely poor reception of the proposed Regulations not only by private industry but also by governments of member states. In the proposed Regulations, the Commission went far beyond the mere compilation of licensing restrictions which they would view as not being objectionable. The wrong premise of the Commission can be illustrated by the following statement from the preamble of the draft regulation:

> The Regulation must specify what obligations in restraint of competition may be contained in a patent licensing agreement. It may be left to the contracting parties to decide which of these obligations they specifically include in the patent licensing agreements to best achieve the desired advantages.
>
> The Regulation must also determine the restrictions or clauses which may not be included in patent licensing agreements to which it applies.

The premise should have been to provide a list of "clean" restrictions to reduce any uncertainty in the industry and also to reduce the administrative burden of the Commission in policing agreements. Instead, we must contend with a most complex, interwoven document which, in Article I, sets out a rather meager list of such "clean" or "white" restrictions; in Article II sets out a set of "gray" restrictions, the presence of which in an agreement would not vitiate the "cleanliness" of any of the "white" restrictions from Article I that are in an agreement; and, in Article III sets out a number of "black" restrictions, the presence of which in an agreement would make "dirty" any restrictions from Article I which are in agreement. Thus, by inference, the Commission went further than it should have in establishing a list of "gray" restrictions by inferring that the legality of the restrictions in Article II might be questionable; and an additional list of "black" restrictions in Article III which they infer to be per se violations of Article 85 (1) of the Rome Treaty. Whether this kind of lawmaking is the proper role of the Commission, or whether it should be left to the European parliamentarians and the courts is an issue that will not be addressed here. However, the author believes this kind of approach was a grave mistake and the Commission should have foreseen the difficulties that would occur as a result of its promulgation of the "gray" and "black" lists in addition to Article I.

The basic error hails from Regulation 19 of 1965, which foresaw the inclusion of a prohibited list in any future block exemptions. This basically wrong approach was compounded by the inclusion of the "gray" list of Article II. The block exemptions require an entirely new approach instead of a superannuated Regulation from 1965. That Regulation is about as ready to be killed off as is the Christmas message from 1962.[1]

A further problem is created by the fact that the English language version of the proposed regulations is almost incomprehensible. The lack of clarity is exemplified in the following passage: "Patent licensing agreements of the category defined in Articles 1 and 3 of this Regulation impose no restrictions which are not indispensable to the attainment of these objectives. In the context of this Regulation such restrictions are excluded by Article 3."

The proper approach would have been, and still could be, the compilation of a set of restrictions which the Commission views as unobjectionable. The Commission should not issue any Regulations about what it considers impermissible. That should be left to the usual

[1] 139 J.O. EUR. COMM. 2918 (1962).

methods of lawmaking. On the other hand, the Commission might wish to promulgate informal guidelines which explain its philosophy about impermissible practices instead of an *ex cathedra* expose of the same.

The author sees no need for qualifying a list of unobjectionable restrictions as the Commission intends to do in Articles II and III of the proposed Regulation. While it is generally true that it is possible to include a restriction in a license agreement the presence of which would have the effect of creating an undesirable result, there still would be no need to tar any unobjectionable restrictions also present in the same agreement as being suddenly unacceptable. The objection should rather focus on condemning that part of the agreement which brought about an undesirable result even when coupled with a per se unobjectionable restriction. Therefore, any compilation of unobjectionable restrictions by way of a block exemption could stand on its own without mentioning any other restrictions which in the view of the Commission would be questionable or objectionable.

Another problem with the draft Regulation is its unduly broad prohibitive approach. The Commission should address itself to problems of restriction of trade between the member states. While these problems might be at the heart of the Commission's objective, this central topic has taken a back seat to the much broader prohibitive tenor of the latest draft. In so doing, the Commission has also placed itself into unnecessary conflict with a number of national laws such as know-how provisions, exclusivity, etc., in the case of field of use restrictions.

The poor approach taken by the Commission throughout this Regulation is further illustrated in the introductory portion where the Commission tries to explain its thinking. For example, it states that "the Commission considers that control over the marketing of a licensed product within the Common Market is not a matter that relates to the existence of the patent," and "obligations on the part of the licensor are not matters which relate to the existence of the patent." These statements further illustrate the broad brush interpretation of the prohibitions of Article 85(1) by the regulators of the Common Market who tend to create broad prohibitions. All one can do then is to create exceptions to the prohibitions. This may be the reason why countries such as the United Kingdom, which have legal systems which find it difficult to accept this kind of "lawmaking," are so vehemently opposed to these proposed Regulations. Fortunately for those of us in the United States, our system does not provide for the promulgation by the Antitrust Division of such regulations without

first engaging in the Constitutional lawmaking process of obtaining authority from our elected representatives.

These pronouncements from the Commission must be viewed in the context of the purpose of the Regulations. In the almost acceptable Article I, the Commission sets forth those licensing restrictions which, each viewed by itself, would not raise an eyebrow within the Commission. Therefore, one might say that the itemized list of the first part of Article I constitutes a list of exceptions to the policing obligations of the Commission. This does not detract from the fact that the theoretical underpinnings of the document are based on entirely incorrect premises.

The EEC Commission's position on exclusive licenses presents neither solace nor sense. It is the first organization in developed countries by which exclusive patent licenses have been attacked. The Commission's attitude stems primarily from a misunderstanding about the nature of patents and of license agreements involving features of exclusivity.

In a speech to a largely United States audience, a senior official[2] of the Commission stated that United States law is an important source for the Commission's antitrust philosophy. He cited *Standard Oil Co. of California v. United States*[3] as the paragon case for the ideological underpinnings of the Commission's position on exclusive patent licenses. There is one hitch: the *Standard Oil* decision dealt neither with patents nor with licensing. That case was concerned with exclusive dealing arrangements in which a buyer was compelled not to use, or to deal in, the goods of the seller's competitors, *i.e.*, a violation of Section 3 of the Clayton Act.[4]

It is interesting to note that the Commission attempted to carry its mistaken reading of the *Standard Oil* case a step further by applying the "quantitative substantiality" test (by trying to quantify the substantial lessening of competition) into their earlier rulings (such as in *Kabelmetall/Luchaire*[5] and *AOIP/Beyrard*[6]) on the perceived legality of certain exclusive patent license agreements. This kind of superficial misreading of United States law would also account for the previ-

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[2] J. Verges, *A Review of EEC Competition Policy and Regulations vis-a-vis Licensing Technology*, 19 (3) IDEA 195, 201 (1978).

[3] Standard Oil Co. of California v. United States, 337 U.S. 293 (1949).

[4] 15 U.S.C. §§ 12-27.

[5] Kabel-und Metallwerke Gutehoffnungshutte/Ets. Luchaire, O.J. EUR. COMM. (No. L 222) 34 (1975).

[6] Association des Ouvriers en Instruments de Precision/Beyard, O.J. EUR. COMM. (No. L 6) 8 (1976).

ous use of United States antitrust decisions as the basis for one or another position taken by Commission officials. On the occasion of such past pronouncements, various of the so-called "cartel cases" decided in the 1940s and 1950s by the United States Supreme Court, were referred to as purportedly illustrating condemnation of certain patent licensing practices. In making such references, Commission officials entirely ignored the fact that very few of these "cartel cases" have any precedent value in judging individual licensing restrictions by themselves because all of these cases involved one or more clearly pernicious practices in addition to one or more licensing restrictions which would, by themselves, be quite legal even today.

The fundamental error of the Commission is that it decided that exclusive licenses fall under Article 85(1) and can be exempted only under Article 85(3). The author believes this attitude of the Commission is entirely unreasonable.

Patents assure a form of legal exclusivity to their owners. For that reason alone, any legal decision concerning exclusive arrangements which does not involve patents immediately loses any value as a precedent.

Now that it has been established that the Commission's views lack any ideological underpinnings for generally condemning exclusive licensing arrangements (on which, incidentally, the EEC court has never spoken but only the Commission in such cases as the *Davidson Rubber*[7] case and the *Raymond/Nagoya*[8] cases) a more reasoned examination of the alleged anti-competitive effects of exclusive patent licenses will be undertaken.

It is a legal axiom that the owner of a right can delegate that right to another. The right to exclude others, which is inherent in the patent right, can be sold or licensed to others. So long as there is a right in the patent owner not to license his patent and to continue to exclude others from the use or practice of the patented invention, the effect remains the same if he exclusively licenses that right to another person. The result then is that it is still one person who has the right to exclude others from practice in the patented invention. Consequently, the exclusive license under a patent right would leave the economy in the same shape as if the patentee had not licensed his rights at all. Therefore, nothing pernicious is perceivable in an exclusive patent license as long as the net result of that act on the economy did not result in any change. This is exactly why exclusive patent

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[7] Davidson Rubber Co., O.J. EUR. COMM. (No. L 143) 31 (1972).

[8] Raymond/Nagoya Rubber Co., O.J. EUR. COMM. (No. L 143) 39 (1972).

licenses have not been condemned in any responsible circles, with the exception of the Commission's mistaken intrusion into this field. It is conceivable that in one extremely rare situation, where it could be established that the acquirer of an exclusive license already has a dominant position in the relevant market in the EEC, the acquisition of the exclusive license would deepen that dominance so that a case for "monopolization" akin to a violation of Section 1 of the Sherman Act[9] (or the reverse of the situation which existed in the *Burroughs/Geha* and *Burroughs/Delplanque*[10] cases), could be established. Even in that situation, it is not the granting but the acquisition of the exclusive license which might bear examination.

In the introduction to the most recent preliminary Draft of the proposed block exemptions, the Commission distinguishes between exclusive patent licenses for manufacturing and using in contrast to exclusive patent licenses for sales of patented goods, with the latter being acceptable only under certain narrow circumstances. This recognition of the separate character and licensability of the three main attributes (manufacture, sale, and use) of patent rights is by now the only surviving feature of the largely defunct Christmas Message of 1962 which would now be officially overruled by the draft Regulation. Furthermore, in the introduction, the Commission uses its own arguments to support its grudging reluctance to place exclusive manufacturing and use licenses on the "white" list of Article I. The Commission makes it very clear that it does not approve of such exclusivity because the patentee waives his right to determine at any time the number of licensees to whom he would grant a license. The Commission objects to the possibility that a patentee, having granted an exclusive license, is no longer in the position of being able to change his mind later to grant licenses to others as well. Whereas, if he had not granted any licenses, or if he had granted only a nonexclusive license, he could decide at any later time to grant further nonexclusive licenses. The Commission does not indicate why this result would be undesirable and the author can see no reason why the Commission would take this attitude. In the absence of an explanation, the aforementioned consequence of granting exclusive manufacturing or use licenses becomes merely an unqualified truism without harmful effect.

The other truism explaining the Commission's dislike for exclusiv-

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[9] 15 U.S.C. §§ 1-7.

[10] Burroughs/Geha Werke and Burroughs Delplanque, O.J. EUR. COMM. (No. L 13) 50, 53 (1972).

ity is that it would have the effect of preventing the licensor himself from manufacturing and using the patented invention which he, if it had been generated by him, would be best qualified to exploit. So what?! Why is the Commission concerned with having the best qualified exploiter do the exploitation? In any event, exclusive licenses normally have minimum performance conditions which make the license cancelable if the conditions are not met. Therefore, if the exclusive licensee is not the best qualified exploiter of the invention then this will become known and the exclusive license can be terminated.

It is clear that the Commission has failed to provide a cogent reason for its suspicious attitude towards exclusive manufacturing licenses. It has not analyzed its reasons and it has in no way demonstrated that exclusive patent licenses would lead to an economically undesirable result. It is interesting to note that, after all that tempest in the introductory comments, it does grant unqualified block exemptions for manufacturing and use exclusivity albeit only for qualified block exemptions for exclusive licenses to sell.

The Commission engages in another faulty assumption in treating exclusive patent licenses to sell in the same way it treats export prohibitions. In its misguided thinking, the Commission tends to lose sight entirely of the fact that patents can in no way be asserted against exports from, but only against imports into, a country if a patentee has a patent in the country to which the import is being sent. The Commission appears to confuse exclusive licenses to sell a patented product with exclusive sourcing agreements, as evidenced by its reliance on *Standard Oil.*[11]

The analysis applied to exclusive licenses in general would also apply to an exclusive license to sell a patented product. The only pernicious result that could flow from exclusive licenses to sell patented products would be the possibility that under some circumstances the free movement of goods within the EEC would be hindered. The internationalization of the doctrine of exhaustion of the patent monopoly within the EEC, as last and most clearly enunciated in the *Centrafarm*[12] case, would take care of that problem. Therefore, no basis is seen for drawing an artificial distinction in the case of exclusive licenses for sales of patented products especially in such an arbitrary fashion as done in the second part of Article I. The fresh winds

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[11] Standard Oil Co. of California v. United States, *supra* note 3.

[12] Centrafarm B.V. v. Sterling Drug, Inc., [1974] C.J. Comm. E. Rec. 15/74.

of the *Sylvania*[13] decision have not yet wafted as far as the Commission.

The concluding part of Article I, despite its convoluted language, reveals that it qualifies the block exemptions granted in Sections II and III in that the exclusive sales license exemption of Section II and the export prohibition exemption of Section III are limited only to cases where either the licensor or the licensee is a relatively small company, the period of the restriction is limited in a manner specified by the Regulation, and the licensee is involved in the manufacture as well. Another provision allows unrelated entities to be sold throughout the EEC. This last provision would appear to make the entire limited dispensation of Sections II and III completely meaningless.

In summary, Article I exempts a number of insignificant licensing restrictions. By the same token, one might include in the block exemption a large number of other similarly innocuous restrictions, such as an obligation by the licensor to maintain patents or to notify the licensee before abandoning any; accounting requirements; audit clauses; etc. Thus, the only significant exemption clarified by Article I is the exclusivity of manufacturing and use restrictions and the limited variety of exclusive sales and export prohibition restrictions. All of the other items of the block exemption are obviously acceptable.

Article II contains restrictions on the licensee which the Commission apparently views as being of questionable validity. If these restrictions had been entirely acceptable, the Commission would have included them in the block exemption provisions of Article I. Thus, the uncertainty is compounded by the Commission's creation of a gray area. This is entirely undesirable.

Article IX of the draft Regulation is the real sleeper because it casts a shadow over the entire block exemption exercise. In this Article, the Commission reserves the right to withdraw the benefit of the block exemption of Article I with respect to an agreement if, upon an examination undertaken on its own initiative or upon the initiative of another, it finds that the net result of an agreement would not qualify it for exemption. Article IX sets forth a number of illustrative conditions which could trigger a personalized examination of an agreement.

In view of the foregoing and in view of the adverse comments of the various experts from both private and government sources, the author expects the controversy to continue for some time.

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[13] Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36 (1977).

Law Center Report

We are pleased to report the publication of the first monograph in the P.T.C. Law, Science and Technology Monograph Series: *The Presumption of Validity: A Study of its Effect on Case Law Since 1952,* by David A. Lowin. (Information on the purchase of this monograph appears at page 313 of this issue.)

This monograph is the result of P.T.C. sponsored research, analyzing over 1,100 cases in the United States District Courts and Courts of Appeals. The cases selected were restricted to those headnoted with specific court reference to the presumption of validity, a limitation which assured that the presumption was at least considered.

The following information was accumulated from each of the cases studied: the court, the judge, the year, the number and types of patents involved, the number and types of patents held valid and invalid, and the reasons for holdings of invalidity. This voluminous information is presented in easily readable tabular form for each court and judge involved, including overall summaries of their records. The monograph also includes several interesting graphic displays of the study results.

One industrial legal advisor to the P.T.C. who critiqued the report commented that the study would be of important help to practitioners in gaining insight into the attitudes of the individual courts throughout the land.

We shall be reporting the publication of other recently completed research programs (IDEA, Volume 20, No. 1, p. 119) in the next issues.

Robert H. Rines
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Recombinant DNA: Issues on the Regulation of Basic Scientific Research

PHILIP L. BEREANO*

The regulation of scientific and technological activities has become a matter of increasing concern in "post-industrial society." Most of the existing controversies and developments of the past several years involve areas of technological application such as nuclear power, supersonic transport, the environmental impact of dams and similar facilities, and the like. It is only recently that similar attention has begun to be focused on areas of scientific activity, and more particularly on the laboratory activities of research scientists. Undoubtedly the most notable instance of this to date concerns the regulation of recombinant DNA research.

This article will provide a context for a discussion of some of the issues which have arisen in regard to regulation of recombinant DNA work, and will explain some of the public policy implications of the recently-issued Guidelines by the United States Department of Health, Education and Welfare (HEW) which governs this research.

Science, Technology and Social Values

A central feature of the traditional or "technocratic" view is that scientists and technologists are involved in activities which are re-

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moved from the realm of values, or else ought to be guided by values which are safe or conventional. The argument supporting the claim that science and technology are value-neutral usually includes an admonition that normative differences are really political and hence must be left to politicians and the political processes. It can be maintained, on the contrary, that values are inescapable elements of any exercise of choice or decision-making, and since the conduct of research in any area like recombinant DNA is of such concern to members of the public and will as a result be regulated by the political processes, the assessment of the potential impact of such research and decisions concerning the direction of such research are permeated by opportunities of choice and hence issues of social value.

A concern for values is not merely the realm of philosophers and theologians. In fact, each of us in our daily lives is constantly dealing with issues of value. Values relate essentially to the process of labeling things "good" or "bad" or placing them somewhere along the spectrum between these two extremes. A social value is an affective conception of the desirable drawn from experience. No matter what individuals or institutions say their values are, values are really only made manifest by the actual processes of choice that an individual or institution undertakes. For example, in the area of biological and medical practice, one of the oldest and most profound ethical admonitions is to primarily observe the command to do no harm, and then consequently to follow the goal of promoting the good. It is a source of wonder that such a powerful, although abstract, statement about the balancing goals to be pursued was formulated several thousand years ago when humankind existed on the margin of survival. If anything, today when we are seeking to apply such precepts to a concrete situation — such as the conduct of recombinant DNA research — this teaching should be understood to have even greater applicability. None of the benefits proclaimed as possible through the result of recombinant DNA research purport to take humankind from the margin of survival and provide it with basic security. Rather, the good which is considered possible through such research would result in the improvement of an already tolerable situation. Labeling the current situation tolerable should be understood to refer to the scientific and technological components of it; surely there is hunger in the world, and disease, and other deprivations, but we should clearly understand that these are largely the results of political and economic factors, not scientific or technological ones. If those political, economic, and social factors are not directly addressed, no amount of advances in the area of DNA or scientific work will, by itself, reduce world hunger or other ills. The

extension of this ancient Hypocratic admonition to our present day implies that future generations have the right to require that we do not recklessly endanger the natural environment or the social fabric; there is not a similar imperative on us to present them with miracle cures.

In this light we must understand that — expressions and acts of scientific collegeality to the contrary notwithstanding — research in the area of recombinant DNA is intensely competitive, and research groups are vying with each other for prestige and prizes. These are significant motivations of the researchers which unfortunately have been largely ignored by the regulatory Guidelines and inadequately addressed by the institutions administering these regulations. Increased involvement by members of the public, who after all are the ones largely paying for the support of such research, the ones likely to reap any of the potential benefits which eventuate, and the ones forced to bear whatever risks materialize into untoward events, would thus seem to be necessary and appropriate. Although scientific researchers in the recombinant DNA area have gone considerably beyond what has traditionally been the norm in informing the public about the implications of their work, the experience to date with the regulatory process indicates that an "old boy network" exists and still flourishes in the DNA field. Our current society has been characterized by many commentators as qualitatively different from those which have preceded it; for instance it is a society in which knowledge itself has become a source of power, much in the way that money in and of itself was a source of power in earlier societies, or a noble title in societies preceding those.[1] Knowledge about scientific developments, as well as access to the technological implementation of such scientific information, have become political commodities. Those who dispense such benefits of scientific and technological development have become important power holders in our society.

History and Background of DNA Regulation

Initial activities which culminated in the regulation of recombinant DNA research have been frequently told and will not be recounted here in detail.[2] In summary, concern about the implications of this

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[1] *See, e.g.*, D. BELL, THE COMING OF POST-INDUSTRIAL SOCIETY (1973).

[2] In addition to many semi-technical articles in SCIENTIFIC AMERICAN and SCIENCE, at least four popular books explore the history of the controversy: M. ROGERS, BIOHAZARD (1977); N. WADE, THE ULTIMATE EXPERIMENT: MAN-MADE EVOLUTION (1977); J. RIFKIN & T. HOWARD, WHO SHOULD PLAY GOD? (1977); J. LEAR, RECOMBINANT DNA: THE UNTOLD STORY (1978).

work by some of the scientists engaged in it led to the convening of a meeting in February 1975 at the Asilomar Conference Center, Pacific Grove, California. This meeting was sponsored by the National Academy of Sciences and supported by the National Institutes of Health (NIH) and the National Science Foundation. It involved attendance by one hundred and fifty people, including fifty-two foreign scientists from fifteen countries, sixteen representatives of the press, and four attorneys (a number of the individuals in the latter two categories arriving uninvited). This conference reviewed research on recombinant DNA molecules and discussed ways to deal with the potential biohazards of the work. It recommended that experiments in the area should proceed providing that appropriate biological and physical containments were utilized, and it recommended that certain experiments judged to pose serious potential dangers be prohibited. Meanwhile, the Director of the NIH had established an advisory committee on recombinant DNA in October 1974. After the Asilomar conference (which the general public first heard about through a major article appearing in *Rolling Stone* newspaper), this advisory committee proposed regulatory guidelines, and held public hearings on them. Final Guidelines were issued on June 23, 1976.[3]

These Guidelines prohibited six categories of recombinant DNA experiments which experts felt posed significant hazards; defined degrees of physical and biological containment necessary to prevent recombinant DNA organisms from escaping into the environment and surviving; described permissable categories of recombinant DNA research and assigned levels of biological and physical containment for each; and described specific roles and responsibilities for principal investigators, research institutions, institutional biohazard committees, and the NIH. Indicative of the increasing problems concerning the evolution of the regulatory framework, the final Environmental Impact Statement on these Guidelines was not published until quite a while after the Guidelines themselves became effective, and after the filing of a lawsuit by public interest groups.

Because research interest in recombinant DNA was growing rapidly, and the regulatory scheme which was established had virtually no experience to build upon (although there were certain superficial similarities to human subjects review panels at research institutions and the like), the next period of time was characterized by considerable confusion and suspicion on the part of both researchers and concerned members of the public. There were several notable

[3] 41 Fed. Reg. 27902 (1978).

examples of localized concern (such as the action of the Cambridge, Massachusetts, City Council in impanelling a citizens' group to investigate the situation, which led to a local ordinance; the passage of legislation regulating this research in New York State which was vetoed by Governor Carey, etc.). And there were at least two well-publicized situations in which the Guidelines were violated (in terms of administrative paperwork) at prestigious schools: Harvard University and the University of California at San Francisco.

The Guidelines set down on paper a list of requirements for different laboratory safety levels, and a shopping list of "do's" and "don'ts" for practices in those laboratories. But in many ways this was essentially a set of "paper platitudes" because there was no way of assuring that these provisions would be routinely followed. For example, in a laboratory classified as P-2, it is forbidden to eat food; yet students of this writer have dropped in at such laboratories at noon time and found personnel eating lunch at the bench. Similarly, a researcher of the highest repute at the University of Washington has admitted that frequently in his laboratory he neglects to wear his laboratory gown. This would be an item of trivia except that the classification on his laboratory is such as to require the wearing of such garb. These examples indicate that one of the most significant avenues of danger in the conduct of this research, and one of the most significant problems with translating paper requirements into real protections, is that arrogance or familiarity can breed carelessness. The local biohazard committees established at each institution consist of people donating a few hours of their time to overseeing this research. They cannot regularly monitor what is going on in the DNA laboratories, and many institutions do not have a biohazard officer employed to assist regularly in this work. And the only sanction provided, withdrawal of funding, was almost too severe to be credible as a deterrence to violation.

The regulatory framework of the 1976 Guidelines (and, we shall see, of the current 1978 ones as well) was organized on the premise that the major risks which had to be dealt with concerned the possibility of the escape of organisms containing recombined DNA into the environment where they might infect humans or precipitate other hazards. That is, all of the many concerns which have been raised by members of the public — such as the ethics of crossing evolutionary boundaries, the political implications of the control over a potentially powerful technology, as well as the dangers to health and the environment — were collapsed into a single set of technocratic parameters which defined the risks in terms of the security of laboratory operations. Thus the con-

cern with physical containment (four different levels of increasingly secure laboratory situations) and biological containment (three different levels of increasingly weakened host-vector systems, each even less likely to be able to survive and compete in the natural environment than the one before) frame the problems as amenable to solution by a large enough corps of architects, engineers, and biologists. It was almost as if the ethical and political issues would go away (or perhaps be overwhelmed) by an increasing concern for conducting experiments within specialized apparatus located inside laboratories where the air pressure was less than that of the surrounding building, with high-powered filters for the exhaust, and so on.[4] Even this technocratic approach, however, did not adequately consider such potential problem areas as malfunctioning of equipment, possible human error or inadvertence, intentional abuse by individuals setting out to circumvent the Guidelines, or unforeseen external events (such as earthquake, fire, and other acts).

Continued public concern, expressed by individuals, public interest groups, and the Coalition for Responsible Genetic Research (a citizens' group), led to a number of public workships and forums, such as at the annual meetings of the American Association for the Advancement of Science. National legislators (most notably Senator Edward Kennedy, Senator Adlai Stevenson, and Congressman Paul Rogers) proposed regulatory statutes. Some commentators suggested that HEW exercise more sweeping regulatory authority under the provisions of section 361 of the Public Health Service Act.[5] Meetings of the NIH Recombinant Advisory Committee (RAC) became focal points of public interest. As a result, on July 28, 1978, the Federal Government proposed revisions in the Guidelines, based both on experience to date operating under the existing Guidelines and these expressions of concern.[6] Responsibility for guiding the regulatory process was moved "upstairs" from the NIH to the level of HEW, and HEW Secretary Califano called a public hearing for September 15, 1978 before a specially constituted departmental panel consisting of Peter Libassi, the General Counsel (chair); Donald Fredrickson, the Director of NIH;

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[4] The official view of some of the issues raised by physical and biological containment can be found in the *Director's (of NIH) Decision Document,* 43 Fed. Reg. 60082, 60084-86 (1973) [hereinafter *Director's Decision Document*]. The recent escape of smallpox from a "secure" laboratory in Britain is discussed in 203 SCIENCE, No. 4383, at 855-6 (March 2, 1979).

[5] 42 U.S.C. § 264.

[6] 43 Fed. Reg. 33042 (1978).

Julius Richmond, the Assistant Secretary for Health; and Henry Aaron, the Assistant Secretary for Planning and Evaluation.[7]

In October 1978 the Department held a meeting in Washington, D.C., for the chairpersons of the local Institutional Biohazard Committees, in order to inform them of experiences under the Guidelines and the planned revisions, and to collect their experiences as part of the re-evaluation. Similarly, on the sixteenth of that month, the HEW panel and its assistants met with approximately a dozen representatives of public interest groups for further exploration of policy issues. Finally, on December 22, 1978, new Guidelines were issued to govern work in this area.[8] In addition, the NIH issued an "Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules" which dealt with some of the detailed provisions in implementing the Guidelines, and were in a format which allowed greater flexibility and ease for revision.[9] The new Guidelines relaxed the safety restrictions by making them at least one step lower in the combined physical-biological containment scheme, and increased certain aspects of formal public participation in the regulatory process. The Guidelines also require that the Food and Drug Administration (FDA) (through a companion notice in the Federal Register) take steps to require that private research in its purview adhere to the Guidelines; request that the Environmental Protection Agency (EPA) (by a companion communication to the Administrator of the EPA) take whatever action it can to require compliance with the Guidelines by companies that carry out DNA research but whose products are not regulated by the FDA; increase the level of NIH activity in the area of assessing risks associated with this research (see discussion below); and generally reflect certain experiences obtained under the operation of the original Guidelines.[10]

The issues which are still current in light of the new Guidelines can be conceptualized as falling either within the scientific domain or within the area of administrative practice. In the first category are the questions about which types of experiments should still be prohibited

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[7] The author testified at those hearings under the auspices of the Coalition for Responsible Genetic Research.

[8] 43 Fed. Reg. 60108 (1978).

[9] The Supplement covers such areas as details of the required paperwork especially regarding The Memorandum of Understanding and Agreement, MUA (the basic contractual obligation under the Guidelines between the researcher, institution, and NIH).

[10] An overview of the new Guidelines can be found in the statement of HEW Secretary Califano, 43 Fed. Reg. 60080 (1978).

(and whether and how to except experiments in the future from such prohibitions), which sorts of experiments should be exempted completely from the Guidelines, what containment levels are appropriate for the remaining experiments which will be covered by the Guidelines (categorizing this large class of future experiments and associate each category with a particular level of physical-biological containment), and continuing assessment of the risks presented by different experiments conducted under different conditions (including such things as the use of different biological hosts than *E. coli,* as well as the biological characteristics of the many hundreds of *E. coli* strains which exist and which can be produced). Included among the administrative issues, would be the detailing of the division of responsibility and roles among the NIH and its organs on the one hand and the research institution and its sub-groups (the principal investigator, the institutional biosafety committee, the biological safety officer) on the other; the composition of regulatory bodies (in particular, the IBCs and the RAC), and general questions of public involvement.

Government involvement in DNA research and regulation has been following the "AEC pathology" in failing to institutionally separate promotional agency activities from regulatory ones. Unfortunately, the new Guidelines do not adequately address this syndrome. The intertwining of regulatory concerns with support and promotion of research activity is a further extension of the "old boy network" which engenders public suspicion, and reminds us of the widely discredited situation which existed for many years in regard to nuclear power. Since the government has recognized what citizens groups have been saying for many years — in regard to atomic energy — and has established separate agencies to deal with these two different aspects of the situation, it is unfortunate that the regulation of recombinant DNA research is still primarily conducted by the NIH, the primary supporter of such research (although under the Guidelines there is a notable increase in the responsibility of the local institutional biosafety committees, and the overall regulatory process has been more thoroughly scrutinized by HEW personnel). Promotion of a technology results in the vesting of professional, as well as of economic, interests in the application and exploitation of that technology. The expectations we have of regulators are far different from the types of commitments associated with promoters. The need to separate these two functions should be recognized more directly and dealt with more satisfactorily.

The 1978 NIH Guidelines

Coverage of the Guidelines. One of the major threshhold regulatory issues has always been how much of the DNA experimentation which

is being conducted can be and should be brought under the Guidelines. The 1976 Guidelines only covered research activities funded by the NIH. Research funded by other agencies (such as the National Science Foundation) was unregulated except insofar as those agencies chose to adopt the NIH Guidelines; over the two-year period in which those Guidelines were in effect, this occurred to a large extent. Work also occurs in research institutions funded from other sources: state, foundations, and private. Recombinant DNA research is also being conducted by the private sector in its own laboratories; some of this may fall in the potential regulatory purview of other government agencies.

As noted above, some commentators have urged HEW to act within the authority granted by section 361 of the Public Health Service Act to "make and enforce such regulations as . . . are necessary to prevent the introduction, transmission, or spread of communicable diseases" from foreign countries into the United States or from one State to another. This provision allows for "inspection, fumigation, disinfection, sanitation . . . and other measures" to carry out such regulations. For a variety of political reasons, HEW did not want to exercise this authority (primarily because many scientists objected to the categorization of recombinant DNA work as equivalent to a potentially "communicable disease"). However, that regulatory authority, if invoked, would cover all scientific research of this type conducted in the United States. The new Guidelines "are applicable to all recombinant DNA research within the United States or its territories which is conducted at or sponsored by an Institution that receives any support for recombinant DNA research from NIH."[11] By simultaneously ordering the FDA to initiate regulation of private activities which fall within its jurisdiction, and urging the EPA to do the same, the Secretary hopes to catch within the regulatory net virtually all recombinant DNA work which is performed in this country. Projects performed abroad and supported by NIH funds are also explicitly covered by the Guidelines, or can be regulated by equivalent host country mechanisms if these are in existence.[12] In addition, although the 1976 Guidelines and the revision proposed in the summer of 1978 did not do so, the new Guidelines clearly recognize that the institutions may adopt policies on their own

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[11] 1978 Guidelines, § IV-B, 43 Fed. Reg. 60123 (1978). As of autumn 1979, however, private sector research and production is still wholly unregulated.

[12] *Id.*

for additional regulation of recombinant DNA work conducted on their premises:

> [T]he Institution, as part of its general responsibilities for implementing the Guidelines, may establish additional procedures, as deemed necessary, to govern the Institution and its components in the discharge of its responsibility under the Guidelines. This may include (i) statements formulated by the Institution for general implementation of the Guidelines and (ii) whatever additional precautionary steps the Institution may deem appropriate.[13]

This provision, coupled with the delegation of front-line responsibility to the institutional biohazard committees, gives the IBCs primary regulatory responsibility over most of the recombinant DNA research being conducted. Whether or not they have adequate competence to carry out these responsibilities is still an important issue (see below).

Recombinant DNA molecules are defined in two places as "either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above."[14]

Experiments not covered fall into either of two categories: those which are prohibited (to which exceptions are possible), and those which are exempted from the coverage of the Guidelines. Six classes of experiments are prohibited by the Guidelines:[15] those derived from pathogenic organisms; those deliberately formed containing genes for the biosynthesis of toxins potent for vertaebrates; the deliberate creation of plant pathogens with increased virulence and host range; the deliberate release into the environment of any organism containing recombinant DNA; the deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire it naturally; and large-scale experiments (*e.g.*, more than ten litres of culture size) unless the recombinant DNAs are known and understood in detail as not being harmful. *Exceptions,* which "means that an experiment may be expressly released from a prohibition,"[16] are possible if approved by the Director of the NIH, upon the recommendation of the RAC, after notice and public comment.[17] (For example, this might be done to per-

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[13] *Id.* § IV-D-1, at 60124.

[14] *Id.* § 1-B at 60108, § IV-c-2, at 60123.

[15] *Id.* § I-D, at 60108.

[16] *Id.* at 60129.

[17] *Id.* § I-D, at 60108 and § IV-E-1-b-(1)-(e), at 60127. *See also* discussion in *Director's Decision Document, supra* note 4, at 60083-84 (1978).

mit risk assessment studies.) At such time they would be assigned appropriate containment levels.

Exempt experiments do not need to be registered with NIH (although it can be notified of them) and need not follow the Guidelines (although as noted above, the institutions themselves through the IBCs can regulate these experiments). The Guidelines set out five categories:[18] molecules that are not in organisms or viruses; molecules consisting entirely of DNA segments from a single non-chromosomal or viral DNA source; molecules of DNA from a prokaryotic or eukaryotic host when propagated only in the same or closely related strain respectively; certain specified recombinant DNA molecules that consist "entirely of DNA segments from different species that exchange DNA by known physiological processes" as contained on a list of such "exchangers" which will be prepared and periodically revised by NIH; and other classes of molecules as established by the Director of NIH with the advice of the RAC after appropriate notice and opportunity for public comment, upon the conclusion that they "do not present a significant risk to health or the environment."[19] The initial list of exchangers is contained as Appendix A to the Guidelines.[20] There has been lively discussion as to whether the list of non-regulated exchangers should be based on considerations of safety and/or notions of novelty (that is, whether or not exchange is known to occur in nature). The Guidelines rely on novelty, as did their 1976 predecessors.[21] Although at least one commentator urged the view that the inclusion of specific exemptions in the Guidelines was premature because the risk assessment studies had not been made on a case by case basis, there had not been specific compliance with the National Environmental Policy Act, nor public participation, nor a finding based on experimental data that the exemption presents no significant risks to health or to the environment (safety considerations), the Director of NIH believed that the five classes of exemption listed were warranted, in part to narrow down the large mass of experiments to those which should receive the limited regulatory resources because they were potentially more hazardous (that is, a logical connection was made between exchanges occurring in nature and a lack of hazard).[22]

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[18] *Id.* § I-E, at 60108-9.

[19] *Id.*

[20] *Id.* at 60130.

[21] *See Director's Decision Document, supra* note 4, at 60082-83 (1978).

[22] *Id.* at 60083.

The Administrative Supplement contains a brief discussion of how the institutions should initiate requests for exceptions and/or exemptions.[23]

Risk Assessment. Because the NIH Guidelines purport to deal with issues of safety, and to protect the general public and the communities adjacent to research sites from undue hazards, while at the same time allowing research to proceed which may provide human benefits, a clear distinction in the concepts of "risk" and "safety" is necessary. Unfortunately the new Guidelines (as their predecessors) do not do so. Risk may be understood as a relatively objective measure of hazards, whereas safety is a subjective expression of a level of risk which is acceptable to a population.[24] In other words, even if the various risks associated with DNA experimentation can be determined once and for all by an authoritative body (and, of course, we are nowhere near that situation at present), the question of safety involves many value issues which can only be articulated and developed by those members of the public which might be exposed to such risks and have the potential of access to the benefits of the research activity.

None of us lives a risk-free existence, and no one should be so foolish as to assume that such a thing is possible. Yet all of us make determinations based on our own notions of safety, as to the level of risks we are willing to run — when we decide to travel by automobile or by railroad, when we decide to put on our automobile seat-belts or not, when we decide whether to smoke cigarettes or cut down our consumption, and the like. Of course, some risks are involuntarily thrust upon us, and some commentators have suggested that people are one thousand times less comfortable with undergoing those risks than with the ones that are voluntarily assumed (although the free will notion of voluntariness is in many ways situational — if employment opportunities are limited, a person may engage in a hazardous job rather than go hungry).

The "adequacy" of safeguards is a determination which is heavily value-laden. Although the new Guidelines increase public participation in DNA regulation, it is not clear that they require sufficient institutional mechanisms to insure that these value issues are resolved through the participation of the only persons who can legitimately provide insight into them, the general public which is affected.

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[23] At. pp. 18-19.

[24] *See* W. LOWRENCE, OF ACCEPTABLE RISK: SCIENCE AND THE DETERMINATION OF SAFETY (1976).

An example of the NIH confusion about the differences between risk and safety can be found in the policy section introducing the discussion of Roles and Responsibilities. "Safety in activities involving recombinant DNA depends on the individual conducting them. The Guidelines cannot anticipate every possible situation. Motivation and good judgment are the key essentials to protection of health and the environment."[25]

What the Guidelines apparently mean is that *risks* involving recombinant DNA research depend upon the individuals conducting the research and the manner in which they conduct it. *Safety,* however, is not their province alone; safety is a concern of the larger community, and in its determination those researchers have an important role to play in enlightening the local public as to some of the relevant factual information which may go into that determination. The motivation and judgment of the researchers are also of interest, and raise significant value issues. It has already been noted that the experience under DNA Guidelines shows that researchers in this area are very competitive, and in going after the honors which may be awarded are facing significant motivations to cut corners.

In regard to risk assessment strictly defined, NIH is supporting a number of activities to develop the much-needed data.[26]

Other Technical Considerations. The new Guidelines, as with the previous ones, contain an extensive discussion of both physical and biological containment mechanisms, and categorize specific types of experiments into appropriate containment configurations.[27] Except for noting again that these represent a relaxation of the earlier containment requirements, these will not be discussed in this article.

Roles and Responsibilities. In addition to the NIH, the main regulatory actors on the local scene consist of the Institution, the Institutional Biosafety Committee, the Biological Safety Officer, and the Principal Investigator. Some significant changes have been made in this part of the Guidelines as compared to their predecessors. The general policy as regards safety (or risk-reduction) and applicability to types of research, have been previously discussed.

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[25] 1978 Guidelines, § IV-A, 43 Fed. Reg. 60123 (1978).

[26] *See Director's Decision Document, supra* note 4, at 60088 (1978).

[27] 1978 Guidelines, § II, 43 Fed. Reg. 60109-115 (1978); and § III, 43 Fed. Reg. 60115-123 (1978).

The Institution (any public or private entity, including governmental agencies)[28] is "responsible for ensuring that the research is carried out in full conformity with the provisions of the Guidelines."[29] Its responsibilities are detailed to a greater extent than heretofore: to establish an IBC, to submit for each research project a Memorandum of Understanding and Agreement (MUA), to ensure compliance with the guidelines and cooperation with NIH, to appoint a Biological Safety Officer for research conducted at the P-3 or P-4 containment level, to require that principal investigators comply with the Guidelines, to ensure appropriate training for the IBC, BSO, the PIs, and the laboratory staff, to determine if there is necessity for health surveillance of personnel engaged in this research and if so to conduct it, and to report to the NIH any significant problems with the violations of the Guidelines and significant research-related accidents and illnesses.[30] The changes in the new Guidelines in regard to the institutional biosafety committees are of particular interest. Most notable, is the explicit delegation in the new Guidelines of responsibility to the IBC for the major regulatory activity. Under the 1976 Guidelines, this responsibility resided with the NIH and the local committees served essentially to pre-screen proposed experiments before they were submitted to the government. Interestingly enough, many legislative proposals advanced by members of Congress in the interim would have gone to the other extreme and pre-empted local regulatory activity by a single national regulatory scheme.[31] The main reasons offered by the NIH for the delegation of authority include the need for increased responsibility of the institutions and the need for a simpler administrative process. There also is a recognition of the practical requirements for enforcement of standards covering experiments at many institutions spread over a vast geography.[32] NIH apparently feels unable to monitor this activity on a day to day basis, and is anxious to share some of that responsibility with local and decentralized institutions.

The Guidelines now state the functions of the IBC and its responsibilities as: reviewing all recombinant DNA research at the institution for compliance with the Guidelines and approving those projects it finds

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[28] *Id.* § IV-e-4, at 60124.

[29] *Id.*

[30] *Id.* §§ IV-D-1(b)(i).

[31] *See, e.g.,* RECOMBINANT DNA RESEARCH AND ITS APPLICATIONS, OVERSIGHT REPORT BY THE U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION, SUBCOMMITTEE ON SCIENCE, TECHNOLOGY, AND SPACE, 95th Cong., 2d Sess., (1978).

[32] *See Director's Decision Document, supra* note 4, at 60093 (1978).

are in conformity therewith; conducting an independent assessment of the containment levels requirements by the Guidelines; assessing the facilities, procedures and practices, including the training and expertise of personnel, involved in such research; authorizing the principal investigator to proceed with the research upon receipt of the proper governmental agency approval or authorizing the initiation of the research prior to agency approval in many instances; periodically reviewing the research being conducted at the institution to ensure compliance with the Guidelines; adopting emergency plans; and reporting to NIH any significant problems or violations.[33] A note in the text of the Guidelines gives some examples of work that might ordinarily proceed without prior funding-agency approval; this includes major categories of DNA research such as any project at the P-1 or P-2 level of physical containment (other than the very first project at the institution), changes in hosts or vectors employed, and, most signifantly, single-step reductions in containment level for certain categories of DNA research.[34] By implication, the Guidelines will also allow the IBC to raise containment levels, although the NIH hardly thinks this will ever be necessary.[35] Prior approval by NIH is only required, in summary, for projects for which containment levels are not explicitly specified in the Guidelines (in which case a full review by NIH including the RAC would be necessary), projects at the P-4 of physical containment, reductions of more than one-step in containment levels, reductions of containment levels for projects involving primate DNA, reductions of containment to level below P-1 and HV-1 (the lowest biological level), initiation of the first project conducted in a facility at the P-3 level of physical containment, and initiation of the very first recombinant DNA projects subject to the Guidelines conducted at the institution.

In order to carry out these responsibilities, the character and composition of the IBC have become topics of major concern. While the IBCs can have the competence to assess safety, the assessment of risk is another matter. Risks generally would not vary from location to location, and therefore the assessment of risks involved in recombinant DNA work would best be performed by a single national body. The IBCs need to obtain this information and fold it into their deliberations. In addition, members of the IBCs are primarily going to be employed at other capacities or have other substantial responsibilities to their work, families, communities and the like. Members of the IBCs are not them-

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[33] 1978 Guidelines, § IV-D-3, 43 Fed. Reg. 60125 (1978).

[34] *Id. See also* NIH Administrative Supplement, 17-18.

[35] *Director's Decision Document, supra* note 4, at 60094 (1978).

selves full-time personnel involved in risk assessment, laboratory inspection, training program certification, or any of the other kinds of substantially time-consuming activities for which the Guidelines purport to give them responsibility. (The Biological Safety Officer, if he or she is a member of such a committee, would be an exception to these remarks.) For most committee members, this is an "add-on" activity, although one which may be undertaken with the highest considerations for its seriousness and public importance. This author's experience as a member of an IBC indicates that members who are not themselves DNA researchers will have substantial difficulties in actually carrying out these duties — difficulties imposed by the technical nature of some of the duties as well as by the substantial time they would take to accomplish.

In this regard, it is interesting to consider the changes mandated by the new Guidelines regarding the composition of the IBCs and some aspects of their functioning, both designed to increase somewhat public participation in and awareness of the procedures the IBCs employ. Note that while this is desirable from the point of view of increasing democratic decision making values and assuring that community values are included in safety determinations, it does not address the problems raised above. The 1976 Guidelines contained merely one paragraph (less than one third of a column in the Federal Register) on the IBCs.[36] Although the NIH collected the *vitas* of all IBC members, no one, including NIH officials, had any clear idea about the existing composition of these committees. This author participated in research activities, along with a group at Stanford University, in the summer and fall of 1978 which attempted to investigate the composition of the existing IBCs. In general they were found to be hopelessly skewed demographically. They were totally non-representative of the communities whose safety and interests were concerned, being overwhelmingly (and in some cases exclusively) male, white, graduate degree holding, and the like. In some institutions they were composed almost completely of recombinant DNA researchers. The new guidelines state:

> The IBC shall comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. At least two members (but no less than 20% of the membership of the committee) shall not be affiliated with the Institution (apart from their membership on

[36] 41 Fed. Reg. 27920 (1978).

> the IBC) and shall represent the interests of the surrounding community with respect to health and protection of the environment...[37]

"In order to ensure the professional competence necessary to review recombinant DNA activities," the Guidelines recommend that the IBC include persons from "disciplines relevant to recombinant technology, biological safety, and engineering," and at least one person who is a non-doctoral laboratory technical staff member. The BSO is required to be a member if the Institution is conducting research at the P-3 and P-4 levels. The Guidelines also suggest that there be members or consultants who are "knowledgeable in institutional committments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment." Finally, they suggest that officials of public health or environmental protection agencies and local governmental bodies be considered for membership as well as "persons active in medical, occupational, health, or environmental concerns in the community."[38] Note that although there is a requirement for members not affiliated with the Institution, there is no *requirement* for there to be membership by well identified public interest groups, environmental organizations, or other organizations with an established track record of concerns for public health and safety.[39] *Vitas* of IBC members should be filed with the NIH, and there are conflict of interest provisions.[40]

Many, if not most, of the existing IBCs cannot directly command sufficient institutional fiscal resources for their functions (which, of course, are increased under the new Guidelines). Despite suggestions that the NIH specifically address this problem, the Guidelines are silent, the NIH taking the position that the inclusion of "overhead" costs in grants should cover these expenses (but not mandating that the Institutions actually do so).[41]

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[37] 1978 Guidelines, § IV-D-2-a, 43 Fed. Reg. 60124-25 (1978).

[38] *Id.* § IV-D-2-b, at 60125.

[39] Public interest witnesses suggested far more explicit requirements regarding public membership on the IBCs, better demographic distribution, and broadened representation from other disciplines such as the policy sciences. Except for increasing the "non-affiliated" membership requirement from one to two or 20% and suggesting representation of local governmental officials, the Guidelines did not officially adopt these recommendations. *See Director's Decision Document, supra* note 4, at 60091 (1978).

[40] 1978 Guidelines, §§ IV-D-2-c and d respectively, 43 Fed. Reg. 60125 (1978).

[41] *See Director's Decision Document, supra* note 4, at 60094 (1978).

The new Guidelines increase public access to IBC activities, by "encouraging" open meetings, and requiring that minutes and other documents be available to the public upon request.[42] These provisions fall far short of the testimony given at the September 1978 hearing and the practice at a notable few Institutions (such as the University of Washington where most meetings are open except for actual voting sessions on research applications, each researcher is required to prepare a lay language summary of their proposed work for the benefit of non-technical members of the IBC and the public, and meetings have been held in the evenings to facilitate public attendance).

The IBC functions on behalf of the Institution to ensure compliance with the Guidelines, by approving proposed research projects if in conformity, by conducting an independent assessment of the required containment levels and of the adequacy of the facilities, procedures, practices, and training and expertise of personnel.[43] It authorizes the Principal Investigator to proceed, and to periodically review all recombinant DNA work being conducted at the Institution, prepare emergency plans, and report any problems, violations, accidents, or illnesses to the NIH.[44]

The role of the Biological Safety Officer is also set out briefly. The Institution is mandated to have a BSO only if P-3 or P-4 work is being carried on (in which case he or she is to be a member of the IBC), and the BSO is to deal with inspections, emergency plans, security, and providing technical advise and reports of problems to the IBC and PI.[45]

The responsibilities of the Principal Investigator dovetail with all the previous roles: not to conduct DNA research subject to the Guidelines without IBC approval, report problems, be adequately trained, etc.[46] Even the responsibilities of the NIH are specifically laid out;[47] of interest are the provisions concerning the RAC which were a matter of considerable testimony and comment.[48] Recognizing that the RAC is

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[42] 1978 Guidelines, §§ IV-D-2-g and h respectively, 43 Fed. Reg. 60125 (1979).

[43] *Id.* § IV-D-3-a.

[44] *Id.* §§ IV-D-3-b, c, d, and e.

[45] *Id.* § IV-D-4. There is no Federal certification for this role, and the assumption is that for research at P-1 and P-2 the regular health and safety program at the Institution will be sufficient. *See Director's Decision Document,* 60095 (1978).

[46] *Id.* § IV-D-5, at 60125-26.

[47] *Id.* § IV-E, at 60126-28.

[48] *Id.* § IV-E-2.

concerned with public policy matters as well as technical ones, "at least 20 per cent of the members shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields." Other Federal agencies have non-voting membership.

Concluding Thoughts

The evolution of regulatory mechanisms for recombinant DNA is a potential harbinger of situations we will have to face more frequently in the future in regard to other areas of scientific inquiry. Citizens are increasingly realizing that such work has important implications for them, and will seek appropriate forms of involvement in the relevant decision-making.

Activity in the area of technology assessment has led us to understand that one of the most fundamental sets of questions that needs to be asked when considering new scientific and technological development concerns not only the attempt to anticipate the probable future consequences of such activity, but to attempt also to *disaggregate* those consequences by asking who actually would bear the risks associated with new developments, who would be paying the costs, and who would have access to the potential benefits. In regard to work in the area of recombinant DNA, it is clear that members of the general public fall into all three of such categories. Much, if not most, of this research is supported by tax dollars paid by the general citizenry; risks to health, safety, and the environment would be widely shared; and the benefits which have been suggested for such research would affect many sectors of society. Thus, members of the general citizenry have a fundamental right to participate in decision-making in this area. Although it is commendable that scientists working the the area of recombinant DNA initially called the attention of the public and regulatory officials to issues raised by such research, in general the regulation of research in this area to date has been characterized by very limited opportunities for meaningful formal input on the part of such persons as scientists in other but related disciplines, non-scientific professionals with relevant perspectives, and ordinary citizens.

Considering the fact that the primary issues passed by this research are not solely scientific nor technological but have major public policy components, the regulatory schema to date have gone against the grain of the past decade's academic research and findings in the area of "science, technology, and public policy" as well as recent political experience and court litigation pointing to the beneficial affects of citizen

participation in many fields; the new Guidelines do not auger significant improvement, unfortunately.

The regulatory process so far has largely been structured around technocratic risk amelioration, how to avoid possible accidents and escape of a virulent bacterial strain from a laboratory. But public policy is not solely the province of a technological elite; in a democracy, decisions affecting the public should be made democratically. Other risks (of misuse, for example), and other concerns, such as the ethical and political implications of genetic engineering (for which recombinant DNA experimentation is necessary precusor), must be more adequately addressed.

Overall, the truly responsible and even conservative position is that the proponents of technological changes which would cause important societal ramifications should have the burden of proof of establishing the benefits, costs, and risks associated with such changes — in terms of probability, severity or magnitude, and societal distribution. The new Guidelines perpetuate a situation which is almost the direct opposite. Except for certain types of experiments, the presumption in the Guidelines (and clearly the operating mode of the Institutions and IBCs) is that research should be permitted unless shown to be harmful. It is a demonstration of the regulators' failure to understand the probabilistic nature of risk (and probably an indication of the foolishness of leaving regulation to agencies supporting the activity in question), that they can claim that because harm has not in fact occurred it is not only unlikely but justifies reducing restrictions. This may be true, but logic equally suggests that absence of harm may have been due to the very restrictions themselves. It is a bit like Alice's conversation about a trial with the Queen in Wonderland: regulation first (and continually eased), and risk assessment afterwards. This hardly seems like either good science or good public policy.*

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*Afterward: In the past few months, Federal regulatory activity on this subject has included increasing the number of biological systems in which approved recombinant DNA experimentation may take place and exempting categories of microorganisms from the Guidelines. These actions, like others, have been taken without any formal risk assessment; such a program has finally been proposed. For specifics, *see* 44 Fed. Reg. 19302-04 (1979) (proposed risk assessment plan); 44 Fed. Reg. 21730-36 (1979) (actions under Guidelines); 44 Fed. Reg. 22314-16 (1979) (proposed actions); 44 Fed. Reg. 42914-17 (1979) (actions under Guidelines); 44 Fed. Reg. 45868-69 (1979) (proposal for voluntary compliance by the private sector).

Government Trademarks*

By William C. Garvert**

Agencies of the United States Government and patriotic societies own trademarks and other marks which have been created for them by statute. Apart from such statutes, agencies of the United States Government routinely file applications for and obtain registration of trademarks, service marks, certification marks and collective marks. Agencies of the United States Government are also involved in opposition and cancellation proceedings before the United States Patent and Trademark Office (USPTO). Suits have been filed against infringers of United States Government agency owned marks.

The above statements may come as a surprise to many persons. However, Government agencies are quite active in the field of trademarks and other marks. This article[1] will discuss the involvement of Government agencies in the area of trademarks apart from the functions performed by the USPTO.

Statutory Provisions

Numerous statutes have been enacted on trademarks and other marks for the benefit of a particular agency or for a patriotic society or other organization.

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*The term "MARK" may be more appropriate since this article is not limited to trademarks but discusses other marks, such as service marks, collective marks and certification marks.

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[1] The opinions expressed herein are those of the author and do not necessarily represent Navy or Government policy. The assistance of Cynthia Barbour in gathering the material used for this article is appreciated.

One such statute[2] gives the Indian Arts and Crafts Board in the Department of the Interior the functions of creating Government trademarks for Indian products, establishing standards and regulations for the use of such trademarks, licensing such use and registering the marks in the USPTO without charge. Criminal penalties await those who use such trademarks without authorization.[3]

Another statute[4] gives the Department of Agriculture authority to issue marks indicating inspection, certification and identification of class, quality, quantity and condition of agricultural products when shipped or received in interstate commerce. Marks issued by the Department of Agriculture for this purpose are set out in Title 7 of the Code of Federal Regulations.

Golden Eagle and the Golden Eagle Insignia[5] and Johnny Horizon and character[6] are marks which are prohibited, except as authorized under rules and regulations[7] issued by the Secretary of the Interior, from being manufactured, reproduced or used in such a manner as is likely to cause confusion, mistake or deception. Smokey Bear and the character[8] and Woodsey Owl, the character and the slogan "Give a Hoot, Don't Pollute"[9] are marks which are prohibited against manufacture, reproduction or use except as authorized under rules and regulations[10] issued by the Secretary of Agriculture.

A compilation of statutes relating to the protection of specific marks is set out in Appendix I. Included in the compilation are statutes enacted protecting Government agency and other marks, and statutes enacted protecting the names and marks of patriotic societies and other organizations.

Registered Marks of Government Agencies

Government agencies have been quite active in filing for an obtaining registrations of marks in the USPTO. Registrations have been

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[2] 7 U.S.C. § 305a.

[3] 18 U.S.C. § 1158.

[4] 7 U.S.C. § 1622h.

[5] 18 U.S.C. § 715.

[6] 18 U.S.C. § 714.

[7] For Golden Eagle, 43 C.F.R. 18.15; For Johnny Horizon, 43 C.F.R. 25; The regulations on Johnny Horizon were removed in 41 Fed. Reg. 42201.

[8] 18 U.S.C. § 711.

[9] 18 U.S.C. § 711a.

[10] For Smokey Bear, 36 C.F.R. 271. For Woodsy Owl, 36 C.F.R. 272.

obtained by agencies covering subject matter varying from antifreeze[11] and appliances[12] to Spanish onions[13] and swine.[14] Appendix II is a list of United States Government agency marks that have been registered by the USPTO.

The issue of whether an agency of the United States Government, without specific statutory authority, is a proper applicant for registration of a mark was raised by the examiner of an application[15] filed by the United States Department of the Interior. The application requested registration as a service mark, a picture mark of an arrowhead having trees, a mountain and a buffalo superimposed thereon. On appeal from the Examiner of Trademarks' refusal of this registration, the Trademark Trial and Appeal Board in *In re United States Department of the Interior*[16] held that since the United States Government, or an official department thereof, is an organization capable of suing or being sued (with its consent) in a court of law it, therefore, is a juristic person[17] and a proper applicant within the meaning of the Trademark Act. Recently, the Board reiterated this view in *In re Mohawk Air Services, Inc.*[18]

In obtaining registrations of their marks, Government agencies occasionally encounter an opposition. In *Lloyd v. Department of Army*[19] an opposition to the Army's application for registration of "COMMAND PERFORMANCE" was dismissed because the allegations of the opposer failed to show that he was using the notation in controversy at or about the time the proceeding was brought, and the absence of such an allegation precludes a finding that the opposer would be damaged by the registration.

The United States Postal Service encountered an opposition[20] to its application to register the mark "FIRST-CLASS MAIL" by a news-

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[11] Winter Safe and Design, Trademark, Reg. No. 703,101.

[12] Energy Conservation Labeling Program Logo, Certification Mark, Reg. No. 1,043,863.

[13] Onion design and Idaho-Oregon Onions, Certification Mark, Reg. No. 981,770.

[14] VALIDATED AND BRUCELLOSIS-FREE HERD with "swine" in double ellipse, Certification Mark, Reg. No. 764,467.

[15] Serial No. 141,999 filed April 10, 1962.

[16] *In re* United States Dep't of Interior, 142 U.S.P.Q. 506 (T.T.A.B. 1964).

[17] 15 U.S.C. § 1127, § 45 of Lanham Trademark Act (1946).

[18] *In re* Mohawk Air Services, Inc., 196 U.S.P.Q. 851, 854 (T.T.A.B. 1977).

[19] Lloyd v. Dep't of Army (not reported), Opposition No. 29,290.

[20] Donahue v. United States Postal Service (not reported), Opposition No. 58,244 (T.T.A.B. 1978).

paper carrier who alleged that the mark was merely descriptive or deceptively misdescriptive and that registration would put the applicant in a position to prevent opposer from using "first-class" to describe his service of delivering newspapers. The Board found that opposer had asserted no use of the mark in question and would be just as free after applicant obtained the registration to use the laudatory term "first-class" as he is now to advertise and otherwise refer to his newspaper delivery service. The opposition was dismissed.

Notices of Adoption of a Mark

A practice of some Government agencies, in lieu of filing an application for registration of a particular mark, is to send to the USPTO a notice stating that the mark has been adopted by the agency as a name identifying and distinguishing a particular article, or is being used by the agency as a descriptive or generic expression. The purpose of such notices is to bring to the attention of the USPTO the existence of the agency's use of the mark, thereby providing ready reference material to bar the registration of a trademark thereon or on a similar mark. The objective of the agency is to hereby prevent others from obtaining a registration of the mark and at very little expense.

The practice of filing such notices was effective in *Ex Parte Sperry Gyroscope Company, Inc.*[21] In that case, Sperry had applied for registration of "ECHO BOX" for high frequency electrical testing apparatus published, communications were received from a Government agency, Navy, which indicated that "ECHO BOX" was and had been used generically as the name of a particular type of high frequency electrical testing apparatus prior to applicant's claimed date of use. The examiner refused registration which was affirmed by the commissioner on the grounds that, from the record, it appeared that "ECHO BOX" was the generic name of the apparatus for which registration is sought.

However, the practice was not effective in *In re Electrada Corporation.*[22] In this case, the applicant had appealed from an examiner's decision refusing registration of "DATACOM" on the ground that it was a generic designation for the goods. In support of his decision, the examiner relied solely on a letter from the Chief, Patents Division, Department of the Air Force stating that the Air Force had used "DATACOM" in 1956 in identifying Air Force Communications Systems, that the term had been in common usage by the Air Force

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[21] *Ex parte* Sperry Gyroscope Company, Inc., 77 U.S.P.Q. 634, (1948).

[22] *In re* The Electroda Corporation, 145 U.S.P.Q. 96, (T.T.A.B. 1965).

and that they considered it within the public domain. The Board held that whether a term is generic is a question of fact, and should not be resolved in the affirmative solely on the basis of an unsupported statement of a single individual, even though the individual is an official of a governmental agency.

The practice of filing notices that a mark has been adopted by an agency as a name identifying and distinguishing a particular article was not effective in *In re Mohawk Air Services, Inc.*[23] In that case, the applicant appealed from an examiner's decision refusing to register "MOHAWK 298" for airplanes, on the grounds that the mark may have falsely suggested a connection with institutions, namely, the United States Army, and national symbols, namely, the Army's use of "MOHAWK" for aircraft. The Army had filed a letter in 1958 in the USPTO requesting that the registration be refused for any of the names used by the Army to designate its aircraft, among which was the name "MOHAWK," adopted for a fixed wing aircraft. Evidence was also of record that the name "MOHAWK" was still in active use by the Army. The Board held that there was no suggestion of a connection with an institution since the alleged similarity is with the name of an airplane and not the Army and that there was no connection with a national symbol which suggests to a person the name of a country for which the symbol stands. The Board further held that the filing of a letter, such as the Army letter, in the USPTO is not a proper means of establishing whatever rights a party may have in and to a designation, and a Government agency may apply to register a mark, oppose the registration of a mark or petition to cancel a registration.

In re Mohawk Air Services, Inc. appears to have sounded the death knell for the effectiveness of the Government agencies practice of filing notices of adoption of names as identifying and distinguishing an article, or of using the name as a descriptive or generic expression. Even if the practice of filing notices is still continued, it suffers from certain flaws. Notices of adoption of a name as identifying and distinguishing an article, do not obtain for the agency mark the important statutory attributes registered marks have, such as constructive notice and prima facie or conclusive evidence of the exclusive right to use the mark. Such attributes are very important in an infringement action to prevent others from using the mark. Notices that the name has been adopted as a descriptive or generic expression often lead to an agency asserting that the mark was descriptive or generic when, in fact, it

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[23] *See supra* note 17.

merely identified the article and distinguished it from like articles. Furthermore, notices that the name has been adopted as a generic or descriptive expression provide no protection against a business concern using the mark for its good and thereby reaping profits flowing from the widespread recognition and good will accorded the mark from its use by the Government agency. As a result of *In re Mohawk Air Services, Inc.*, the Government agencies which used the practice of filing notices of adoption will, no doubt, in the future increase the number of applications filed for registration of marks used to identify and distinguish an article, and increasingly file oppositions and institute cancellation proceedings against marks which they are using as descriptive or generic expressions.

Oppositions by Government Agencies

Government agencies have filed oppositions to registration of marks before the USPTO when they believed they would be damaged by the registration of the mark.

In United States Treasury v. Synthetic Plastics Co.[24] an opposition was filed to the application for registration by Synthetic Plastics Co. of "GUEST STAR" for grooved phonograph records. The United States Savings Bonds Division of the Treasury Department had been using the name since 1947 for a radio program promoting the sale of savings bonds and opposed the registration. The opposition was sustained and registration refused.

The Urban Mass Transportation Administration, a part of the Department of Transportation, opposed the registration by the Ford Motor Company of "DIAL-A-RIDE" for advice and consulting in establishing busing systems for others, alleging that the term was generic for a family of Government-sponsored mass transportation demonstration projects. The Board found from the evidence that both the applicant and the opposer had used the mark as descriptive of the services and refused registration.[25]

A French business filed an application for registration of "FBI" as a trademark for men's and women's apparel, basing priority on a French registration. An opposition filed by the Federal Bureau of Investigation was dismissed by the Patent Office Trademark Trial and Appeal

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[24] United States Treasury v. Synthetic Plastics Co., 151 U.S.P.Q. 750, Opposition No. 42,274 (T.T.A.B. 1966).

[25] Urban Mass Transp. Adm. v. Ford Motor Co. (not reported), Opposition No. 53,371 (T.T.A.B. 1974).

Board[26] and suit was brought to deny the defendant the opportunity to register the mark in the United States. Reliance was placed on 15 U.S.C. § 1052(a) which prohibits registration of a mark which may disparage or falsely suggest a connection with persons or institutions or bring them into contempt; 15 U.S.C. § 1052(d) which prohibits registration of a mark previously registered or used and not abandoned, which would cause confusion, mistake or deceive; and 18 U.S.C. § 709 which prohibits use of "FBI" to convey the impression that such use is approved, endorsed or authorized by the Federal Bureau of Investigation. The Court held that the mark "FBI" was used by applicant with three identifying words, "Fabrication Bril International," and this composite mark reduced to a minimum the possibility of falsely suggesting a connection with the Federal Bureau of Investigation, that the parties were in unassociated and unrelated environments and not engaged in competition in a commercial market so no confusion would arise, and that applicant was not using the mark in a way to convey the impression that the Federal Bureau of Investigation had approved such use.[27]

NASA opposed the registration by the Record Chemical Company of "APOLLO 8" for moth preventative and mothproofing agent-air freshener. NASA alleged that registration of the mark to denote the commercial products, would deceive and mislead the public through the connotation that the product and company were associated with, sponsored or supported by, or engaged in a cooperative effort with NASA. NASA also alleged registration would mislead through the connotation that the products were a by-product of the space program licensed through NASA's technology utilization and patent licensing programs, and that registration would detract from and dilute the historical significance of the Apollo program. The Board found no statute or other enactment which created a prohibition against commercial use of "APOLLO 8." The Board also found that the applicant's goods were essentially consumer items for use in households, whereas NASA's technology licensing and utilization programs involved highly technical and esoteric products not related to applicant's product. It was also found that the use of the mark for air freshener products was

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[26] FBI v. M. Bril & Co., 172 U.S.P.Q. 310 (T.T.A.B. 1974).

[27] FBI v. Société M. Bril Co., 187 U.S.P.Q. 685 (D.C. 1975).

not patently offensive or disparaging of NASA's achievements. The opposition was dismissed.[28]

In *NASA v. Gause,*[29] NASA opposed the registration of "APOLLO SPACE DOLLAR" for non-monetary gold plated coins on the ground that certain memorabilia commemorating the Apollo space flights had been distributed by NASA and registration would create confusion, mistake or deception concerning applicant's relationship to NASA and would mislead the public into believing that the coins were associated with the Apollo space flights. The evidence showed that the applicants had purchased Eisenhower dollars which had on the reverse side a design adapted from the official emblem for the Apollo II flight. The applicants had then plated the coins with gold and sold them as "APOLLO SPACE DOLLAR U.S. SILVER DOLLAR." A letter in the file from the Acting Director of the Mint stated that the new dollars, of cupronickel clad coin, should not be referred to as silver dollars. The Board found the mark was being used for an improper purpose, that it was merely descriptive, and that it implied an official sanction of sponsorship by NASA which was deceptive and misleading.

Cancellations Filed by Government Agencies

Government agencies have petitioned to obtain cancellation of a registration already issued. The Federal Trade Commission is given specific statutory authority[30] to apply to cancel registrations of any mark registered on the principal register, if the mark becomes descriptive, abandoned, was registered fraudulently or contrary to specified provisions of the Lanham Act or prior Acts, or is being used by or with the permission of the registrant to misrepresent the source of goods or services. In addition, the Federal Trade Commission may petition to cancel certification marks if the registrant does not or is not able to control the mark, engages in the production of items covered by the mark, permits its use for other than to certify, or discriminates in certifying the goods or services of any person. Other agencies have petitioned to cancel marks when they believed they would be damaged by the registration.

In *Federal Trade Commission v. Elder Mfg. Co.*[31] the Federal Trade Commission filed petitions to cancel two trademark registrations is-

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[28] NASA v. Record Chemical Co. Inc., 185 U.S.P.Q. 563 (T.T.A.B. 1975).

[29] NASA v. Gause (not reported), Opposition No. 57,677 (T.T.A.B. 1977).

[30] 15 U.S.C. § 1064.

[31] FTC v. Elder Mfg. Co., 84 U.S.P.A. 429 (1950).

sued under the Act of February 20, 1905, alleging the one mark had been abandoned and the other had been obtained by false representation. The Commissioner held that Section 14 of the Act of 1946 (Lanham Act),[32] under which the action was brought, did not give the Federal Trade Commission jurisdiction to petition to cancel 1905 Act registrations. The Commissioner affirmed the decisions dismissing the petitions.

In a cancellation proceeding brought some years later, the Federal Trade Commission was more successful. In *Bart Schwartz Textiles v. Federal Trade Commission,*[33] a petition was filed to cancel the mark "FIOCCO," registered for textile fabric in the piece of cotton, rayon, synthetic fibers, and mixtures thereof, on the grounds of fraud in the declaration of ownership of the mark and the right of others to use the mark. Fiocco, an Italian word, had been used by persons in the textile industry to designate the fiber content of various textile fabrics. The court found that the applicant's president knew this when he signed a declaration forming a part of the registration application stating that no other person, etc., had a right to use the trademark in commerce regulated by Congress, and therefore that such statement was fraudulently made and constituted a ground for cancellation of the mark.

The Federal Trade Commission is presently involved in another cancellation proceeding[34] brought under Section 14 of the Lanham Act.[35] In the petition filed with the USPTO Trademark Trial and Appeal Board, the Federal Trade Commission has alleged that the mark "FORMICA"[36] has become the common descriptive name of the articles and substances included in the registrant's description of goods.

The Department of Transportation (DOT) was successful in obtaining cancellation of a trademark. Scanwell Laboratories, under a Federal Aviation contract, developed an instrument landing system using a V shaped antenna array and agreed not to affix any restrictive marking on any data delivered under the contract. Instruction manuals for the instrument landing system were prepared for the FAA and identified the product as "V-RING ARRAY." The antenna arrays were subsequently purchased from Scanwell and identified by "DIRECTIONAL V-RING ANTENNA ARRAY." Scanwell requested the FAA, when using "V-RING," to indicate that the mark is regis-

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[32] *See supra* note 29.

[33] Bart Schwartz Textiles v. FTC, 129 U.S.P.Q. 258 (C.C.P.A. 1961).

[34] 382 PAT. T.M. & COPYRIGHT J. A1 (June 8, 1968).

[35] *See supra* note 29.

[36] FORMICA, Trademark, Reg. No. 421,496.

tered and owned by Scanwell. DOT petitioned to cancel the registration of "V-RING" for directional antennas owned by Scanwell Laboratories on the grounds that the mark was merely descriptive when applied to directional antennas, as had been used by the FAA to describe directional localizer antenna arrays for a long time prior to the registration. On appeal, the court held that "V-RING" was descriptive of the antennas.[37]

The Federal Bureau of Investigation was not successful when it sought cancellation of a trademark. The F.B.I. petitioned to cancel the registration of "FINDER," obtained by an F.B.I. contractor, on an automatic fingerprint reading machine that had been developed under a contract with the F.B.I. The F.B.I. alleged that "FINDER" was adopted and used to describe a project between the parties, that both had used the term in a descriptive manner and that the name had been known throughout the law enforcement community as the fingerprint reading machine developed by the F.B.I. The Board found that the contractor had devised the term for the product and, as the holder of a registered mark, enjoyed the benefit of certain presumptions which the F.B.I. failed to overcome. On appeal to the CCPA, the decision denying cancellation was affirmed.[38]

Cancellation proceedings brought by Government agencies have not been limited to petitioning to cancel only federal registrations. In proceedings in Texas, the cancellation of a state registration was obtained. Randolph Air Force Base had adopted "WINGSPREAD" for an unofficial base newspaper, first published on the base and later published by a commercial publisher under contract. In 1960, the Sequin Publishing Company began publishing the unofficial base newspaper and later obtained a state registration on "WINGSPREAD." The contract for publication of the base newspaper was let to a different commercial publisher and he was sued by the previous publisher for his use of "WINGSPREAD." At the request of the Air Force, the Government intervened and obtained a cancellation of the Sequin Publishing Company's state registration.[39]

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[37] Scanwell Laboratories v. Dep't of Transp., 179 U.S.P.Q. 238 (C.C.P.A. 1973), 198 U.S.P.Q. 147 (C.C.P.A. 1978).

[38] Dep't of Justice v. Calspan Corp., 196 U.S.P.Q. 326 (T.T.A.B. 1977).

[39] United States v. Sequin Publishing Company (not reported) Dist. Ct. Texas, Bexar County; and Sequin Publishing Co. v. Herald Publishing Co. of Texas, U.S.D.C. for WD of Texas, Civil No. SA 75-CA-21 (1975).

Infringement Suits Filed for Government Agencies

Suits for infringement of government-owned trademarks have been filed against infringers. In many instances, the suits are settled prior to trial and the Government has an excellent record in stopping the infringing use.

In *United States v. PX Markets, Inc.*,[40] suit was filed on December 29, 1952, at the request of the Army and Air Force Exchange Service for an injunction to prevent the defendant's use of "PX." A consent agreement was entered onto in October 1957 under which defendant agreed to stop using the plaintiff's trade-names "P-X Market," "P-X Markets, Inc." and "P-X Super Market." Defendant was permitted to use the letters P and X provided the ampersand (&) was between the P and X and was not less than three-fourths of the P and X in width, height, and weight, and of the same color lighting.

Suit was filed in February 1953 at the request of the Army and Air Force Exchange Service against Sol Elsner and Gus Niedweske, d/b/a Surplus Post Exchange.[41] A consent decree was entered into in May 1953 under which defendants agreed not to use the names "Surplus Post Exchange," "Post Exchange" or "PX" or any names or styling similar thereto.

Suit was filed on March 24, 1953, at the request of the Army and Air Force Exchange Service against George Abrams, d/b/a PX Package Store.[42] A consent decree was filed on June 24, 1953, under which the defendant agreed to discontinue use of the letters "PX".

Suit was filed on March 10, 1953, at the request of the Army and Air Force Exchange Service against the Army and Navy Post Exchange, Inc.[43] A consent decree was approved in August 1956 under which the corporate name of the defendant was changed to "Sam's Army & Navy Exchange, Inc.," the Government trade names "Post Exchange" and "PX" were not to be used, and defendant agreed to use the word "Sam's" with the word "Exchange" whenever the latter was used apart from the corporate name, so as to read "Sam's Exchange."

The foregoing four suits, instituted at the request of the Army and Air Force Exchange Service, are interesting considering there were no Federal registrations of the PX or Post Exchange marks at the time of

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[40] United States v. PX Markets, Inc. (not reported), Case No. 32442 (N.D. Ca.)

[41] United States v. Elsner (not reported), Case No. 130-52 (D.N.J.).

[42] United States v. Abrams (not reported), Case No. 1682 (S.D. Ohio).

[43] United States v. Army & Navy Post Exchange, Inc. (not reported), Case No. 14936 (E.D. Pa.).

the suits. Since these suits, the Army has filed for and obtained registrations of PX[44] and Post Exchange[45] as service marks.

In *United States v. Edel Post,* d/b/a Post Exchange,[46] suit was filed at the request of the Army and Air Force Exchange Service for infringement of the trademarks "Post Exchange" and "PX," Reg. Nos. 854,349 and 854,348. The suit was dismissed on the plaintiff's motion on March 14, 1972, because the defendant had died.

In addition to the suits which have been filed for infringement of the "PX" and "Post Exchange" marks, a suit was filed on November 9, 1953, at the request of the Department of Agriculture, to enjoin use of a registered trademark, No. 559,448 for grading beef. A consent decree was entered on January 11, 1954, enjoining defendant from using any mark bearing the characteristic of the registered mark.[47]

Conclusion

Involvement of Government agencies in using and obtaining trademarks and other marks, in opposing registrations, in petitioning to cancel registrations, and in guarding against unauthorized use of Government trademarks, has been quite extensive. In view of *In re Mohawk Air Lines,*[48] applications by Government agencies for registration of marks, and agency initiated opposition and cancellation proceedings, will likely increase. Once government agencies obtain more registrations, greater policing of these marks, resulting in more infringement actions being brought for Government agencies, may also be expected.

APPENDIX I

STATUTES ON PROTECTION OF SPECIFIC MARKS

Agency and Other Marks

Coast Guard, USCG, USCGR, United States Coast Guard, Coast Guard Reserve, United States Coast Guard Reserve, Coast Guard Aux-

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[44] PX, Service Mark, Reg. No. 854,348.

[45] Post Exchange, Service Mark, Reg. No. 854,349.

[46] United States v. Edel Post (not reported), Case No. Civ-72-141 (D. Okla.).

[47] United States v. Choice Meat Packing, Inc. (not reported), Case No. 16021-BH (S.D. Cal.).

[48] *See supra* note 17.

iliary, United States Coast Guard Auxiliary, Lighthouse Service, Life Saving Service — prohibition against use without authority of Commandant — 14 U.S.C. 639.

Golden Eagle and insignia — prohibition against manufacture, reproduction or use except as authorized under rules and regulations issued by Secretary of Interior — 18 U.S.C. 715.

Johnny Horizon and character — prohibition against manufacture, reproduction or use except as authorized under rules or regulations issued by Secretary of Interior — 18 U.S.C. 714.

Function of Indian Arts and Crafts Board to create Government trademarks for Indian products and register them in Patent Office without charge — 7 U.S.C. 305a.

Government trademark used or devised by the Indian Arts and Crafts Board in the Department of Interior — prohibition against use without authorization — 18 U.S.C. 1158.

American Revolution Bicentennial — protection of logos, symbols or marks originated thereby — 84 Stat. 1389, Pub. L. No. 91-528.

Smokey Bear and character — prohibition against manufacture, reproduction or use except as authorized under rules or regulations issued by Secretary of Agriculture after consultation with the Association of State Foresters and the Advertising Council — 18 U.S.C. 711.

Woodsy Owl and character and slogan "Give a Hoot, Don't Pollute" — prohibition against manufacture, reproduction or use except as authorized under rules and regulations issued by Secretary of Agriculture — 18 U.S.C. 711a.

Marks indicating inspection, certification and identification of class, quality, quantity and condition of agriculture products when shipped or received in interstate commerce — authority to issue and prohibition against use except as authorized — 7 U.S.C. 1622(h).

Federal, national, United States, U.S. — prohibited for use by collecting agencies or private detective agencies — 18 U.S.C. 712.

Great seal of United States and seals of President or Vice President of United States — prohibited against use and sale except as authorized — 18 U.S.C. 713.

Seals of Departments or Agencies of the United States — prohibition against falsely making and knowingly using fraudulently made seal — 18 U.S.C. 506.

Official badges, identification card, or other insignia, of the design prescribed by the head of any department or agency for use by any employee or officer — prohibited against manufacture, sale or possession — 18 U.S.C. 701.

Federal, United States, national, reserve, Deposit Insurance — prohibited for use in financial businesses — 18 U.S.C. 709.

Federal Deposit, Federal Deposit Insurance, Federal Deposit Insurance Corporation, Federal, United States, Federal Home Loan Bank, National Agriculture Credit Corporation, Federal Intermediate Credit Bank, Department of Housing and Urban Development, Housing and Home Finance Agency, Federal Housing Administration, Government National Mortgage Association, United States Housing Authority, Public Housing Administration, HUD, FHA, PHA, USHA, Federal Bureau of Investigation, F.B.I., Reconstruction Finance Corporation — use in certain instances prohibited — 18 U.S.C. 709.

Statutes on Marks for Patriotic Societies and Other Organizations

American Legion — exclusive right to the name — 36 U.S.C. 48.

American Symphony Orchestra League — exclusive right to the name — 76 Stat. 929.

American War Mothers — exclusive right to the name — 36 U.S.C. 100.

AMVETS (American Veterans of World War II) — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 67 p.

Big Brothers of America, Big Sisters of America — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 895.

Blinded Veterans Association — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 867.

Blue Star Mothers of America, Inc. — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 956.

Board for Fundamental Education — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 516.

Boy Scouts of America — exclusive right to have and use all emblems and badges, descriptive or designating marks, and words or phrases now or heretofore used in carrying out its program — 36 U.S.C. 27.

Civil Air Patrol — exclusive right to name and insignia, emblems and badges — 36 U.S.C. 206.

Columbus University — relating to the use of the words — 67 Stat. A27.

Conference of State Societies, Washington, D.C. — relating to the name and seal, emblems and badges — 36 U.S.C. 418.

Disabled American Veterans — exclusive right to the name — 36 U.S.C. 90h.

Eleanor Roosevelt Memorial Foundation — exclusive right to the name — 77 Stat. 8.

The Foundation of the Federal Bar Association — relating to the name — 36 U.S.C. 587.

4-H Club — relating to the words and the emblem of the 4-H Club consisting of a green four-leaf clover with stem and the letter H in white or gold on each leaflet, or any sign, insignia, or symbol in colorable imitation thereof — 18 U.S.C. 707.

Future Farmers of America — relating to the name and the initials FFA — 36 U.S.C. 286.

Girl Scouts of America — the exclusive right to have and use all emblems and badges, descriptive or designating marks, and words or phrases now or heretofore used in carrying out its program — 36 U.S.C. 36.

Ladies of the Grand Army of the Republic — exclusive right to the name, emblems, seals and badges — 36 U.S.C. 78o.

Little League — relating to the name and emblems — 36 U.S.C. 1086.

Military Chaplains Association of the United States of America — exclusive right to the name — 36 U.S.C. 316.

National Conference on Citizenship — relating to the name and emblems, and seals and badges — 36 U.S.C. 446.

National Music Council — exclusive right to the name, seals and badges — 36 U.S.C. 676.

National Safety Council — relating to the name and emblems, seals and badges — 36 U.S.C. 477.

National Society of the Daughters of the American Revolution — exclusive right to the name, emblems, seals and badges — 36 U.S.C. 18c.

National Woman's Relief Corps, Auxiliary of the Grand Army of the

Republic — exclusive right to the name, emblems, seals and badges and designating marks, words or phrases — 36 U.S.C. 1017.

Naval Sea Cadet Corps — exclusive right to the name, insignia, emblems and badges — 36 U.S.C. 1056.

Paralyzed Veterans of America — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 1160.

Red Cross — unauthorized use of the Greek red cross on a white ground, or any sign or insignia made or colored in imitation thereof or the words "Red Cross" or "Geneva Cross" or any combination of these words — 18 U.S.C. 706.

Sons of Union Veterans of the Civil War — relating to the name and emblems, seals and badges — 36 U.S.C. 547.

Reserve Officers Association of the United States — exclusive right to the name, seals, emblems and badges — 36 U.S.C. 238.

Swiss Confederation — unauthorized use as a trademark, commercial label, or portion thereof, or as an advertisement or insignia for any business or organization or for any trade or commercial purpose, the coat of arms of the Swiss Confederation, consisting of an upright white cross with equal arms and lines on a red ground, or any simulation thereof — 18 U.S.C. 708.

United States Olympic Association — penalty for improper use of the emblems of the United States Olympic Association consisting of an escutcheon having a blue chief and vertically extending alternate red and white bars on the base with five interlocked rings displayed on the chief, or any other sign or insignia made or colored in imitation thereof, or the words "Olympic", "Olympiad" or "Citius Altius Fortius" or any combination of such words — 36 U.S.C. 379.

United Spanish War Veterans — the exclusive right to the name — 36 U.S.C. 56f.

The United States Blind Veterans of the World War — exclusive right to the name — 36 U.S.C. 87.

Veterans of Foreign Wars of the United States — exclusive right to the name and seal, emblems and badges — 36 U.S.C. 117.

Veterans of World War I of the United States of America, Inc. — exclusive right to the name, emblems, seals and badges — 36 U.S.C. 777.

Veterans Organization Badge or Medal — unauthorized use on mer-

chandise of any badge, medal, emblem or other insignia or any colorable imitation thereof of any veteran's organization incorporated by enactment of Congress or of any organization formally recognized by any such veteran's organization as an auxiliary thereof — 18 U.S.C. 705.

APPENDIX II

REGISTERED MARKS OF GOVERNMENT AGENCIES

AGRICULTURE

Service Marks

589,232	IFYE and symbol
605,595	International Farm Youth Exchange
930,200	USA Foreign Trade Fair
937,773	PLENTIFUL FOODS and design
1,016,465	PACIFIC CREST TRAIL and crest

Collective Marks

392,502	The NATIONAL POULTRY IMPROVEMENT PLAN and symbol
400,952	U.S. RECORD OF PERFORMANCE and design
400,953	U.S. REGISTER OF MERIT and design
400,954	U.S. PULLORUM TESTED and design
400,955	U.S. PULLORUM PASSED and design
400,956	U.S. PULLORUM CLEAN and design
400,957	U.S. PULLORUM CONTROLLED and design
403,361	U.S. APPROVED and design
403,362	U.S. CERTIFIED and design
508,012	The NATIONAL TURKEY IMPROVEMENT PLAN and symbol

Certification Marks

559,448	USDA on shield
614,913	USDA on shield
620,565	The NATIONAL TURKEY IMPROVEMENT PLAN and symbol
633,783	USDA on shield
641,884	Dotted V in a half circle design
764,467	VALIDATED and BRUCELLOSIS-FREE HERD with swine in double ellipse
931,033	USDA FOOD on shield
981,770	Onion design and IDAHO-OREGON ONIONS

ARMY
(Inc. War Dept.)

Trademarks

428,842	YANK
529,813	YANK and circle
703,101	WINTER SAFE and design
801,354	PENTAGRAM NEWS
877,012	UP COUNTRY
1,062,747	OR plus design
1,064,897	FLIGHTFAX
1,070,982	ORVAL RIGHT and owl figure
1,074,853	Design only and border
1,080,990	TRIP'N TICKET TALK
1,080,992	PASTIMES

Service Marks

539,444	COMMAND PERFORMANCE
546,424	PROUDLY WE HAIL
681,624	THE BIG PICTURE and design
808,713	W and design
808,990	THE ARMY HOUR
813,200	WORLD WIDE
854,348	PX
854,349	POST EXCHANGE
895,692	BASE EXCHANGE
895,693	BX
914,646	AAFES Service Shield with legend EES
915,803	AAFES Service Shield with Legend ALEX
915,804	AAFES Service Shield
916,504	AAFES Service Shield with Legend PACEX
917,873	AAFES
935,790	ARMY and AIR FORCE EXCHANGE SERVICE
944,261	A & AFES
988,614	REVERENTIA LEGUM
1,018,536	RUN-IN CHEF with Logo
1,019,008	THE RUNNING CHEF with Logo
1,073,371	MONEY SAVER with Logo

Certification Mark

504,860	JAN

COMMERCE

Trademarks

960,944	SUMSAT
962,079	NATIONAL TECHNICAL INFORMATION SERVICE
962,080	NTIS

Service Mark

967,222	NTISearch within ellipse

Certification Mark

1,043,863 Energy Conservation Labeling Program Logo

ENERGY
(Inc. AEC and FEA)

Trademarks
(Applns. Pending)

Appln. No. 54,738 THE PLAIN BROWN RAPPER
Appln. No. 73,506 ENERGY ANT with Figure

Service Marks

815,175 EXHIBIDOME
873,231 Rare earth symbol
1,084,336 ENERGY ANT

HEALTH, EDUCATION AND WELFARE

Trademarks

961,533 (Combined Registration) ERIC
1,060,741 CANCERGRAM

Service Marks

961,533 (Combined Registration) ERIC
996,901 MEDLARS
998,738 WHO
1,003,414 WORLD HEALTH ORGANIZATION
1,003,832 MESH
1,004,387 TOXLINE
1,009,583 TIRC
1,018,262 CANCERLINE
1,028,099 CHEMLINE
1,048,694 HEWCAS
1,057,544 Logo of United States — Japanese Cooperative Medical Services Program

INTERIOR

Trademarks

895,736 SELECTED WATER RESOURCES ABSTRACTS
979,201 OKLAHOMA INDIAN ARTS AND CRAFTS COOPERATIVE on double circles enclosing 3 teepees
1,032,632 OKLAHOMA INDIAN ARTS AND CRAFTS COOPERATIVE on double circles enclosing 3 teepees

Service Marks

784,960 Arrowhead enclosing NATIONAL PARK SERVICE and scene
813,641 BPA and electrical power transmission tower in a rectangle
840,173 LAND and WATER CONSERVATION and drawing in a circle
877,917 LEWIS and CLARK TRAIL and 2 human figures in a rectangle

886,047	Three dots inside intertwined triangles
932,392	USA on design
943,477	ENVIRONMAN
951,006	Design in a circle
1,050,231	INDIAN ARTS AND CRAFTS BOARD and design in a circle

Certification Mark

1,019,073	INDIAN ARTS AND CRAFTS BOARD and other wording and a circle in a rectangle

NASA

Trademark

1,032,871	NASTRAN

NAVY

Trademark
(Appln. Pending)

Appln. No. 182-254	TOMAHAWK

Service Mark (Appln. Pending)

Appln. No. 182,253	TOMAHAWK

Certification Marks

617,308	AN
620,564	AN
626,398	AN

TRANSPORTATION

Service Marks

958,003	TRANSPO
1,096,327	CARDIS

Certification Mark

1,058,022	Star of Life insignia

UNITED STATES POSTAL SERVICE

Trademarks

953,033	(Combined Registration) Postal Service Emblem
978,628	(Combined Registration) UNITED POSTAL SERVICE
1,007,112	(Combined Registration) EXPRESS MAIL
1,034,297	(Combined Registration) MR. ZIP

Service Marks

960,087	POSTIQUE
975,033	(Combined Registration) Postal Service Emblem
986,214	U.S. MAIL
978,628	(Combined Registration) UNITED STATES POSTAL SERVICE
1,007,112	(Combined Registration) EXPRESS MAIL
1,018,955	CONTROLPAK
1,032,534	EXPRESS MAIL PROGRAMMED SERVICE

1,034,297	(Combined Registration) MR. ZIP
1,042,499	ZIP CODE
1,094,739	FIRST CLASS MAIL
114,513 (Appln. Pending)	International Express Mail Logo

Role of the Scientist as Judge in NRC Administrative Proceedings*

Oscar H. Paris**

The administrative proceedings of the United States Nuclear Regulatory Commission (NRC) which are associated with the licensing of nuclear facilities are unique among the administrative proceedings of federal agencies. These NRC proceedings are presided over by specialized adjudicatory tribunals on which scientists and engineers, as well as attorneys, sit as judges. In certain other federal agencies, Administrative Law Judges (ALJ's) may have available a staff which includes technical persons on whom they can call for assistance. In still other agencies, ALJ's make their decisions on the basis of expert testimony alone, without benefit of additional expertise. But in NRC proceedings scientist-judges, working as partners or lawyers, sit at hearings and participate in rendering decisions.

This unique arrangement was provided for by Congress in a 1962 Amendment to the Atomic Energy Act of 1954.[1] Prior to that time, adjudicatory proceedings of the Atomic Energy Commission (AEC) (predecessor to the NRC) were presided over by a single administrative law judge. The 1962 Amendment authorized the AEC:

> To establish one or more Atomic Safety and Licensing Boards, each comprised of three members, one of whom shall be qualified in the conduct of administrative proceedings and two of whom shall have such technical or other qualifications as the Commission deems appropriate to the issues to

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*This paper was presented at the 1979 AAAS Meeting in Houston, Tex.

**The author is an environmental scientist and a member of the Atomic Safety and Licensing Board Panel of the United States Nuclear Regulatory Agency, Washington, D.C.

[1] The Atomic Energy Act of 1954, 40 U.S.C. §§ 2011 *et seq.* (1954).

> be decided, to conduct such hearings as the Commission may direct and make such intermediate or final decisions as the Commission may authorize with respect to granting, suspending, revoking or amending of any license, authorization or site permit under the provisions of this Act. (The Atomic Energy Act of 1954, as amended, section 191.)[2]

The intent of Congress in authorizing the Atomic Safety and Licensing Board was to facilitate bringing technical expertise to bear in resolving the difficult scientific and technical problems associated with atomic energy licensing. Congress also hoped that the use of the Board would facilitate safety determinations and enhance public confidence in such determinations. Congress expected the two technical members of the Board to be persons of "recognized caliber and stature in the nuclear field." It also expected the third member to be, although not necessarily, a lawyer; s/he may be, but does not have to be, an ALJ. Finally, the 1962 amendment authorized the Commission to establish a panel of lawyers and nuclear scientists and engineers from whose ranks Atomic Safety and Licensing Boards could be appointed.

The composition of the Licensing Boards was changed following enactment of the National Environmental Policy Act of 1969 (NEPA). Initially the AEC interpreted its jurisdiction under NEPA to be restricted to the radiological impact of nuclear facilities. This interpretation, however, was challenged by Intervenors, and in *Calvert Cliffs' Coordinating Committee* v. *United States Atomic Energy Commission.*[3] The D.C. Circuit decided in favor of the Intervenors. The court ruled that NEPA mandates a case-by-case balancing of benefits against environmental costs in licensing proceedings. In other words, environmental matters were now cognizable issues in AEC hearings. As a consequence, environmental scientists were added to the Licensing Board Panel, and subsequently the two technical members of each Board consisted of one nuclear scientist or engineer and one environmental scientist.

In the Energy Reorganization Act of 1974,[4] Congress separated the regulatory function of the old AEC from its other function (which included the promotion and development of peaceful uses of atomic energy). This Act created a separate and independent Nuclear Regulatory Commission, to which the functions and personnel of the Atomic Safety and Licensing Board Panel were transferred. The mis-

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[2] *Id.* at § 191.

[3] 449 F.2d 1109 (D.C. Cir. 1971).

[4] The Energy Reorganization Act of 1974, 5 U.S.C. §§ 5313-5316; 42 U.S.C. § 5801 *et seq.* (1974).

sion of the NRC is to protect the public health and safety and to protect the environment in the use of nuclear facilities and materials. It is not a responsibility of the NRC to decide whether nuclear power is or is not desirable, but rather whether a particular nuclear facility is or is not harmful. It also determines what conditions must be imposed on nuclear facilities to assure protection of the public health and safety and of the environment.

There are five NRC Commissioners appointed by the President. The Atomic Safety and Licensing Board Panel is responsible directly to the Commission; it is independent of all other organizations within the NRC. At present, the Panel has 61 members. Eighteen of these are full-time: 10 attorneys, 5 nuclear physicists and reactor engineers, and 3 environmental scientists. The 43 part-time members include physicists and reactor engineers, environmental scientists, and anti-trust lawyers and economists. Twenty-one of the technical part-time members are either deans, department heads, research institute directors, or professors at major universities throughout the country. The expertise represented among the environmental scientists includes oceanography, marine and freshwater ecology, terrestrial ecology, fish and wildlife ecology, and public health. Ten of the attorney members have either served as ALJ's or are on the ALJ Register of the Civil Service Commission. All of the attorneys had extensive trial experience before being appointed to the Panel.

Panel members are assigned to Boards by the Panel chairperson, a lawyer, who consults with the technical advisor to the panel, a nuclear physicist. In making such assignments, consideration is given to the nature of the case, availability and caseloads of panelists, and the technical expertise needed in the proceeding in question.

Members are appointed to the panel by the Commissioners, following a search for qualified candidates conducted by the chairperson of the Panel, who is assisted by a search committee consisting of full-time panel members. Selections are based on expertise that a candidate brings to the Panel, his or her training and professional experience, achievements, and independence and other personal qualities necessary to adjudication. Each appointee is given a full field investigation by the FBI and must qualify for top secret security clearance before the appointment becomes final. Finally, appointees must comply with the NRC's conflict of interest regulations.

The lawyer-member of a Board serves as the Board's chairperson. S/he presides at hearings, flanked by the two technical members. During hearings technical members contribute questions, comments, and observations as they see fit, and the chairperson consults with them

before rendering a decision from the bench. Parties to a hearing always include the applicant and the NRC Staff, who are represented by counsel and, in a contested hearing, the intervening party or parties. Intervenors may be represented by counsel or may appear *pro se*. A case can be contested without intervenors if the NRC Staff and the applicant are in controversy over an issue. The Board decides the controverted issue.

NRC proceedings are governed by the Administrative Procedures Act of 1946[5] and by the Regulations of the Nuclear Regulatory Commission.[6] The chairperson of the Board, *i.e.,* the attorney member, takes the lead in matters of law and procedure. S/he can issue procedural orders and memoranda for the Board without consulting the technical members. It is customary, however, for the chairperson to obtain the concurrence of the other Board members even on procedural matters if the members are available for consultation. Occasionally it may be necessary for a Board to issue an order in the absence of the chairperson. For example, an order on a motion for extension of time may be required when the chairperson is away at a hearing. In that case, one or both technical members would consult by phone with the chairperson and then draft and issue the order. The Panel has a full-time legal counsel in Bethesda, with whom technical members can consult on legal matters if necessary.

Before a Board issues an order dealing with substantive matters, the members discuss and debate the issues and reach a consensus. The technical members play a major role in these discussions. For example, a Board may be deciding which of a number of contentions submitted by an intervenor are cognizable in the proceedings. The contentions usually are of a technical nature, so the technical members take a leading role in the Board's deliberations. The nuclear member assumes primary responsibility for evaluating contentions relating to reactor safety and design, and the environmental member takes the lead in evaluating contentions relating to environmental impact. The attorney member takes primary responsibility for assessing problems related to points of law, regulations, precedence, etc. If Board members find themselves in disagreement on some issue, they debate the matter, and usually are able to reach a conclusion in which all members concur. If not, the majority rules and the order issues. The minority member could, if s/he wished, issue a dissenting view with the order.

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[5] Freedom of Information Act, 5 U.S.C. § 552 (1974).

[6] 10 C.F.R. Parts 0-199.

The evidentiary hearings are formal adjudicatory proceedings. The chairperson is responsible for the Board's compliance with the Administrative Procedures Act and the Commission's Rule of Practice.[7] Most of the evidence received is technical, given by expert witnesses. The technical members of the Board take primary responsibility for evaluating the evidence and examining the witnesses. The Rules of Practice require witnesses to submit direct written testimony in advance of the hearing. Thus the parties and the Board have an opportunity to study the scientific and technical evidence prior to hearing. At the hearing the witness will be subject to direct examination during which s/he is usually asked to summarize the written testimony that is introduced as an exhibit, in order to provide the attending public with some idea of what is in the evidentiary documents. Following the direct examination, the witness is subjected to cross-examination.

The technical members of the Board will frequently question the witness to clarify something the witness said, to further probe into a technical area, to develop facts, or to explore the basis of an expert's opinion. Technical Board members may also assist cross-examiners in phrasing technical questions. Ideally they will also advise the chairperson when cross-examination becomes repetitious or unproductive.

Board members may have questions of their own to ask the expert witness, derived from their own study of the written testimony or from the witness' oral testimony. Expert witnesses need not have first hand knowledge of the facts, of course. They may give a professional opinion, based on statements made outside the proceeding in scientific or technical documents, which often are offered as supporting evidence. It is necessary for the technical members of the Board to determine whether an opinion of the witness is scientifically acceptable, whether the data on which the expert bases an opinion are adequate and reliable, and whether the witness has correctly and completely reported information contained in supporting documents. If a witness is reluctant in his or her testimony, the Board members make certain that an exploration is made to discover the reasons for the witness' reticence.

In Licensing Boards administrative proceedings evidence is not handled as it is in a court trial. In a court trial the judge is not obligated to seek evidence beyond that offered by the parties, and the jury cannot ask for additional information. In Board proceedings, however, the Board has a responsibility to take whatever steps are necessary to

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[7] 10 C.F.R. Part 2.

get a complete evidentiary record. If the record is inconsistent, the Board must seek additional evidence that will settle the inconsistency, either by calling its own witnesses or by instructing the parties to produce additional evidence. The evidence in the record must support and protect the Board's decision.

To be admissable under NRC Rules of Practice, evidence need only meet the criteria provided for in the Administrative Procedures Act, *i.e.,* it must be relevant, material, reliable, and not unduly repetitious.[8] If there is any question about the admissability of some evidence, the general practice is to admit it. If it is of a technical nature, as is usually the case, the technical members of the Board assign weight to it.

Ground rules which Atomic Safety and Licensing Boards follow in proceedings are set forth in an appendix to the NRC's Rules of Practice.[9] For example, the Licensing Board must determine the matters in controversy in contested proceedings, and may be called upon to make its own technical judgments on those matters. In exercising this independent technical judgment the Board depends primarily on its scientist members.

In uncontested cases, or with respect to uncontroverted matters in contested cases, the Board is authorized to rely on the testimony of the applicant and the staff. The Board's role is not to conduct a *de novo* evaluation of the application in such cases, but rather to decide whether the record of the proceeding contains sufficient information, and whether the review by the staff has been adequate to justify issuance of a construction permit. This role of Licensing Boards has been approved by the United States Court of Appeals, D.C. Circuit, in *Union of Concerned Scientists* v. *United States Atomic Energy Commission.*[10] If a Board is not satisfied with the record or with the review of the staff in an uncontested case, it will call for additional evidence, just as it would in a contested case. In addition, if a Board determines that there are serious safety, environmental, or security matters which, although not in controversy, should be explored, it is authorized to examine and decide such matters on its own initiative.[11]

When the record in a proceeding has been closed, the parties submit Proposed Findings of Fact and Conclusions of Law, after which the Board prepares its decision. In writing a decision, the members of a

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[8] 10 C.F.R. 2.743(c).

[9] 10 C.F.R. Part 2, Appendix A.

[10] 499 F.2d 1059 (D.C. Cir. 1974).

[11] 10 C.F.R. 2.760A.

Board usually divide the responsibility so that each member deals with those issues which fall within his or her general area of expertise. Thus the attorney member writes those portions of the decision which deal with matters of law and which relate to controverted issues on points of law. In addition, as chairperson, s/he coordinates and integrates the work of the Board into a unified decision. The nuclear scientist or engineer writes those portions which deal with reactor design and safety, and the environmental scientist writes the portions relating to environmental impact. Either technical member may write that part of the decision relating to health effects, since both are usually well informed with respect to radiological health. In rendering a decision, the Board functions as a collegial body; decisions are signed by all members of the Board.

By consulting prior to the commencement of writing, the Board members determine whether they are in basic agreement with respect to the outcome of the decision. Usually differences in opinion are resolved by discussion at that time. After each Board member has prepared a draft of his or her portion of the decision, it is given to the other Board members for their comments. Sometimes this exchange will uncover differences in opinion among the Board members, which additional consultation may resolve. If a major issue remains unresolved at the writing of the decision, the majority issues the initial decision, and the minority member writes a dissenting opinion. Thus, the views of the dissenting member are placed on the record and become known to the parties, the public, the Appeal Board, the Commission, and to the courts if an appeal should go that far.

How do scientist-judges use their technical expertise in adjudication? A scientific fact on which a decision is stated to rest must be in the evidentiary record of the case — with a couple of exceptions. One exception is general scientific fact which an informed lay person might reasonably be expected to know. Another exception is any scientific or technical fact within the knowledge of the Commission as a body. In general, the technical member of a Board is not free to draw scientific facts from his or her own knowledge and use them as a basis for a decision. But if a Board member is aware of facts or research which may contradict testimony, s/he can get such contradictory information into the evidentiary record in several ways: the Board member can question witnesses about the contradictory facts with which s/he is familiar, the Board can instruct the parties to present witnesses who can testify on the contradictory information, or it can call its own witnesses to testify on the matter. Thus the technical Board member can use his or her own knowledge to bring relevant information before the Board.

Another important way in which the scientist-judge uses his or her own technical knowledge is in evaluating testimony. S/he may, for example, find that a calculation presented in evidence is incorrect, or that an assumption in a model is invalid. In such a circumstance the Board member uses his or her own knowledge to accept or reject findings of fact. In a contested case, a scientist-judge might be able to accept part of the logic of each adversary but the final conclusions of none. In such a case it may be possible for the scientist-judge to reach his or her own conclusion based on the acceptable facts offered by two or more of the parties. The conclusion would be derived from the Board's own technical judgment, but it would be based on facts contained in the record.

Still another important, but less easily defined, way in which a scientist-judge uses his or her expertise in adjudication involves what can be termed "cast-of-mind." The scientist or engineer, through years of training and experience, learns to think like a scientist or engineer — just as a lawyer learns to think like a lawyer. Consequently, a technical member of a Board is equipped to closely monitor the testimony of the expert witness — who also thinks like a scientist or engineer. This intellectual conditioning tends to enable the scientist-judge to readily distinguish important points from unimportant points, to quickly determine what is relevant and what is not, to formulate questions that will critically probe technical testimony. The technical Board member also has a certain psychological advantage when he or she is questioning an expert witness. The expert witness who is being questioned by another expert is less inclined to be evasive or vague. If the technical Board member phrases and delivers his or her questions properly, the expert witness may be disarmed by the suspicion that the Board member knows more about a topic than he or she does. Occasionally he or she may even be correct in this suspicion.

The "cast-of-mind" and the technical knowledge of the scientist-judge can, on the other hand, impart certain disadvantages to his or her performance as adjudicator. For example, while questioning a witness a technical Board member may fail to probe for the reasons behind an answer or statement of an expert witness, because the technical Board member already knows the reasons for the witness' statement. The witness fails to see the necessity of providing the supporting facts, because they are so familiar to him or her, and the Board member fails to ask about them, because they are also familiar to him or her. The result may be an incomplete record, a decision which rests on facts not contained in the record, and ultimately a remand or reversal by the Appeal Board.

Another disadvantage associated with using scientist-judges is that they are not trained in cross-examination. They may not know how to use unbiased language in phrasing questions. Consequently, a party may get the impression that a Board member has already made up his or her mind because of the way a question is phrased.

Finally, there are some minor problems associated with teaming scientists and lawyers together as a tribunal. Scientists believe that all things are testable and, given appropriate assumptions, that almost anything is possible. Lawyers, on the other hand, believe that all things are arguable, almost irrespective of the evidence, until a decision is made — and then the matter is set in concrete. These differences result from the different "cast-of-mind" of scientist and lawyer, of course. They occasionally arise in the deliberations of a Board before and after hearings and bother some panelists more than others.

The lawyer-scientist combination on NRC Boards, on the other hand, offers some important advantages. Technology has grown to such an extent that a person who decides to become an expert in a technical area has to devote a major portion of his or her life to its study. If one devotes most of one's life to the study of, say, aviation, one is very apt to believe that aviation is a good thing in spite of the risks inherent in it. The FAA must have on its staff aviation experts, experts who are charged with the responsibility of imposing and enforcing safety regulations on the aviation industry. But, by virtue of their training and experience, these regulators can reasonably be expected to have a certain degree of sympathy toward the aviation industry. The same can be said for some technical members of Atomic Safety and Licensing Boards. Nuclear reactor engineers, having spent a fair portion of their lives studying and working with nuclear reactors, are apt to believe that reactors are good things, in spite of the risks inherent in them. The mixed composition of the Boards, however, tends to counteract bias such as this. The lawyer and environmental scientist have not had the training and experience of the engineer, and tend to be pretty independent in their thinking with regard to reactors. By the same token, the environmental scientist member of a Board might be a fisheries ecologist whose bias may cause him or her to tend to think that fish populations should be completely protected regardless of cost. The lawyer member, of course, has none of the biases of either technical member, and can be relied upon to render fair and equitable judgement based solely on the evidence. The use of a tribunal in which each member has different expertise provides an effective means of getting around the knowledge-bias problem.

Arguments concerning the use of adjudicatory proceedings as a

means of resolving technical or scientific controversies were put forward in support of and in opposition to a proposal to create a science court for weighing scientific facts in controversial national issues.

Opposition to a science court was advanced recently by Dr. William J. McGill, President of Columbia University, who stated, "To those of us raised in the traditions of academic freedom that atmosphere is reminiscent of the days of Galileo and the Inquisition."[12] McGill argues that the adversary method for arriving at truth is not appropriate for arriving at public policy on scientific matters. He believes that the conflicting advocacy of a courtroom does not contribute to the understanding of scientific questions and favors instead the creation of special commissions constituted of highly credible scientists to formulate public policy on technical matters such as public health and safety.

A different point of view on the science court was expressed by Barry M. Casper of the University of Minnesota's School of Public Affairs. Although Dr. Casper is against using science courts as a means of dealing with technical aspects of controversial public policy issues, he would use scientist-judges to decide narrowly defined technical questions, such as the determination of risks of certain consumer products (and, presumably, of nuclear reactors in specific localities). In the case of public policy issues, he would use the adversary process as a vehicle for developing a public record on technology policy issues, but he would let politicians and other citizens judge the record for themselves.[13]

It is not the purpose of this article to enter the debate on the science court. However, experience indicates that the debates of academic scientists rarely resolve issues. Rather, they tend to foster and perpetuate opposing schools of thought. There is no mechanism in academic science for critically probing opposing arguments. Scientists spend more time talking with others who share their points of view than with those who oppose them — it is more comfortable to do so.

Dr. McGill argues that the only effective method for resolving safety questions and arriving at sensible judgments about nuclear research is by objective analysis "by our best scientific minds". Such a group of experts would bring more than their technical knowledge to such an analysis; they would also bring the strong biases which they have developed through their long association with the technology under consideration. On the other hand, as Dr. Casper points out, the adver-

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[12] McGill, *Advisory Legal Process, Scientific Research,* 3(3) COLUMBIA TODAY 2.

[13] Casper, *Technology Policy and Democracy,* 194 SCIENCE 29-35.

sary process is well suited to bring out unstated assumptions, to reveal undocumented assertions, to discover selective presentation of data, and to find the rationale behind differences in emphasis. No procedure presently exists that is as effective at extracting the truth from an expert as placing him or her under oath and subjecting him or her to skillful cross-examination by an attorney who has a stake in proving the opposite.

Social Science and the Issue of Obviousness: Some Observations on Diversity, Stability, and Change*

Myles Hopper**

One of the most troublesome issues in the field of intellectual and industrial property is the manner in which district and circuit courts reach decisions regarding the validity or invalidity of patents. The issue is of enormous private and public importance given, among other things, the financial interests and the possible sanctioning of monopolies which are involved in any patent litigation. For these and other reasons which will be discussed, patent law must not be viewed as merely as technical sub-field of our legal system. Rather, the judicial response to patent cases must be recognized as having a profound effect upon the social, economic, and technological spheres of our society.

This recognition, along with much dissatisfaction over the judicial decision-making process in patent cases, has resulted in a large body of literature analyzing the arguments presented to the courts and the nature of the decisions themselves. The literature includes many dif-

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ferent approaches from a wide variety of academic perspectives. As an outgrowth of an earlier article on cultural anthropology and patent law,[1] the present paper continues the discussion of selected relationships between social science and law. Patent validity cases are viewed as an appropriate vehicle for this analysis because of the large variety of socio-legal issues inherent in them.

Specifically, what follows is an attempt to conceptualize more thoroughly the nature of certain problems in patent litigation, especially the difficulty involved in the proof of obviousness or non-obviousness, and the judicial responses to these cases. A set of observations is offered which attempts to demonstrate that well-established ideas in the social sciences regarding the organization of social systems and nature of human cognition help considerably in our understanding of the legal process in this and other areas of law. The study begins with a brief review of some relevant literature in order to clarify further the base-line problem of our inquiry. Historical and descriptive studies of problems in patent law are explored for their emphasis on the § 103 obviousness issue.[2] Following this is an examination of several surveys of patent invalidity rates, and the

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[1] *See* M. Hopper, *The Use of Cultural Anthropology in Patent Litigation: An Unexpected Synergism,* 20 (1) IDEA 1 (1979).

This article was an attempt to integrate two previously unrelated fields:

> "The analysis... consists of several interrelated topics. First, a brief explanation of cultural anthropology is offered which focuses on the psycho-social phenomenon of innovation. Second, several recurrent themes of patent law are discussed, particularly the issue of obviousness or non-obviousness and the difficulty of proof of same in patent law litigation. Third, a well-known recommendation for the proper structure of judicial inquiry in patent litigation is analyzed and its deficiencies suggested in light of recent case law. Fourth, the manner in which anthropologists and other social scientists study the issue of obviousness or non-obviousness when engaged in applied social science projects is explored. Some theoretical and methodological perspectives are shown to have potential utility in improving the success with which patent litigation arguments can be organized and presented." *Id.* at 2.

The central analytical section of the argument involved the comparison of the methodology of a particular applied anthropology project in Latin America and one suggested in patent law for successful proof of obviousness or non-obviousness.

[2] *See* M. Sears, *Combination Patents and 35 U.S.C. § 103,* 3 DET. COLL. L. REV. 83, 102 (1977) (footnotes omitted).

causes thereof, as manifest in the district and circuit courts.[3] Obviousness is again suggested to be a crucial theme. Finally, two recent articles using interdisciplinary approaches are reviewed for their discussions of the difficulties in recognizing obviousness or non-obviousness and, in turn, proving it when necessary.[4]

Having established the existence of the § 103 problem and its major configurations, the paper moves to a discussion of the concept of system as it applies to patent law and social science. The analysis of systems is critical to the social sciences and to this area of the law especially given the problems posed by § 103. An extension of this analysis consists of an examination of selected features of the cognitive process of decision-making within the courts, themselves viewed for certain purposes as small-scale social systems. The remainder of the paper concerns the manner in which evidence is interpreted and meaning is assigned to facts. It is concluded that the analysis has applicability to our understanding of the legal process in all societies and is not limited to "advanced" or literate peoples.

The Literature

A review of a selected sample[5] of the vast literature will serve (1) to illustrate the set of concerns which seem to comprise a common bond among the authors, and (2) to establish the relevance of the inquiry regarding social systems and cognitive processes suggested above.

There are many themes which can be identified, two of which merit attention in the context of this paper. First, there is an intense concern over the rates at which and the manner in which patents are invalidated by the district and circuit courts. Second, the requirement of non-obviousness as one element of patent validity is viewed as a complex and troublesome intellectual stumbling block over which attor-

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[3] L. Baum, *The Federal Courts and Patent Validity: An Analysis of the Record,* 56 J. PAT. OFF. SOC'Y 758 (1974); C. Kitti, *Patent Invalidity Studies: A Survey,* 20 (1) IDEA 55 (1970); G. KOENIG, PATENT INVALIDITY: A STATISTICAL AND SUBSTANTIVE ANALYSIS (1st Rev. ed. 1976); D. LOWIN, THE PRESUMPTION OF VALIDITY: A STUDY OF ITS EFFECTS ON CASE LAW SINCE 1952, Law Science and Technology Monograph Series, Entrepreneurial Workshop, Franklin Pierce Law Center (1979).

[4] One article is Hopper, *supra* note 1. The other is J. Field & T. Field, *Post Hoc Evaluations of Obviousness: Preliminary Report of an Attempt to Identify, Empirically, the Characteristics of a Superior Evaluator,* 20 (1) IDEA 29 (1979).

[5] The sample has been chosen to illustrate the central themes of this paper. Additional references are provided in context of the analysis of the sample itself.

neys and judges constantly trip. These two interrelated themes will be seen to permeate the literature.

Historical and Descriptive Studies.[6] This particular category of study is probably the largest. It consists of works which analyze the historical development of the present patent law and describe the configurations of specific problems of judicial interpretation of its content.[7] The articles concentrate in large part on the problem of obviousness and its place in the 1952 Patent Law. Non-obviousness was established as a requirement in § 103 which reads:

> ....
>
> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[8]

The issue of obviousness is generally couched in a broader overview of the policy considerations and constitutional conflicts behind the patent system generally. This scope is clearly revealed in the following excerpt:

> The broad philosophy governing our patent laws is directly traceable to the United States Constitution; thus, it is not surprising that some of the specific applications of this philosophy to particular fact situations have their roots in the 1790 era. The doctrine that there can be no patentable invention in so combining old process steps, mechanical elements or substances merely to take advantage of their known functions or properties is one such specific application which has been unanimously reaffirmed by the United States Supreme Court. This reaffirmance is directly contrary to the position taken by many patent lawyers and others and has rekindled a campaign to induce Congress to enact repudiative legislation.
>
> Constitutional strictures upon the patent system are at the heart of this debate. The Court is committed to the view that the Constitution ordains a high standard of patentability to promote technical progress and the Congress lacks power to authorize a patent system on any other premise. Its critics argue that the Constitution can be interpreted to permit Congress to use its patent power to stimulate "progress" by encouraging introduction to

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[6] The headings are the author's. It is possible to categorize the studies differently, for different purposes.

[7] *See, e.g.,* P. Federico, *Commentary on the New Patent Act, 35 U.S.C. at 1* (1952); S. Reisinfeld, *The New United States Patent Act in the Light of Comparative Law,* 102 U. PA. L. REV. 291 (1954); Note, *The Standard of Patentability – Judicial Interpretation of Section 103 of the Patent Act,* 63 COLUM. L. REV. 306 (1963); Sears, *supra* note 2.

[8] 35 U.S.C. § 103 (1952).

> the market place of new commercial items based on the application of old technology without any creation of new technical knowledge.[9]

Invalidity Surveys. This group of studies[10] is also extensive and is related to the historical and descriptive papers in the sense that both focus on court determination of validity. The analyses concentrate on three major items: (1) the number and types of patents litigated in district and federal courts; (2) the statutory reasons for the finding of invalidity (*i.e.*, what section of 35 U.S.C. 100 *et. seq.* has been violated); and (3) the comparison of these data among the various jurisdictions.

One most recent survey by Kitti summarizes the practical reasons for the intense interest in the behavior of the courts.[11] Many policy makers and patentees are motivated, for political and economic reasons, to reduce the uncertainty of the value of patents. They are most interested in understanding the reasons behind invalidity decisions so that whatever remedies are suggested will be appropriate. As Kitti mentions, the suggested remedies include limiting the grounds for litigation and using adversarial hearings prior to the granting of the patent. While this study is technically of high quality, it does not attempt to explain in any detail the reasons for the variations in validity rates which exist among the district and circuit courts. There are, of course, numerous explanations for the variations in judicial response and some of the body of this analysis will be referred to in subsequent sections of this paper.[12] In any event, there appears to be considerable question as to the meaning of the patterns uncovered in validity surveys. Kitti has concluded that rates of invalidity have not been well established and that there are important and unexplained discrepancies among the studies in the absolute numbers of patents which are litigated and in the percentages of invalidity. In addition, Kitti maintains that the value of validity rates to patentees is still largely unstudied as is the effect of validity rates on potential infringers: "While the ability of a patent to provide an incentive to innovation is influenced by validity rates, it is impossible to determine what the effects will be."[13]

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[9] Sears, *supra* note 2.

[10] *See, e.g.*, P. Federico, *Adjudicated Patents, 1948-54*, 38 J. PAT. OFF. SOC'Y 233 (1956); Baum, *supra* note 3; KOENIG, *supra* note 3; Kitti, *supra* note 3; LOWIN *supra* note 3.

[11] Kitti, *supra* note 3, at 56-7.

[12] *See, e.g.*, LOWIN, *supra* note 3, and Baum, *supra* note 3.

[13] Kitti, *supra* note 3, at 75-6.

Regardless of this uncertainty, it is clear that the existence of high invalidity rates, whatever the complex of causes, is likely to continue. While some of the reasons for this pattern will be addressed, at the moment the reader should keep in mind Koenig's admonition that the source of the problem cannot be viewed simply as a difference between standards of the United States Patent and Trademark Office (USPTO) and the courts:

> The percentage of patents held invalid by the courts during the period from 1953 through 1972 represents approximately 0.1 percent of the patents issued during that twenty year period. Some of the patents involve very small improvements in very crowded fields. Despite the application of the clearest guidelines, many of the inventions analyzed appear to be borderline cases of patentability. If the Patent Office sometimes appears to be too lenient in the granting of a patent, the courts sometimes appear to be too strict in the application and, in some cases, the misapplication of the standards of patentability set out in the statute. But there is no basis for declaring a "notorious difference between the standards applied by the Patent Office and by the courts".[14] As this study shows, there are many factors involved.[15]

Baum suggests that there are several fundamental reasons for the behavior of the courts.[16] In brief, he cites: (1) the controversy, evident among the judiciary, concerning the possibility that the standards of the USPTO are unduly low; (2) the judiciary's fear of granting monopolies too freely, thereby exacting too high a price from the public; and (3) the impact on lower federal courts of decisions by the Supreme Court. Baum has observed that:

> Not all federal judges have responded to the Supreme Court's decisions on patent validity. Some are unaware of those decisions, while others do not see the Court's mood as relevant to their own determinations. A few judges simply believe that the Court's view of patent law is wrong. But most judges have followed the lead of the Supreme Court, and the Court's effect has been felt across the whole judicial system. That effect has been a powerful one . . .[17]

> It is most unlikely that a time will come in the near future at which the great majority of patents adjudicated are found valid. For at least five decades, patents in the federal courts have faced a considerable chance of invalidation; we may expect that condition to continue for many decades in the future.[18]

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[14] Graham v. John Deere Co., 38 U.S. 1, 148 U.S.P.Q. 459, 467 (1966), *cited in* KOENIG, *supra* note 3, at §§ 1-7.

[15] KOENIG, *supra* note 3, at § 1-7.

[16] Baum, *supra* note 3, at 766-83.

[17] *Id.* at 783.

[18] *Id.* at 784.

Following the Supreme Court's lead in this instance is problematic, especially in those difficult cases which deal with § 103 questions of obviousness. As a reason for invalidating patents, § 103 is very frequently cited.[19]

Interdisciplinary Studies. Two recent articles[20] focus in considerable detail on what might be called the hindsight problem. Simply, hindsight is nothing more than an attempt to comprehend something after it has occurred. In patent cases this means that the degree of obviousness of an innovation must be ascertained retrospectively, a feat which necessitates the discovery and description of historical ideas long since colored by intervening events. J. Field and T. Field recognized that non-obviousness is as difficult to define as forseeability, both of which terms, to be applied, demand the use of hindsight: "It seems to be widely perceived among the patent bar that (at least) unconscious application of *hindsight* results in the invalidation of patents which ought to be sustained based on the state of the art *at the time* of the invention." [Emphasis in the original.][21]

The purpose of the Fields' study is to test the simple, but important hypothesis that "sensitivity to degrees of obviousness of useful responses to more or less useful problems does, in fact, vary".[22] The ultimate interest of the authors is to determine the extent of the variations, should they in fact exist, and whether the variations are "correlated with other identifiable factors, *e.g.,* certain kinds of training, employment in the...(USPTO), employment as a patent attorney, etc."[23] By utilizing various tests and procedures developed by psychologists,[24] the Fields tentatively concluded that when a particular problem which does not present a specialized scientific or technological issue is being analyzed experience with patents does not provide any special ability to employ hindsight in the evaluation of the degree of obviousness of the innovation. They conclude that the tools of psychology are most likely useful in further analysis of the meaning and process of hindsight and suggest that the potential should be exploited.

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[19] *See* LOWIN, *supra* note 3, and Koenig, *supra* note 3, for detailed analysis of all of the grounds for invalidity and their frequency of use by the courts.

[20] Field & Field, *supra* note 4, and Hopper, *supra* note 1.

[21] Hopper, *supra* note 1, at 22.

[22] Field & Field, *supra* note 4, at 32 (footnotes omitted).

[23] *Id.* at 32.

[24] *Id.* at 32-3. The measures or tests scrutinized included, among others, semantic differential, polygon preference, peer ratings, personal value orientation, Adjective Check List, Similies Test, Torrance Test and Guilford Test.

In a related article,[25] a step by step guide for judicial inquiry into obviousness was presented.[26] It was demonstrated through a case study known as the Vicos Project[27] that applied social science programs in particular make use of a similar scheme for collecting, organizing, and analyzing their data.[28]

> The earlier discussion of patent law presented Shapiro's scheme as a good example of guidelines which could be used for directing judicial inquiries into obviousness or non-obviousness. It is also apparent that these guidelines have utility for directing the formulation of a complete and persuasive legal argument to the court. Patent attorneys must address all of the items enumerated in the scheme in order to develop a comprehensive history of the innovation and its relationship to the state of the art. Interestingly, but not surprisingly, anthropologists have a similar set of needs because of their desire to assess an innovation's potential for social acceptance... What frequently appears to be of obvious value and utility to anthropologists is often rejected or utilized in unpredictable ways by the recipients of the innovation.[29]

Thus, social scientists and patent attorneys are both interested in the related issues of obviousness and utility and the manner in which an innovation is accepted or rejected.

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[25] Hopper, *supra* note 1.

[26] N.H. Shapiro, *Toward a Realistic Standard of Patentability,* 16 (2) IDEA 3, 12 (1974). The scheme is as follows:

1. Was the problem solved by the invention a problem recognized by those working in the art to which the invention pertains?
2. If the problem was known to persons working in the art:
   a. How long was the problem known?
   b. Did motivation exist for a solution to the problem?
   c. What prior attempts were made to solve the problem by the inventor and others in the art?
   d. Was the inventor's solution to the problem contraindicated by the teachings of the others working in the art?
   e. Was the success of the invention in solving the problem considered surprising by persons working in the art:
3. What tributes were paid to the invention, such as:
   a. Laudatory comments of others working in the art?
   b. Commercial success due to the invention?
   c. License right acquired from the inventor?
   d. Copying of the invention by competitors?

[27] *See* Hopper, *supra* note 1, at 20-25.

[28] For discussion of applied anthropology *see, e.g.,* G. FOSTER, APPLIED ANTHROPOLOGY (1969). Generally, *see* W. GOODE & P. HATT, METHODS IN SOCIAL RESEARCH at 29-40 (1952); A. Gouldner, *Explorations in Applied Social Science,* 3 SOC. PROB. 169 (1956); W. BENNIS, K. BENNE, R. CHIN, THE PLANNING OF CHANGE: READINGS IN THE APPLIED BEHAVIORAL SCIENCES (1964).

[29] Hopper, *supra* note 1, at 18.

Interdisciplinary studies such as the above attempt to explore the legal process through approaches which, at first glance, might seem irrelevant. But, as will be discussed more thoroughly, one affect of these studies can be to demonstrate forcefully that the problems being studied cannot be characterized merely as "legal."

Themes in the Literature. The various studies discussed above, when viewed in their entirety, reveal the existence of several major and interrelated themes which were suggested at the outset of the brief review of the literature and which should be clarified further at this point.

First, the existence of some type of process of obtaining and protecting patents has been recognized as vital to our national interest. The process functions both as an incentive to innovation and a check against unwarranted monopoly. Second, the studies of the decisions of the courts regarding the validity of patents reveal what appears to be a high rate of invalidity even given the supposed existence of a "presumption of validity."[30] The factors which cause this rate of invalidation have been variously analyzed and there is not total agreement among analysts as to their significance and meaning.[31] Additionally, the studies reveal significant discrepancies in data collection and interpretation which are confusing.[32] Yet it is clear that the invalidity rates are of sufficient concern to warrant the extensive study which continues apace. Third, of all of the potential grounds for invalidity, § 103 obviousness is the most difficult to define, understand, and apply. Fourth, the problematic use of hindsight is central to judicial determinations of obviousness. Yet it is unclear precisely how hindsight is employed by various judges and, therefore, it is difficult to predict what evidence will be most persuasive to the court in the efforts of a party to achieve its particular goals in litigation should the need arise. A discussion of *Scully Signal Company v. Elec-*

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[30] *See* LOWIN, *supra* note 3. The presumption is codified in 35 U.S.C. § 282. As Lowin has written: "The presumption that an issued patent is valid has its origin in the historic judicial deference to expert agencies acting in the fields of their expertise. The Patent Office is such an expert agency (*id.* at 1)... [I]t is because of the strict scrutiny of the patent application process and the expertise of the Patent Office that there is a presumption of validity... What [the presumption does is] to effect the burden of proof during an adversarial proceeding where the validity of a patent is in issue. Since the patentee has already satisfied the burden of proving patentability to the expert agency, the burden of showing that the patent in suit is invalid must be borne by the party alleging invalidity." (Id. at 2).

[31] See Baum, *supra* note 3; KOENIG, *supra* note 3; and Kitti, *supra* note 3.

[32] Kitti, *supra* note 3, at 67-8.

tronics Corporation of America[33] included the following illustrative conclusion:

> ... The proper analysis of data is one of the special difficulties in patent litigation. The court is asked to look back to a temporal baseline (the time of the creative act) through hindsight. This hindsight often is colored by events which occur after the creation of the innovation. Thus, what was nonobvious at the outset can become, through exposure and general social usage, familiar and obvious by the time of litigation. It should be recalled that one of Scully's main complaints was that the court incorrectly used the degree of obviousness to itself as a criterion for judging the validity of the patent in question.[34]

It was then suggested that in patent cases like *Scully* what is presented to the courts, and what they are asked to interpret, is a picture of a type of social system in which individuals and institutions interact over time in a complex manner. What follows here is a more detailed exploration of the utility of the concept of social system when applied to the "art" or "industry" and to the court, and a further examination of the cognitive process used by all parties to analyze innovations and the systems in which they arose.

The Concept of System

A comparison has been drawn between the tasks of social scientists and patent attorneys regarding the collection and analysis of data or

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[33] 570 F. 2d 355 (1977). In Hopper, *supra* note 1, *Scully* was summarized:

> *Scully* involved a 1968 suit for infringement of a patented technique designed to incorporate "fail safe" features into various hazardous machinery. Defendant, Electronics Corporation of America (ECA), in turn alleged both non-infringement and invalidity of the patent. At the conclusion of the presentation of evidence, ECA sought to amend its pleadings in order to allege fraud by Scully against the Patent Office, such fraud resulting from Scully's failure to reveal allegedly anticipatory patents. The district court held that ECA in fact had infringed the patent and that Scully had not defrauded the Patent Office since the patent had not been anticipated within the meaning of 35 U.S.C. § 102. However, the Court also found that the patent was invalid for obviousness within the meaning of 35 U.S.C. § 103. Further, the Court denied ECA's motion to amend the pleadings and awarded attorney's fees to plaintiff as a result of "exceptional" conduct on the part of ECA. In this appeal, Scully challenged the findings of obviousness and ECA, in a cross appeal, sought to overturn the lower court's denial of its motion to amend. The appeals court upheld the lower court's findings of patent invalidity for obviousness as well as its denial of ECA's motion to amend its pleadings.

[34] Hopper, *supra* note 1, at 25-6.

evidence.[35] Both professionals have the task of defining the system of people and institutions being analyzed and then selecting, from all of the data collected, those which accurately explain how the system operates. A picture must be presented which is neither too broad nor too narrow, but which explains adequately events and their significant interrelationships. This process necessitates an appreciation of a holistic approach and, through it, the ability to demonstrate the systematic connections among the data so that those who have not collected them can be persuaded that the picture is an accurate one. Because patent attorneys must analyze a complexity of technological, social, and psychological interrelationships within an industry or "art", the following passage is as applicable to them as it is to the social scientists for whom it was originally written:

> Since anthropologists [representative of social scientists in this case] believe that a culture or social system is a logical, integrated, holistic phenomenon in which every part fits together in meaningful patterns, they assume that every bit of data in the system has meaning... Obviously, this doesn't mean that all data are immediately significant to every problem... It does mean that the time and context may arrive during a major study when data previously thought to be insignificant will acquire great importance.[36]

For purposes of further discussion, it would be helpful to offer a definition of "system" which is general enough to be applied to the needs of both anthropology and patent law. Thus a system can be regarded as: "(1) something consisting of a set (finite or infinite) of entities (2) among which a set of relations is specified, so that (3) deductions are possible from some relations to others or from the relations among the entities to the behavior or history of the [entirety]."[37] Social scientists study systems which range from sets of dyadid interactions to large scale societies in which enormously complex interactions occur among peoples whose relationships are no longer primarily face-to-face. Naturally, data collection techniques and theories have been developed for the study of complex social systems which differ considerably from those used in the study of smaller scale systems. Nevertheless, the studies, whether dealing with the total system or a section or sub-system therein, must attempt to present a view which is as nearly complete or holistic as possible relative to the specific goals of the study. As the above definition suggests, one reason for

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[35] *Id.* at 27.

[36] FOSTER, *supra* note 28, at 65, *cited* and discussed in Hopper, *supra* note 1, at 27.

[37] A. Rapoport, *General Systems Theory*, 15 INT'L ENCYCLOPEDIA OF THE SOC. SCI. 452, 453.

this approach is the desire to have sufficient data to be able to predict accurately or, at least, to discuss with a degree of confidence aspects of the system not actually observed or observable.

In the event that the applicability of the concept of social system remains less clear when used in reference to patent law than anthropology, some further explanation is in order. Again, the concept of obviousness is central. As the *Scully* case, *supra,* so clearly indicates, the proper reference group when assessing the obviousness of an innovation consists of those in the art at the time of the introduction of the innovation. Those working in the art comprise a reality which satisfies all of the requirements in the definition of a system offered above. That is, there exists a set of entities or units (inventors, industrialists, shops, factories, marketing operations, etc.) all of which physically and psychologically interact in a patterned fashion, the study of which makes it possible to deduce not only certain specific interactions or relations on the basis of knowledge gained about others, but also the behavior and history of the system as a whole.

If Shapiro's framework for judicial inquiry into obviousness[38] is reviewed again it should be apparent that by answering the three sets of questions posed one can construct a picture which satisfies the definition of system we are using here. The "set of entities" is, of course, those working in the art and those who use the art, for example licensees and consumers. The "set of relations" consists of all of the actual interactions and common concerns which characterize any modern industry. Specifically, Shapiro mentions such possible relations as past and present common recognition of the existence of a shared problem, common motivation to solve the problem, and actual attempts to solve the problem. If the set of entities and the set of relations are properly identified and studied it is both possible to deduce certain other items concerning the way the system is likely to respond to any one innovation and the meaning of the history of the system's response to the technological problem addressed by the innovation. In formulating a legal argument attorneys should possess the proper information regarding the perception of the obviousness of an innovation to those in the art and their historical interactions concerning a given technological problem. Thus armed, it is then possible to use persuasively information from those items in Shapiro's third category: "(1) Laudatory comments of others working in the art; (2) commercial success of the innovation; (3) license rights acquired from the inventor; (4) copy-

[38] *See* Shapiro scheme, *supra* note 26.

ing of the invention by competitors."[39] Logically, the argument should work also in reverse. That is, armed with information from the third category, it should be possible to reconstruct, with some degree of accuracy, what many of the perceptions and historical interactions of the industry must have been prior to the introduction of the innovation in question. Of course, this is precisely what Shapiro and others suggest we do.

In summary, when patent attorneys attempt to argue the obviousness or nonobviousness of a particular innovation they must organize and communicate to the court a picture of the operation of a complex social system with a large number of actors and institutions, shared and conflicting values, motivations, perceptions of reality, and a history which often is hard to identify as it relates to a particular innovation. What complicates this task even further is the nature of the cognitive responses that judges will make to the presentation of evidence.

Judgment and Condition

It seems important to consider the possibility that in weighing and interpreting evidence regarding an innovation and its place in the art or system to which it is related judges will respond to the innovation much as will any other potential user. It seems reasonable to suppose that judicial hindsight and cognitive reactions to an innovation are characterized by many of the same features that characterize these processes in all people. In order to clarify this thought, it might be fruitful at this point to reconsider some of the observations previously made regarding hindsight[40] and the concept of "screening."[41]

Judicial hindsight is an inevitability because of the necessity of evaluating, among other things, historical data. And it appears probable that experience with patent issues, absent any highly specialized skill in a given question being litigated, does not confer a special skill or likelihood of accuracy in the use of hindsight. Skill in the use of hindsight will vary. For this, and other reasons to be explored, the facts of any case will have a different *meaning* to each interpreter. The cognitive process which the court uses resembles the "screening" which occurs when an individual or group reacts to an innovation (new configuration) introduced into the system:

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[39] *Id.*

[40] *See* Hopper, *supra* note 1; Field & Field, *supra* note 4.

[41] The concepts and processes of "screening" were discussed fully in context of an analysis of innovation as a psycho-social phenomenon. *See* Hopper, *supra* note 1, at 2-7.

> Once a new configuration has been given expression, the question remains as to whether it will be accepted and utilized . . . To be accepted, the innovation must pass through what amounts to a dual selection process. Under normal circumstances, this "screening", a complex psycho-social activity, tends to eliminate those innovations which are too inconsistent with the range of behavior and values considered acceptable . . . and those innovations which appear to contribute little to the satisfaction of fundamental needs. *It should not be assumed that screening results in the same selection for all persons simultaneously.* (Emphasis added.)[42]

While potential users of an innovation and judges hearing a patent case evaluate the innovation for different reasons, all appear to employ personal screening mechanisms in their judgments. This probability gives added significance to plaintiff Scully's complaint that the court inappropriately used its own reactions to the obviousness of the innovation rather than the reactions of those in the art at the time of the creation of the innovation. Interestingly, the Scully court's own conclusion regarding its reactions indicates its awareness of this problem:

> While weight must be given to the presumption of validity, and this circuit is quite prepared to sustain patents which meet the statutory criteria, the time has long since gone, if it ever existed, when district courts and courts of appeal could refuse to make an independent assessment of § 103 obviousness in light of all the evidence presented. To criticize a court for making an independent assessment is to criticize it for doing what the law requires. The process involves the ever-present risk of an over-use of hindsight, as well as the possibility of blunders by lay judges; but this court has no license, even if it wanted one, to adopt another approach.[43]

While the Scully court recognizes the problems involved in independently evaluating the obviousness of the innovation, it suggests that the law requires it to do so. It is fortunate, in one sense, that this independent assessment is required since it appears inevitable that it would occur anyway. It is almost inconceivable that judges could use hindsight and not allow their own reactions to the obviousness of the innovation to color their understanding of the reactions of others at an earlier point in time. The remainder of this paper, concerning the collection and interpretation of evidence, will explore the behavior of the primary participants in the patent litigation system which we have been examining — those in the art, attorneys, and judges. An examination of selected aspects of the problem as viewed by social scientists, whose profession also is the collection, interpretation, and communication of data, will help to illustrate some of the reasons

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[42] Hopper, *id.* at 4. *See, e.g.,* A. WALLACE, CULTURE AND PERSONALITY at 120-63 (1961) for a review of this general topic.

[43] 570 F.2d 355, 362.

that disagreement concerning patent invalidity decisions is inevitable and so disconcerting.

Collecting and Interpreting the Facts

An interesting debate in the social sciences concerns the validity and importance of various methods and philosophies of data collection. Two of these perspectives, phenomenology and empiricism, characterize much of the work of social scientists, attorneys, and judges. In comparing these methodologies, Severyn Bruyn has developed the following guide:[44]

Observing Phenomenologically

1. Investigate particular phenomena without definite perceptions of their nature.
2. Observe in phenomena that which appears immediately to our consciousness.
3. Look for similarities in phenomena as given to consciousness; distinguish their essences and essential relations infinitively.
4. Explore how the phenomena constitute themselves in consciousness while continuing to suspend prior conceptions of their nature.
5. Examine what concealed meanings may be discovered through the application of ontological conceptions[45] of reality.

Observing Empirically

1. Investigate particular phenomena with definite preconceptions of their nature.
2. Observe in phenomena that which immediately appears to the senses.
3. Look for similarities and differences between what is observed and what is operationally defined; distinguish their conditions statistically.
4. Explore how the phenomena constitute themselves in reason relative to social typologies.
5. Examine what concealed meanings may be discovered through the application of theoretical conceptions of social action.[46]

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[44] S. BRUYN, THE HUMAN PERSPECTIVE IN SOCIOLOGY: THE METHODOLOGY OF PARTICIPANT OBSERVATION (1966). Bruyn's work is merely representative of the enormous amount of literature dealing with the methodological and philosophical postures of social (and other) scientists. One of the best studies is A. KAPLAN, THE CONDUCT OF INQUIRY: METHODOLOGY FOR BEHAVIORAL SCIENCE (1964). Another very helpful volume is GOODE & HATT, *supra* note 28. A more recent book is P. RUNKEL & J. MCGRATH, RESEARCH ON HUMAN BEHAVIOR: A SYSTEMATIC GUIDE TO METHOD (1972).

The discussion of methodology in this paper does not pretend to be complete. While it is tempting to treat the material more comprehensively in these pages, the task is far more complex than current space or time permits.

[45] Roughly, ontology is the study of being or existence in the world. For the social scientist, the ontological problem is to identify realities and their meaning as the people being studied see them.

Bruyn correctly observes that social scientists emphasize one approach though usually not to the full exclusion of any other. Similarly, attorneys preparing their patent cases must be regarded as data collectors who attempt to construct a notion of the reality of the system being studied. While a full examination of this topic is beyond our present purposes, it is fascinating to consider how attorneys, relative to the above methodologies, gather and organize certain information so that its meaning to them might be successfully communicated to others. Attorneys, like social scientists, are likely to drift back and forth between the methods.

In patent cases, for example, methodological dexterity would be necessary to gain an understanding of the numerous items regarded by Shapiro as fundamental to arguing a § 103 obviousness case. Attorneys first might attempt to comprehend the meaning to the par-

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[46] BRUYN, *supra* note 44. There is also a distinction between the methods and philosophies of participant observation and empiricism which should be mentioned. In comparing the two, some of the relationships of phenomenology and empiricism become more clear. Participant observation is an approach to gathering data which seeks to balance appropriately the activities of the researcher as a participant in the group being studied and as a more objective observer. A very helpful analysis of the technique is found in B. JUNKER, FIELD WORK: AN INTRODUCTION TO THE SOCIAL SCIENCES 32-69 (1960). Bruyn has written:

> The traditional empiricist considers himself (as a scientist) to be the primary source of knowledge, and trusts his own senses and logic more than he would trust that of his subjects. The participant observer, on the other hand, considers the interpretation of his subjects to have first importance, and initially the observer may not want to understand these interpretations objectively; he may want to understand them subjectively through his own involvement with the culture before he can understand them from any viewpoint. Thus, the two methods differ in emphasis; however... both approaches do not entirely ignore the methodological interests represented so well in their opposite.
>
> What is especially distinctive about the method of participant observation is the manner by which the researcher gains knowledge. By taking the role of his subjects he re-creates in his own imagination and experience the thoughts and feelings which are in the minds of those he studies. It is through a process of symbolic interpretation of the "experienced culture" that the observer works with his data and discovers meanings in them (Bruyn, *id.* at 12).

While attorneys should not be expected to engage in full-scale participant observation, their investigations often make use of the technique, although not systematically.

ticipants within the system of the introduction of an innovation and the responses which are made to it. However, they then must evaluate carefully their own impressions and weigh their own conclusions regarding events in the system against the meanings assigned to them by the regular participants. This is necessary because of the demands of the legal system itself. Attorneys are forced to organize and interpret data in context of their knowledge of the law and its substantive and procedural requirements. There is understandable pressure to regard themselves as the appropriate primary source of knowledge and interpreters of meaning given the need to respond to the specialized rules of the legal system which determine which meanings are likely to be persuasive or, for that matter, relevant.

For the social scientist, the struggle to comprehend meaning is one which Bruyn has characterized as ontological, at least in part. The following applies also to attorneys who, like social scientists, function both as theorists and researchers:

> The ontological problem of the theorist is how to establish the nature of human reality — i.e., that which people see as basic in their world. The researcher looks for the meaning of reality in the culture he studies, and is therefore concerned with discovering and verifying the existence of a certain reality through human meanings. The theorist, however, must bring these meanings together into some larger whole; in so doing, he creates a certain reality for himself.[47]

When attorneys develop what they refer to as the theory of a case they organize particular meanings into a larger whole which represents one way of understanding the reality of the system being addressed. This interpretation is then communicated to the court with varying degrees of success. A major problem in achieving successful communication of this sort is the fact that attorneys, like social scientists, often develop an unwarranted degree of certainty about their knowledge of any one case and this can result in less than persuasive arguments regarding the reality of the unit being described. The tendency to unwarranted certainty or biases about the data seems to derive largely from the intense immersion in particular cases (for attorneys) or case studies (for social scientists). Biases are often unrecognized or, if recognized, often unacknowledged. Naturally, these biases can seriously deter from the ultimate persuasiveness of an argument if nothing is done to compensate for them.

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[47] BRUYN, *supra* note 44, at 62.

Cases, Case Studies, and Judgments

Much has been written in law and social science about the nature of cases and case studies.[48] The parallel is in itself interesting and through an examination of it there is something to be learned about the difficulty of minimizing the problems in effective communication mentioned above. Consider the following excerpts from a discussion of the case study as a method in social research:[49]

> The case study ... is a way of organizing social data so as to preserve the *unitary character of the social object being studied.* Expressed somewhat differently, it is an approach which views any social unit as a whole.[50]
>
> ... [t]he *wholeness* of any object, whether physical, biological, or social, is an intellectual construct. Concretely, there are no limits which define any process or object. Every variable ultimately links with any other.[51]
>
> ... Clearly, one of the ways by which the unit is studied as a totality is the collection of a broad array of data about it.[52]
>
> ... Most of the difficulties in the use of this method can be reduced to one, although a more complex classification is possible. Interestingly enough, the basic danger in its use is the *response of the researcher.* The researcher comes to feel a false sense of certainty about his own conclusions ... [E]ach *case* which is developed as a unit takes on complete dimensions in the mind of the researcher. He comes to feel certain that he could answer many more questions about his case than can be answered from his file records.[53]
>
> This danger, then is one which the observer *himself* creates. The consequences of this feeling of certainty are many ... Since the researcher feels so very certain about the area of experience he is investigating, he feels no need to check the over-all design of proof.... It must be repeated at this point that we are not separating one type of researcher from any other type. Any investigator who absorbs the facts from a large number of cases

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[48] *See, e.g.,* K. LLEWELLYN, THE BRAMBLE BUSH: ON OUR LAW AND ITS STUDY (1930); M. GLUCKMAN, THE JUDICIAL PROCESS AMONG THE NORTHERN BAROTSE (1955); GOODE & HATT, *supra* note 28, at 313-40; E. HOEBEL, THE LAW OF PRIMITIVE MAN: A STUDY IN COMPARATIVE LEGAL DYNAMICS 29-45 (1954); J. Holleman, *Trouble Cases and Trouble-Less Cases in the Study of Customary Law and Legal Reform,* 7 LAW & SOC. REV. (No. 4) 585 (1973); M. Gluckman, *Limitations of the Case-method in the Study of Tribal Law,* 7 LAW & SOC. REV. (No. 4) 611 (1973).

[49] GOODE & HATT, *supra* note 48, at 330-36. The authors correctly point out that this approach is as rigorous as any other if used properly; it should be remembered that not all social scientists use case studies.

[50] *Id.* at 331.

[51] *Id.* at 332.

[52] *Id.* at 333.

[53] *Id.* at 334.

> will begin to feel that he really has a satisfactory sample, no matter how much knowledge he has about sampling design.[54]
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> ... [W]hen the investigator feels so much "at home" with each case, he may be tempted to "feel" the right explanation — even though a second reader of our cases might come to an entirely different explanation. (Emphasis in the original.)[55]

The issues raised in this passage are reminiscent of an argument in *Scully, supra,* which bears repeating. Without in any way commenting on the merits of the case or on plaintiff's presentation, it is interesting to recall that the apparent certainty of plaintiff that his argument regarding non-obviousness was convincing and flowed naturally from the facts of the case was met by an "entirely different explanation" offered by the court, (*i.e.,* the "second reader"). As was discussed elsewhere,[56] cases such as *Scully* are open to penetrating inquiry. The courts appear unprepared to accept the evidence from either side without inquiring into the total context in which the innovation developed. This is what the court meant when it held that Scully did not explain convincingly the *reasons* why the industry had not succeeded in developing a similar innovation earlier.

There seems to be little doubt that plaintiff's counsel in *Scully* was reasonably certain that his conclusions were accurate and that the court would agree with the meanings he had attached to the evidence. Interestingly, although he was wrong about the court, he may have been absolutely right about the evidence. The problem possibly was not one of adequacy of the evidence but one of the overall design of proof and its communication. Proximity to the case might have produced assumptions regarding the proof of validity which a more distant second reader could not share. A different result *might* have been reached through another organization and presentation of the meaning of the evidence. But it should be remembered that this discussion is largely speculative expecially since the potential for diversity of interpretations is so great in any event.

In discussing the nature of legal cases and the judicial response to them, Llewellyn[57] commented on the importance of facts and the ways in which relevant ones will be selected and then interpreted by the various parties in the court. His remarks stem partly from the

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[54] *Id.* at 335.

[55] *Id.* at 336.

[56] Hopper, *supra* note 1, at 26.

[57] LLEWELLYN, *supra* note 48, at 25-40.

same observations presented above, namely that the response of the attorney to the material being studied can produce (and be produced by) biases and misleading certainties about its meaning. These biases and certainties will vary from observer to observer including judges and juries. In addition, one can see that the difficulty of persuasive communication of meaning is further compounded by demands of the adversarial systems, perceptions of legal relevance, and procedural rules of evidence. Llewellyn writes:

> Obviously the case cannot be decided... without some statement of the facts. That is, of the facts the court *assumes,* adopts as the basis for its decision... [W]hoever prepares it [the statement of facts], it is prepared with reference to the opinion, and peculiarily if the judge prepares it, it is prepared to make the opinion look sound, look right, persuade. What is the relation of this statement of "the facts" to the brute raw events which happened long before? What is left in men's minds as to those raw events has been canvassed... by two lawyers. But canvassed through the screen, of what each considered *legally* relevant to win his case. It has then been screened[58] again in the trial court through the rules about what evidence can be admitted. The jury has then reached its conclusion, which — for purposes of the dispute — determines contested matters for one side. The two lawyers have again sifted — this time solely from the record of the trial — what seemed to bear on points upon appeal. Finally, with a decision already made, the judge has sifted through these "facts" again, and picked a few which he puts forward as essential — and whose legal bearing he then proceeds to expound. It should be obvious that we are now miles away from life. Again we may not. By some miracle it may be there is no distortion. Or by some other each successive distortion may have neatly cancelled out the last. But it is current doctrine that the age of miracles is past. (Emphasis in the original.)[59]

The problems of data or evidence collection and interpretation have been especially vexatious in cases which rest on determinations of non-obviousness. It seems clear that these problems are not likely to diminish appreciably in the near future and that the diversity in judicial responses to § 103 will persist. In spite of the apparent frustration of many patentees and attorneys, it is not certain by any means that this diversity is as disruptive as might be imagined.

Diversity, Predictability, and Stare Decisis

A study of patent cases and problems of understanding § 103 obviousness illustrates that diversity of thought and behavior is to be expected in any social system whether small-scale (including courtrooms) or entire cultures. The diversity naturally includes variations in the assignment of meaning to that which the participants of a sys-

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[58] Note Llewellyn's use of the concept of screening. This use appears to be very close to that discussed above in the section on Judgment and Cognition.

[59] LLEWELLYN, *supra* note 48, at 38.

tem directly experience or construct in their imaginations. When discussing the range of reactions among individuals to the introduction of an innovation into their social reality it was observed that the existence of variations indicates that any social system is populated by individuals and groups whose thought and behavior are not uniform. Rather, the system represents what has been referred to by A.F.C. Wallace as an "organization of diversity".[60] People can interact effectively not because they extensively share uniform patterns of motivations, perceptions of reality, and behavior, but because they can and do develop complimentary or equivalent patterns.[61] This organization of diversity is most apparent in large, complex societies, but Wallace maintains that:

> [A]s any set of persons establish a system of equivalent mutual expectancies, an organized relationship comes into existence. Such a system of equivalent mutual expectancies may be termed an *implicit contract,* in the general sense of the word "contract" ... The relationship is based not on a sharing, but on a complimentarity of cognitions and motives ... Thus, the relationship between the driver of a bus and the riders is a contractual one, involving specific and detailed mutual expectancies. The motives of drivers and riders may be as diverse as one wishes; the contract establishes the system.[62]

The importance of the existence of mutual expectancies is that it allows those within a system to predict the behavior of others. Behavior normally can be expected to fall within a range of acceptable diversity.[63] Thus, the actors in a system can continue to participate

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[60] WALLACE, *supra* note 42, at 27, discussed in Hopper, *supra* note 1, at 5.

[61] *See* WALLACE, *id.* at 26-41. Wallace refers to "the perception of partial equivalence structures" as the psychological mechanism upon which socio-cultural organization is dependent (*Id.* at 40); Wallace acknowledges his indebtedness to aspects of numerous studies. Among others he cites G.H. MEAD, MIND, SELF, AND SOCIETY (1934); A. HALLOWELL, CULTURE AND EXPERIENCE (1955); E. Tolman, *Cognitive Maps in Rats and Men,* 55 PSYCH. REV. 189 (1948); G. MILLER, E. GALANTER & K. PRIBRAM, PLANS AND THE STRUCTURE OF BEHAVIOR (1960). The discussion of the mechanisms underlying social organization is, of course, central to much of social science and social psychology. A number of theoretical approaches purport to explain the various elements which contribute to the organization of social systems. The reader might wish an *introductory* overview and should see M. BIESANZ & J. BIESANZ, INTRODUCTION TO SOCIOLOGY (2nd ed. 1973).

[62] WALLACE *supra* note 42, at 41.

[63] This means that there is a range of idiosyncratic personal or sub-group behavior which is tolerated before an act is labeled "deviant". The range varies in any one society over time (an aspect of social change) and among societies depending on such interlocking factors as degree of adherence to tradition, size, and isolation and insulation from "outsiders".

with each other in systematic (contractual) activities because they suppose that specific actions will produce predictable reactions. Behavior, therefore, can be planned in advance knowing that ordinarily there will be a certain regularity to the interactions.

Furthermore, this discussion allows a conclusion to be drawn regarding the doctrine of *stare decisis* as a force in maintaining order in the legal process.[64] *Stare decisis* is but one element of the legal system, itself one of a variety of formal and informal mechanisms for maintaining reasonable degrees of predictability and regularity in social systems. Just as the organization of social systems does not rest upon uniformity of thought and behavior among participants, an orderly legal process does not demand that the critical doctrine of *stare decisis* should rest upon rigid adherence to precedent. Numerous countervailing pressures and traditions have always conditioned the use of precedent and have allowed the courts to depart from it when they deem it appropriate to do so.[65] Departures vary from court to court and result in different responses to similar problems among the jurisdictions. In addition, any one court might reverse itself and, in cases involving more than one judge, diversity in holdings and rationales are commonplace. And yet, litigants continue to argue in the courts with the understanding that the diversity normally will fall within an acceptable range and that much of it is predictable anyway. These comments regarding *stare decisis* are offered to suggest that stability and diver-

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[64] The literature on *stare decisis* is extremely extensive. An excellent and representative selection is offered in R. ALDISERT, THE JUDICIAL PROCESS: READINGS, MATERIALS AND CASES at 777 (1976). Aldisert includes, among others: J. Hanna, *The Role of Precedent in Judicial Decision,* 2 VILL. L. REV. 367, 367-69, *cited* at 780; R. Pound, *Remarks on Status of the Rule of Judicial Precedent* in *Survey of the Conference Problems,* 14 U. CIN. L. REV. 324, 328-32 (1940), *cited* at 781; T. Currier, *Time and Change in Judge-Made Law: Prospective Overruling,* in 51 VA. L. REV. 201, 235-38 (1921), *cited* at 819; R. Traynor, *Reasoning in a Circle of Law,* VA. L. REV. 739, 743-47 (1970), *cited* at 834. "*Stare decisis* or, in its complete form, *stare decisis et non quieta movere* is usually translated 'to stand by (or adhere to) decisions and not to disturb what is settled' .... The General American doctrine as applied to courts of last resort is that a court is not inexorably bound by its own precedents but will follow the rule of law which it has established in earlier cases, unless clearly convinced that the rule was originally erroneous or is no longer sound because of changing conditions and that more good than harm will come by departing from precedent." Hanna, *id.* at 780.

[65] *See e.g.,* Hanna, *supra* note 64, at 780; Pound, *supra* note 64, at 781; Cardozo, *supra* note 64; Traynor, *supra* note 64, at 834. Currier, *supra* note 64, at 794-5, suggests that the use of *stare decisis* is based on values which can be weighed in a decision to adhere to or depart from precedent. The values include: (1) stability, (2) protection of reliance, (3) efficiency in the Administration of Justice, (4) equality, (5) the image of justice.

sity are as compatible within the legal system as they are within the larger social system. This notion is, in one sense, elementary; but its implications are many and important. A dynamic and responsive legal system need not suffer from instability merely because there is diversity in judicial response to legal issues, the disposition of which is complicated by the demands of a constantly changing environment. Indeed, constructive social change rests on the existence and exercise of diversity of thought and behavior. The recognition that change and instability are not synonymous is firmly rooted in social science and jurisprudence.[66] Again, Llewellyn dealt squarely with this issue in a discussion of precedent, regularity and predictability:

> Our society is changing, and law, if it is to fit society, must also change. Our society is stable, else it would not be a society, and law which is to fit it must stay fixed. Both truths are true at once... [I]t now becomes our task to inquire into how the system of precedent which we actually have works out in fact, accomplishing at once stability and change.[67]

> ... What I wish to sink deep into your minds about the doctrine of precedent... is that it is two-headed. It is Janus-faced. That it is not one doctrine, nor one line of doctrine, but two, and two which, *applied at the same time to the same precedent, are contradictory of each other.* That there is one doctrine for getting rid of precedents deemed troublesome and one doctrine for making use of precedents that seem helpful. That these two doctrines exist side by side... Until you realize this you do not see how it is possible for law to change and to develop, and yet to stand on the past. You do not see how it is possible to avoid the past mistakes of courts, and yet to make use of every happy insight for which a judge in writing may have found expression... Nor until you see this double aspect of the doctrine-in-action, do you appreciate how little you can predict *out of the rules alone;* how much you must turn, for purposes of prediction, to the reactions of the judges to the facts and to the life around them...[68]

> People — and they are curiously many — who think that precedent produces or ever did produce a certainty that did not involve matters of judgment and of persuasion, or who think that what I have described involves equivocation by the courts or departure from the court-ways of some golden age — such people simply do not know our system of precedent in which they live.[69]

Conclusion

This discussion has progressed a long distance from its starting point, but the progression is suggested by the material itself. It seems

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[66] *See,* Aldisert material, *supra* note 64. *See generally,* WALLACE, *supra* note 42, at 136-63; BENNIS, BENNE & CHIN, *supra* note 28; and, for a fascinating analysis of change and planning models, *see* R. BOGUSLAW, THE NEW UTOPIANS: A STUDY OF SYSTEM DESIGN AND SOCIAL CHANGE (1965).

[67] LLEWELLYN, *supra* note 48, at 66.

[68] *Id.* at 68.

[69] *Id.* at 69.

appropriate to offer one additional observation. The cross-cultural study of legal systems[70] indicates that the preceding discussion is applicable not merely to our own and other industrial nations. Rather, all cultures constantly manifest the presence of a struggle to balance the conflicting demands of stability and change, diversity and order. In so doing, people must constantly make choices as to which behaviors and which values they will reinforce and encourage. The choices, including ones within the legal system, are based on what Hoebel calls "postulates" or "the broadly generalized propositions held by the members of a society as to the nature of things and as to what is qualitatively desirable and undesirable."[71] All cultures seem to face a similar problem in regard to these postulates:

> The postulates of a society may or may not be explicitly expressed by its members. There may or may not be total agreement as to what they are. The judicial duel as well as the political struggle is often a contest to determine which of several postulates shall prevail or how the specific interpretation of a postulate shall be formed in its application to the legislation being fought over or in the case at hand.[72]

All legal cases are crucibles within which a wide variety of important social, psychological, and specifically legal issues can be found. It is unfortunate, therefore, that issues in patent law tend to be relegated to the study of law and *science,* or at best intellectual and industrial property, and are not explored more widely for their implications concerning law and *society.* A patent case, like any other, is an indication of the way our society functions, its values, its stresses and strains, its potential for change, and its capacity for introspection and insight. A patent case, like any other, is a window through which a social system can be viewed and analyzed.

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[70] *See, e.g.,* LAW IN CULTURE AND SOCIETY (Nader ed. 1969); *The Ethnography of Law,* 67 AM. ANTHROPOLOGIST (No. 6) (Special Issue Pt. 2) (1965); M. GLUCKMAN, POLITICS, LAW AND RITUAL IN TRIBAL SOCIETY (1965); M. GLUCKMAN, THE JUDICIAL PROCESS AMONG THE BAROTSE OF NORTHERN RHODESIA (1954); E. HOEBEL, THE LAW OF PRIMITIVE MAN (1954); K. LLEWELLYN & E. HOEBEL, THE CHEYENNE WAY: CONFLICT AND CASE LAW IN PRIMITIVE JURISPRUDENCE (1941).

[71] HOEBEL, *supra* note 70, at 13.

[72] *Id.* at 17.

Federal Natural Gas Rate: Regulation or Deregulation

Louis J. Recchione*

Since the early 1970's a severe shortage in the supply of natural gas committed to the United States interstate market has existed. During this period under federal law a system of ceiling prices was established to regulate the interstate sale of natural gas. Congress and the Federal Power Commission sought to change the system of natural gas rate regulation to provide incentive to drill for more gas. A national controversy developed over what type of natural gas plan should be employed. The debate centered on the question of whether gas supplies could be increased by raising the existing ceiling prices or by eliminating them. The controversy was settled on November 9, 1978 by the passage of the Natural Gas Policy Act[1] which provided a plan for gradual deregulation of newly discovered natural gas. This article examines and explains the former methods of regulation, the recent natural gas regulation controversy, and finally, analyzes the Natural Gas Policy Act itself.

The Natural Gas Act

The Natural Gas Act[2] grants broad regulatory powers to the Federal Power Commission (FPC) over the sale and transportation of natural gas in interstate and foreign commerce. Because public interest is affected by the sale of natural gas to the public, federal regu-

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[1] Pub. L. No. 95-621.

[2] 15 U.S.C. § 717-717W, 52 Stat. 821 (1938).

lation over its movement in interstate and foreign commerce has been deemed necessary.[3]

The production, gathering, intrastate transportation, and sale of natural gas, although originally exempted from federal regulation[4], are now regulated.

The Natural Gas Act requires that any rates charged by a company be just and reasonable.[5] The FPC has the authority to hold hearings to determine the legality of a rate[6] and to order a readjustment of the rate to conform with a just and reasonable standard.[7] Rates charged for transportation and sale of natural gas must be recorded and open for public inspection[8], and no changes in rates can be made without a thirty-day notice to the Commission and to the public.[9] Price discrimination between different gas customers is prohibited.[10] Natural gas companies are also prohibited from engaging in the transportation or sale of natural gas unless a certificate of public convenience and necessity has been properly filed with the FPC and remains in force.[11] The Commission may require a natural gas company to extend its service after a notice and hearing;[12] no company may abandon service without permission.[13]

The Natural Gas Act stipulates that if any of its provisions are held invalid, the remaining provisions shall not be held invalid.[14] This is important to note because the statute has been amended many times since its passage in 1938. The Natural Gas Act still remains in effect notwithstanding the most recent federal natural gas legislation. Natural gas rates must still adhere to the just and reasonable standard.

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[3] 15 U.S.C. § 717(a).
[4] 15 U.S.C. § 717(b).
[5] 15 U.S.C. § 717c(a).
[6] 15 U.S.C. § 717c(e).
[7] 15 U.S.C. § 717d(a).
[8] 15 U.S.C. § 717c(c).
[9] 15 U.S.C. § 717c(d).
[10] 15 U.S.C. § 717c(b).
[11] 15 U.S.C. § 717f(c).
[12] 15 U.S.C. § 717f(a).
[13] 15 U.S.C. § 717f(b).
[14] 15 U.S.C. § 717(v).

Phillips Petroleum Corporation v. Wisconsin

During the first sixteen years following the passage of the Natural Gas Act, independent producers of natural gas remained outside the jurisdiction of FPC regulation. Independent natural gas producers do not engage in interstate transportation of gas from the field to the consumer markets, and are not affiliated with an interstate natural gas company. The independent producer sells his gas to an interstate pipeline transmission company.

In 1951 the FPC instituted an investigation of the Phillips Petroleum Company to determine if it was a natural gas company.[15] If Phillips was found to be a natural gas company, its rates were to be examined under the just and reasonable standard. The Commission issued an opinion that Phillips was not a natural gas company; the Commission thus could not exercise jurisdiction over its rates. The Court of Appeals reversed this decision,[16] and Phillips appealed to the United States Supreme Court.[17]

Petitioner Phillips argued that its sales to interstate pipelines were part of the production and gathering of natural gas, and were thus exempt from FPC jurisdiction by the Natural Gas Act. The Commission had held that a sale of gas incidental to the production and gathering process was also exempt from jurisdiction.

The Court in *Phillips* relied on its decision in *Interstate Natural Gas Company v. FPC.*[18] Interstate Natural Gas Company produced gas in one state and delivered it to three interstate pipeline companies within that state. It contended that it was a gathering company. The Court held that Interstate's sales were in interstate commerce: regulation of the rates was a matter of national rather than local concern, because the gas sold was for consumption out of state. Unreasonable charges at the sale to a pipeline would have to be passed on to out-of-state consumers; the Natural Gas Act was passed to avoid this situation.

The *Phillips* decision emphasized the position taken in *Interstate:* "[T]he rates charged may have a direct and substantial effect on the price paid by the ultimate consumer. Protection of the consumer against exploitation at the hands of the natural gas companies was the primary aim of the Natural Gas Act."[19] Consequently, sales of

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[15] *In re* Phillips Petroleum Company, 10 F.P.C. 246 (1951).

[16] 205 F.2d 706 (D.C. Cir. 1953).

[17] Phillips Petroleum Company v. Wisconsin, 347 U.S. 672 (1954).

[18] 331 U.S. 682 (1947).

[19] 347 U.S. 672 at 685 (1954).

independent gas companies were no longer exempted from regulation by the FPC as sales by producers or gatherers. Independent natural gas producers who sold their gas to interstate pipelines would henceforth be considered natural gas companies within the meaning of the Natural Gas Act.

Shortly after the *Phillips* decision in 1954, the FPC codified the holding rendered in it. The Commission promulgated Rules 174,[20] 174(A),[21] and 174(B).[22] The principal requirements were that independent producers had to file rate schedules and a notice of intent to file rate schedules (subject to approval), secure FPC permission to abandon service, and secure certificates of public convenience and necessity in order to operate.

An economic rationale for natural gas rate regulation could also be found. There are very few pipelines in service and little, if any, competition exists at the point of distribution. The natural gas industry has been characterized as a natural monopoly or an oligopoly, depending on how many pipelines serve at the point of distribution.[23] Consequently, the natural gas industry has been classified a public utility, subject to the regulation of natural gas rates.[24]

It must be noted here that mere regulation of rates is not a denial of property without due process of law.[25] For example, in *Smyth v. Ames*[26] a railroad corporation complained that the rates they could charge by law constituted a denial of property without due process of law. The Supreme Court held that a railroad was entitled to demand a fair return on the property it used for the public convenience. The Court established a minimum level of compensation for determining a regulated rate. An owner of a regulated business must be able to recover his cost of operation, including a reasonable profit. To determine a just and reasonable rate of return, the rate base of the company must be calculated. The rate base is the capital investment, consisting of the original cost of the used and useful physical plant of the company, minus accrued book value, plus working capital. A rate of return at a comparable level as that paid out in nonregulated indus-

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[20] 19 Fed. Reg. 4534 (1954).

[21] *Id.* at 5081.

[22] *Id.* at 8807.

[23] Note, *Natural Gas Rate Regulation: The Conflict in the Application of the Just and Reasonable Standard,* 12 TULSA L. J. 293 (1976) [hereinafter Natural Gas Rate Regulation].

[24] *Id.* at 297.

[25] Munn v. Illinois, 94 U.S. 113 (1877).

[26] 169 U.S. 466 (1898).

tries having similar risks is multiplied by the rate base to compute the return investors are to receive. The rates charged are determined by dividing the necessary return and operating costs of the enterprise by all the services rendered.

Institution of Area Rates

A severe problem was created for the FPC by the Supreme Court ruling in the *Phillips* case. Suddenly, every independent producer was brought under the Commission's ratemaking jurisdiction and was required to meet the just and reasonable standard. Prior to that time the FPC had been operating on a company-by-company basis like other public utility commissions. The FPC was deluged with applications for rate determinations (over 2,900 between 1954 and 1962). It took the Commission 82 hearing days and 10,626 pages of testimony, including 235 exhibits, but by 1960, of the thousands of applications the Commission had received, only ten has been completed.[27]

The delay involved in the application process and rate hearings had the effect of freezing natural gas prices. As a compromise measure, the FPC permitted gas sales to be made under temporary certificates of convenience and necessity, subject to approval at a later rate hearing.[28] After being subjected to pressure from Congress for inefficient performance, the FPC decided to change its ratemaking procedure in 1960.[29] The Commission found the use of the rate base, multiplied by the rate of return for a prudent investment, to be an unworkable formula. The natural gas industry could not be considered a traditional public utility. The Commission determined that, since the gas industry could not be effectively regulated as a public utility by analyzing the costs of the individual producers, an industry-wide approach had to be taken.[30] The new approach divided the country into five producing areas, and rates were to be determined on the basis of area data.[31] Rate guidance levels were established for each area. The objective was to set prices that were adequate to maintain the supply of gas needed by the consumers but no higher than necessary to ac-

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[27] S. Breyer & P. MacAvoy, *The Natural Gas Shortage and the Regulation of Natural Gas Producers,* 86 HARV. L. REV. 941, 954 (1973).

[28] Natural Gas Rate Regulation, *supra* note 23, at 306.

[29] *Id.* at 307.

[30] Phillips Petroleum Company, 24 F.P.C. 537 (1960).

[31] F.P.C. Statement of General Policy No. 61-1, 24 F.P.C. 818 (1960).

complish that purpose.[32] The Supreme Court acknowledged that natural gas was a commodity unusually difficult to regulate, and thus adhered to the Commission's area rate method, allowing it to dispense with the public utility approach to natural gas rate regulation.[33]

Two-Tier Rates Established

The FPC instituted a second method which rejected the public utility concept in natural gas regulation and instead used two ceiling prices. A higher ceiling price was charged for natural gas from new wells, while a lower ceiling price was charged for gas from old wells.[34] The Commission's rationale for the two-tier pricing system was to prevent producers who drilled their wells in prior years at a lower investment cost from deriving a windfall profit from the newly established price. The producers, on the other hand, favored the establishment of one price for both new and old gas. In its decision to grant the higher rate for gas from new wells, the Commission acknowledged the increased popularity and need for natural gas, as well as the higher costs incurred for exploration and drilling.[35] This two-tier system of natural gas pricing continues to be employed by the Commission today.

The Supreme Court approved the two-tier gas pricing method in the *Permian Basin Area Rate Cases*.[36] The Court stated, "We find no objection under the Natural Gas Act to this dual arrangement. We have emphasized that courts are without authority to set aside any rate adopted by the Commission which is within a zone of reasonableness. The Commission may within this zone, employ price functionally in order to achieve relevant regulatory purposes . . ."[37]

The Natural Gas Shortage and Curtailments

By 1970 a significant number of interstate pipelines had not been able to meet contractual commitments to deliver several trillion cubic feet of natural gas.[38] The FPC gave official recognition to the natural

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[32] 24 F.P.C. 537 (1960).

[33] Wisconsin v. F.P.C., 373 U.S. 294, 310 (1962).

[34] Opinion No. 468, 34 F.P.C. 159 (1965).

[35] *Id.* at 185-188.

[36] 390 U.S. 747 (1968).

[37] *Id.* at 797.

[38] J. Jimison, *Natural Gas Curtailments: Managing the Gas Shortage*, The Library of Congress, Congressional Research Service at 1 (1978) [hereinafter Jimison].

gas shortage when it issued Order No. 431 in April, 1971.[39] The Commission required all interstate pipelines to report whether or not their supplies were adequate to meet deliveries. Pipelines that anticipated shortages were required to file a curtailment plan.

Dwindling natural gas reserves in the late 1960's and early 1970's were one of the main reasons for curtailments in this period. Reserves declined from 198.1 trillion cubic feet (tcf) of natural gas in 1967 to a low of 148.6 tcf in 1972. This amounted to a decline of nearly 50 tcf in reserves, a 25% decrease in five years. In 1973 the situation worsened when reserves dipped to 134.4 tcf, a decline of 63.7 tcf and a 32% decrease from 1967. The consumption of natural gas was more than twice the amount of new supplies of gas in 1972. The addition to gas reserves in 1973 was only 6.51 tcf, the lowest reserve addition on record until that time.[40]

In Order No. 491,[41] the Commission acknowledged the harmful effects of curtailment, which were both economic and environmental. The Commission reported school and factory closings and denial of utility service to homes. Industry had to utilize other fuels, resulting in a harmful environmental impact and depletion of supplies of other fuels. The FPC recognized not only a natural gas shortage but a national energy emergency.[42]

In January 1973, the FPC issued a policy statement establishing categorical priorities for curtailments of natural gas by pipelines. These priorities were based on the ultimate use to which the gas would be put. The highest priority was accorded to residential and small commercial uses, the lowest priority to heavy industry.[43] From April, 1973 to March, 1974, 17 of 42 major interstate pipelines reported curtailments totaling 1.2 tcf.[44]

Opinion No. 699: Nationwide Natural Gas Rates

In the early 1970's there was no doubt that the demand for natural gas was far greater than the supply, as evidenced by extensive curtailments. In Opinion No. 699[45] the FPC sought to insure that allow-

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[39] 45 F.P.C. 570.

[40] 1 F.P.S. 5-322.

[41] 50 F.P.C. 742 (1973).

[42] 1 F.P.S. 5-334-35.

[43] Order No. 467, 49 F.P.C. 85.

[44] 1 F.P.S. 5-337.

[45] *Id.* at 5-307.

able interstate natural gas rates be adequate to produce supplies to meet reasonable demand,[46] while at the same time protecting the consumer against exploitation by the natural gas companies. The Commission hoped to establish rates high enough to provide economic incentive to find enormous volumes of new gas.[47] To achieve these goals, the FPC instituted a nationwide rate of 42 cents/m.c.f., applicable to sales made from wells discovered after January 1, 1973.[48] The Commission established the uniform national rate so that it could use its manpower resources more effectively by avoiding duplicative procedures by natural gas producers to establish just and reasonable rates.[49]

The Fifth Circuit Court of Appeals sustained Opinion 669's establishment of a just and reasonable national rate for wellhead sales of natural gas in *Shell v. FPC*.[50] The court concluded that the standard of review must allow considerable deference to the Commission's expertise due to the experimental nature of the regulation.[51]

To determine the rate charged in Opinion 699, the Commission relied on production cost records submitted by natural gas producers throughout the country. These production costs included investments made for exploration, drilling, labor, equipment and capital.

Opinion 699 was amended in December 1974. The national rate was reset to 50 cents/m.c.f., with a one cent per year escalator added.[52]

Opinion No. 770

The purpose of Opinion 699 to establish national natural gas rates that would provide incentive for increased production, was not achieved. The gas shortage and the consequent curtailments in the interstate market were to continue into 1975 and 1976. Natural gas producers still had little incentive to commit their product to the interstate market. The unregulated intrastate market was receiving $1.29/m.c.f. in late 1975 and $1.55/m.c.f. in early 1976. Fuel oil was

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[46] *Id.* at 5-313.

[47] *Id.* at 5-314.

[48] *Id.* at 5-307.

[49] *Id.* at 5-314.

[50] 520 F.2d 1061 (5th Cir., 1975), *cert. denied,* 426 U.S. 94 (1976).

[51] *Id.* at 1071-72.

[52] Opinion No. 669 H, 39 Fed. Reg. 43199.

selling for a price as high as the equivalent of $1.67/m.c.f., with only an 85% B.T.U. parity value.[53]

The FPC issued Opinion No. 770 on July 27, 1976, increasing the rate for new natural gas to $1.42/m.c.f.,[54] applicable to gas from wells discovered after January 1, 1975. The new rate which was allowed to escalate by one cent per quarter, amounted to a 270% increase in price and was intended to encourage the flow of more gas into the interstate market. The rate for natural gas from wells commenced between January 1, 1973 and January 1, 1975 was increased to $1.01/m.c.f., to be escalated at one cent per year.[55]

The Commission stated that the rate was just and reasonable on the basis of three factors: decreased productivity, increased drilling costs, and the expense of federal income taxes.[56] Productivity is measured in terms of the amount of natural gas derived for each foot drilled.[57] The Commission permitted a 14% increase in drilling costs over the prior opinion.[58] The federal income tax allowance accounted for 43 cents of the new gas price.[59]

Opinion No. 770 was subject to a rehearing and partial modification on November 5, 1976, prompted by 24 petitions to intervene and 27 applications for rehearing, reconsideration, or clarification of Opinion No. 770. This rehearing, referred to as Opinion No. 770A,[60] confined and clarified Opinion No. 770. The $1.42/m.c.f. rate with the one-cent-per-quarter escalator was affirmed as being just and reasonable. The $1.01/m.c.f. rate, established for natural gas from wells discovered during 1973 and 1974, was reduced to 93 cents/m.c.f. with a one-cent-per-year escalator each calendar year. The rate plan established in Opinion 770A remained in effect until the passage of the Natural Gas Policy Act.

Curtailment in 1977

As stated above, the FPC granted a 270% increase in natural gas

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[53] Natural Gas Rate Regulation, *supra* note 23, at 316 n.125.

[54] Opinion No. 770, 41 Fed. Reg. 3364.

[55] *Id.*

[56] Committee on Interstate and Foreign Commerce of the House of Representatives, *The Productivity Factor in Federal Power Commission Opinion No. 770,* October 1976 at 1.

[57] Opinion No. 770, 41 Fed. Reg. 3370-72.

[58] *Id.* at 3365.

[59] Committee on Interstate & Foreign Commerce, *supra* note 56, at 1.

[60] 61 Fed. Reg. 50199.

rates in July, 1976 by instituting a $1.42/m.c.f. rate. The Commission intended to provide incentive for natural gas producers to sell on the interstate market, because the new price was competitive with that being paid for intrastate gas and other fuels. A cursory review of prices of other fuels during this period reveals the invalidity of their assumption: Throughout 1975 and 1976, intrastate producers of natural gas were consistently commanding prices in excess of $2/m.c.f. In December 1976, the high price for a new contract in the intrastate market reached $2.33/m.c.f.[61] In 1976, natural gas in the intrastate market sold at a rate that was 25% of the B.T.U. equivalent price of imported crude oil,[62] which comprises approximately 50% of the oil consumed in the United States.[63] Industry and utilities used the equivalent of 6 million barrels of oil a day in natural gas consumption because of its low price in relation to other fuels.[64]

One might reasonably conclude that the interstate rate allowed by the FPC in Opinion 770 was inadequate to induce producers to sell on the interstate market. The natural gas crisis of the winter of 1976-77 supports this conclusion.

Six months after the FPC granted a 270% increase in interstate rates, the United States experienced the worst natural gas shortage in history. The curtailment to low priority users was so severe that approximately 4,000 plants closed, leaving 1.2 million people out of work in February, 1977.[65] Even the highest priority user, the residential user, was threatened with curtailment.[66]

At the height of the 1976-77 curtailment crisis most wells were producing at maximum, but the supply of gas remained inadequate. The amount of gas produced, however, and the amount of gas available to be produced are two different things. Many gas fields have no wells erected on them.[67] At a time when the industry could have sold

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[61] American Gas Association, *Impact of the President's Proposed $1.75 per M.C.F. New Gas Price Ceiling on Domestic Gas Production* at 4 (1977) [hereinafter A.G.A., Impact of New Gas Price Ceiling].

[62] Executive Office of the President, Energy Policy and Planning, *The National Energy Plan,* U.S. Government Printing Office, Washington, D.C., (1977) at 18 [hereinafter National Energy Plan].

[63] *Id.* at 14.

[64] *Id.* at 18.

[65] Jimison, *supra* note 38, at 1.

[66] *Id.* at 2-3.

[67] *Id.* at 3.

as much gas as could be drawn from the earth, it did not have the incentive to drill more wells. The wells that were installed were operating at capacity, and the established rate was nearly three times the highest rate the interstate producers had ever received. The demand for interstate gas was so great that one would think the gas companies could have reaped a significant profit by increasing productivity. One can only conclude that the gas companies did not have the incentive to increase the supply to the interstate market. Natural gas production did not generate a profit commensurate with the magnitude of the investment.

Some would contend that the natural gas crisis of the winter of 1976-77 was caused by an unusually severe winter. Overall that winter was only seven per cent colder than normal.[68]

Natural Gas Rate Regulation by the Carter Administration

On August 4, 1977 the Department of Energy Organization Act was passed,[69] establishing the Department of Energy in the executive branch. The statute placed special emphasis on the increasing shortage of energy resources. The Department was created to promote the general welfare by assuring effective administration of federal energy policy and programs.

The Department of Energy Organization Act established the Federal Energy Regulatory Commission (FERC). FERC was to consist of five members appointed by the President and confirmed by the Senate. The members were appointed to serve terms of either two, three, or four years. No more than three members of the same political party were allowed to serve at one time.[70] The powers vested in the FPC concerning natural gas regulation were transferred to FERC, which was given the authority to regulate natural gas rates under the Natural Gas Act, to issue certificates of public convenience and necessity, and to regulate curtailment by natural gas companies.[71]

On April 20, 1977 the Carter Administration introduced a National Energy Plan, which provided that all new natural gas was to be priced at whichever was higher $1.75/m.c.f. or refinery acquisition

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[68] *Id.*

[69] 42 U.S.C.A. § 7101.

[70] 42 U.S.C. § 7171.

[71] *Id.* at § 7172.

costs of domestic crude oil.[72] The plan was passed by the House of Representatives[73], but suffered defeat in the Senate, which passed a bill calling for the gradual deregulation of newly discovered natural gas.[74] Members of the House and Senate energy conference reached a compromise on a natural gas pricing plan in May 1978[75] and on the published text of the Natural Gas Policy Act in August, 1978.[76] The Natural Gas Policy Act was passed by the Senate on September 27, 1978,[77] and approved by the House on October 15, 1979.[78] The lengthy debate over natural gas rate regulation had come to an end. President Carter endorsed the Natural Gas Policy Act[79] on November 9, 1978.[80]

Review of the Natural Gas Policy Act

The Natural Gas Policy Act has established a system of wellhead price ceilings for several different categories of natural gas.[81] The Act provides that wellhead price controls will be eliminated for five of these categories on specific future dates.[82]

The category known as "New Natural Gas" will have price controls eliminated on January 1, 1985.[83] This category includes new offshore leases, new onshore wells, and new onshore reservoirs.[84] Prior to 1985, new natural gas may be sold at the rate of $1.75/million B.T.U.s plus the sum of an annual inflation adjustment factor and a monthly price escalation.[85]

Gas from wells in the second category, "New Onshore Production Wells,"[86] which are in excess of 5000 feet deep, will be deregulated on

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[72] Pagliano, *Natural Gas Producers: Regulation,* The Library of Congress, Congressional Research Service at 3 (1978) [hereinafter Pagliano].

[73] *Id.* at 3.

[74] S. 2104, 95th Cong. 1st. Sess., 123 Cong., Rec. S16323 (1977).

[75] 35 CONG. Q. 1292 (May 27, 1978).

[76] Senate Report 95-1126.

[77] 124 CONG. REC. S16,265 (1978).

[78] 124 CONG. REC. H12,819 (1978).

[79] Pub. Law No. 95-621.

[80] 17 WEEKLY COMP. OF PRES. DOC. 1085 (November 13, 1978).

[81] Pub. Law No. 94-621, Title I, Subtitle A.

[82] *Id.* at § 121.

[83] *Id.* at § 121.

[84] *Id.* at§ 102(c).

[85] *Id.* at § 102(b).

[86] *Id.* at § 103.

January 1, 1985; gas from similar wells less than 5,000 feet deep will be deregulated on July 1, 1987.[87] Pending deregulation, a rate of $1.75/million B.T.U.s plus the annual inflation rate may be charged for natural gas in this category.[88]

"High Cost Natural Gas"[89] includes gas produced from wells in excess of 15,000 feet deep drilled after February 19, 1977. Pending deregulation a rate of $1.75/million B.T.U.s plus the sum of the annual inflation adjustment factor and the monthly escalator may be charged.[90]

The fourth category is "Gas Sold Under Existing Intrastate Contracts." The price allowed to be charged pending regulation is the contract price.[91] The fifth category is "Sales of Gas Made Under Rollover Contracts" (expired contracts entered into before the passage of the NGPA). The allowable rate pending deregulation is the higher of the expired contract price or $1.00/million B.T.U.s plus the annual inflation adjustment factor.[92] Both the fourth and fifth categories will be deregulated on January 1, 1985, provided each of these intrastate sales is charging more than $1.00/million B.T.U.s on that date.[93]

The Natural Gas Policy Act (NGPA) has given the Federal Energy Regulatory Commission jurisdiction over gas production and sales in intrastate commerce. Never before had FERC or the FPC had jurisdiction over the rates for natural gas sold in intrastate commerce. Before the producer may charge a particular rate, natural gas categories in a given geographic area must be determined by state agencies for state lands and federal agencies (such as the U.S. Geological Survey) for federal lands. Category determination for rate eligibility will be subject to review by FERC. It can be appealed to the courts only if FERC remands or reverses a federal or state agency determination. A producer may collect the price for which he believes his gas to be qualified under the NGPA pending a final determination of eligibility. The producer will be required, however, to refund any sum plus interest which is in excess of the amount subsequently al-

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[87] *Id.* at § 121 (a) and (c).

[88] *Id.* at § 103(b).

[89] *Id.* at §121(b).

[90] *Id.* at § 107.

[91] *Id.* at § 105.

[92] *Id.* at § 106.

[93] *Id.* at § 121(a)(3). *supra* note 81, at 2.

lowed by the Commission or the courts.[94] Natural gas sales at a higher rate than that allowed under the NGPA are prohibited, and violators are subject to criminal and civil liability under the Act.[95]

The NGPA allows the President to reimpose price controls on natural gas by written order which can only be vetoed by both Houses of Congress. Congress itself is authorized to reimpose price controls without executive action. Reimposition of price controls may only occur between July 1, 1985 and June 30, 1987 for a maximum of one 18-month period. Prices must be limited to the maximum lawful levels allowed in Title I subtitle A of the NGPA.[96]

Interstate distribution companies supplied by interstate pipelines are required under the NGPA to pass along the higher costs of new natural gas to large industrial users who use the gas for boiler fuel to generate steam and electricity. A portion of the wellhead rate that the interstate distribution company must pay the producer would be charged only to these industrial users.[97] This practice was meant to encourage industrial users to switch to alternative sources of fuel, preferably coal, the most abundant fossil fuel in the United States. The effect of charging these increments to the industrial user will be to conserve gas supplies and to allow the lower rate of natural gas to be available to residential and other high priority consumers.

Industrial boiler users of natural gas will bear the portion or "increment" of gas costs above $1.48/million B.T.U.s according to this incremental pricing policy. This rate will be adjusted each month for inflation until the price industrial users pay for gas reaches the price of fuel oil in the region.[98] Residential and small commercial users will have to bear a portion of the higher gas costs only when the price that industrial users pay for gas reaches the level of fuel oil.[99]

The NGPA requires FERC to establish a specific mechanism for passing through incremental costs to industrial boiler fuel users.[100] Interstate pipelines are required to keep a special increment pricing account, with incremental costs to be charged by means of a surcharge.[101] The Commission is also required to apply incremental

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[94] Pub. L. No. 95-621 § 503.

[95] *Id.* at § 504.

[96] *Id.* at § 122.

[97] *Id.* at § 201.

[98] *Id.* at § 203.

[99] *Id.* at § 204.

[100] *Id.* at § 201.

[101] *Id.* at § 204.

pricing to nonboiler industrial users within eighteen months of passage of the Act, subject to Congressional review.[102] Schools, hospitals, electric utilities, agricultural establishments and industrial users consuming less than 30 m.c.f. of natural gas per day are exempted from incremental pricing. Other gas users may be exempted from incremental pricing, subject to Congressional review.[103]

The Natural Gas Policy Act authorizes the President to declare a natural gas supply emergency when shortages develop or the supply available to high priority users is threatened. A presidential gas emergency declaration will expire after 120 days unless it is extended due to continued emergency conditions.[104] This presidential emergency authority is similar to that allowed by the Emergency Natural Gas Act of 1977 which has expired.

In a declared emergency the President may authorize interstate pipelines and distributors to make emergency purchases of gas under any contract terms deemed necessary.[105] If the emergency gas purchases are not adequate to meet high priority needs, the NGPA gives the President the authority to allocate certain supplies of gas as necessary but only after an affected pipeline or distributor has stopped deliveries to all but high priority customers.[106] The NGPA also provides that certain agricultural and industrial users will not be curtailed unless gas is needed for high priority users. The Act requires the Secretary of Energy to establish rules that will protect these specified agricultural and industrial gas users from curtailment, unless the Commission finds that alternative sources of fuel are reasonably available.[107]

Analysis

The former system of federally regulated rates for natural gas used in interstate commerce has resulted in severe shortages and curtailments. The Natural Gas Policy Act will result in an increased supply of interstate natural gas, will benefit the consumer, and will limit the use of more expensive forms of energy.

The rates allowable under the NGPA promise significant increases in the production of natural gas when compared with production es-

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[102] *Id.* at § 202.

[103] *Id.* at § 203.

[104] *Id.* at § 301.

[105] *Id.* at § 302.

[106] *Id.* at § 303.

[107] *Id.* at § 401.

timates established in FPC Opinion 770A. By 1985, a cumulative increase of production of 7.5 trillion cubic feet of gas is projected. In 1985 alone, 2.3 t.c.f. more gas production is projected than under the former system. By 1990 cummulative additional production is projected to reach 26 t.c.f., with an additional 4.7 t.c.f. in that year alone, as compared to estimates under the former system.[108]

Regulated rates on the interstate market have resulted in curtailments in recent years, while unregulated intrastate markets had surplus gas. The unregulated rates under NGPA will result in more gas being committed to the interstate market. The producer will be able to charge the same wellhead price for gas used in either market. This will result in a more even distribution since the producer will have incentive to produce for both markets equally, rather than favoring production for the higher priced intrastate market.

Curtailments in the interstate market have an immediate adverse affect on the economy. During gas shortages the low priority user, the industrial gas consumer, is the first to have gas curtailed. This has caused thousands of plant closings and temporary layoffs for millions of workers in recent years. This, in turn, causes a decrease in productivity and loss of income to both labor and industry. In 1977 3.19 t.c.f. of natural gas was curtailed to industry alone, causing oil imports to rise by nearly a million barrels a day. Approximately two-thirds of all curtailed gas is replaced by oil. During one period from April 1976 to March 1977, imported oil used to replace curtailed gas caused approximately $4.7 billion to flow from the United States to oil producing nations.[109]

One might make the assertion that increased natural gas production resulting from deregulation will deplete the supply. Authorities estimate that the remaining recoverable gas resources are between 700 and 1200 t.c.f. At the present rate of consumption, this means that 35 to 60 years of conventional gas supplies remain.[110] Increased drilling activity, induced by a deregulated wellhead price, will result in more discoveries. In addition to recoverable gas from conventional sources, there exists a tremendous potential to derive gas from unconventional sources, such as natural gas from coal seams, peat gasification and shale gasification. The most conservative estimate

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[108] American Gas Association, *Forecast Production of Lower 48 Conventional Natural Gas Under the House/Senate Gas Pricing Compromise* at 1 (1978).

[109] American Gas Association, *The Impact of Gas Curtailments on the Growth of Oil Imports Since 1973* at 1 (source: FERC).

[110] A.G.A., Future for Gas Energy at 8-9.

concludes that over three hundred years of gas consumption at our present rate of consumption can be supplied by these unconventional sources.[111]

The Natural Gas Policy Act will protect the consumer in several respects. The incremental pricing policy will pass the higher costs of new gas to industries using gas as boiler fuel. This will allow the consumer to pay a lower rate for gas, and may persuade industry to switch to coal for boiler fuel. More gas available for residential use will benefit the consumer by protecting him from higher priced forms of energy such as oil and electricity. The price of old gas will continue to be regulated, resulting in lower prices than the deregulated gas. Gas producers will therefore be prohibited from charging the higher rates for gas from old wells, which represent a much smaller investment than wells drilled today.

Approximately half of the oil consumed in the United States today is imported oil. It is estimated that gas production as allowed by the NGPA will cause oil imports to be reduced by as much as 1.4 million barrels a day. This will reduce the outflow of dollars to the oil-producing nations by six to eight billion dollars annually.[112] Of all the bills included in the National Energy Act, the NGPA will result in the largest reduction in dollar outflow and oil importation.[113]

We produce 95% of all the gas we consume.[114] To assure that this record of self-sufficient gas production continues, producers must be provided with sufficient incentive to develop the tremendous potential supply of gas in the United States from conventional and unconventional sources. Such incentive has been provided by the natural gas rate deregulation plan of the Natural Gas Policy Act. The present deregulated rate will result in a supply that will allow self-sufficiency to continue.

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[111] *Id.* at 18-19.

[112] Democratic Study Group, *U.S. House of Representatives Fact Sheet* No. 95-54 at 16.

[113] 36 CONG. Q. 3041 (October 21, 1978).

[114] A.G.A., Future For Gas Energy at 11 and 13 (derived from statistics).

The Program on Government Regulation

Professor Michael S. Baram of Franklin Pierce Law Center is pleased to announce The Program On Government Regulation. This program brings faculty and student interests to bear on the dynamic field of government regulation, particularly on issues which involve science and technology. Directed by Professor Michael Baram, program participants include Law Faculty and students, and faculty from other institutions and disciplines.

Program activities include research projects, and clinical and educational studies in four broad subject areas:

- Improving government regulation of risks to health, safety and environmental quality;
- Developing alternatives to government regulation for the management of risks arising from scientific and technological developments;
- Assessing the regulatory and non-regulatory approaches of other industrial nations to the management of risks;
- Improving state and local regulation.

Research now being undertaken includes the following projects:

- Legal and ethical issues in federal regulation of risks arising from scientific and technological developments (U.S. National Science Foundation, Evist Program).
- Regulation of health, safety and environmental quality and the use of cost-benefit analysis (Administrative Conference of the United States).

- Assessment of alternatives to government regulation for managing risks to health, safety and environmental quality (Ford Foundation).

In addition, students are engaged in several independent research studies and clinical education programs on:

- Regulatory policies of EPA, OSHA, FDA, and CPSC for controlling carcinogenic substances.
- Federal programs for radioactive waste management.
- Decision processes pertaining to radiation form high voltage transmission lines (with Carnegie-Mellon University's program on engineering and public policy).
- Protection of beach and intertidal zones in New England from oil spills.
- Administrative law reforms for New Hampshire agencies (with N.H. Office of Administrative Procedure).

Further information, including publications, newsletters, and reports on some of the foregoing activities, are available upon request. Please contact Professor Michael Baram, Director, Program on Government Regulation, Franklin Pierce Law Center, 2 White Street, Concord, New Hampshire 03301, Telephone (603) 228-1541.