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PTC Staff, Research and Program Expansion

Full-time Director Appointed

We are pleased to announce the appointment of attorney Robert Shaw, formerly of the Massachusetts Institute of Technology Patent Department, as full-time Director of the PTC Research Foundation.

For the past few years, Mr. Shaw has been developing and teaching patent application preparation and prosecution courses at the Franklin Pierce Law Center, and has acquired an intimate understanding of and background in the Law Center's programs and future plans for providing new lawyers, stemming from engineering, scientific and technical backgrounds, for the patent bar and the legal and government professions more generally. He is thus in a particularly advantageous position to enlist and supervise the graduate law input to IDEA as one component of his new responsibilities.

Mr. Shaw will be closely assisted in his new administrative duties by PTC Senior Fellow William Yates, formerly head of the Dow Chemical Patent Department, and Harry M. Saragovitz, former Chief Patent Counsel for the Department of the Army, who has been temporarily serving as acting PTC Director and will assume the functions of Associate Director and Washington, D.C. Director of PTC activities, President Robert H. Rines of the Law Center, Howard S. Curtis, Secretary of the Law Center and Executive Vice President of the Academy of Applied Science, and Ms. Nancy Metz, program director of the Law Center's Entrepreneurial Workshop, in which research activities are initiated for ultimate PTC research projects.

Some Current Research Activities

Among the recent and current projects of the PTC are the following:

Preparation for publication of completed studies, partially supported by the National Science Foundation and by the Academy of Applied Science, showing the effect of technical publications upon the stimulation of invention in some ten fields of technology over the past quarter century.

Preparation for publication of a comparison of the backgrounds, operational practices, and views of current inventors in diverse fields as to the United States, its problems, patent system, strengths and weaknesses and the incentives and deterrents to innovation.

Preparation for publication of the results of consultative assistance to the National Academy of Engineering in formulating its summary to the nation of recommendations stemming primarily from the recent government domestic policy reviews to rekindle innovation and strengthen the patent system for the balance of this decade.

A survey of firms who have litigated patents, other patent-holding companies and institutions, and the patent bar, as to the circumstances where they might voluntarily resort to properly structured arbitration or similar dispute resolution, as a substitute for the judicial arena.[1]

Program Expansion

Innovation Clinic for Inventors

The need in the area of industrial and intellectual property for a reliable source of preliminary consultation that is available to the inexperienced inventive community and the public, has recently been stressed by the American Patent Law Association. As the nation's only legal aid clinic in this area, the Innovation Clinic of the Law Center has been trying to serve this purpose in the New England area; and, in a more sophisticated approach, has been providing patent application experience to law students under the guidance of supervisory lawyers, in handling limited patent application filing needs of academic innovation programs at Carnegie-Mellon's Center for Entrepreneurial Development, Dartmouth's Invente Program, student inventions stemming from M.I.T.'s Innovation Center and from the University of Massachusetts.

With Mr. Shaw's full-time residence at the Law Center and an expanded group of advisory patent lawyers, joining Professors Field and Rines and Mr. Yates and Mr. Saragovitz, the Innovation Clinic expects to work closely with the American Patent Law Association for reliable public consultation in this area and to expand its effectiveness and service — with expected support from PTC corporate members.

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[1] Stimulated by PTC Conference, IDEA, Vol. 18, No. 4.

Patent Trial Advocacy Program for the Bar

Also in consort with the APLA, we are in the serious stages of planning for jointly sponsored week-long summer patent and related trial advocacy training programs at the Law Center for the patent bar. Details are expected to be announced in the near future.

Patents on Microorganisms

ARTHUR P. GERSHMAN*
JOSEPH SCAFETTA JR.**

Introduction

The U.S. Court of Customs & Patent Appeals has twice ruled in two companion cases that microorganisms are patentable. This article will review the background of the cases and the rulings in each of the two cases. A discussion of the potential impact of the decision follows, particularly as it relates to the new field of genetic engineering. Finally, practical advice will be offered to the legal practitioner who desires to obtain patent protection for microorganisms.

Part I

*Background of the Bergy*** Case*

Three co-inventors, Bergy, Coats and Malik, all microbiologists at the Upjohn Research Laboratory, prepared a biologically pure culture. A patent application was filed in which the fifth claim reads as follows:

> 5. A biologically pure culture of the microorganism Streptomyces vellosus, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.[1]

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[1] *In re Bergy,* 563 F.2d 1031, 1032, 195 U.S.P.Q. (B.N.A.) 334, 345 (C.C.P.A. 1977), *vacated sub nom., Parker v. Bergy,* 438 U.S. 932, 198 U.S.P.Q. (B.N.A.) 257 (1978).

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**Associate, Wigman & Cohen, Arlington, Virginia; M.Pat.L., Georgtown University, 1973; J.D., University of Pittsburgh; B.S.A.E., Pennsylvania State University, 1969. Mr. Scafetta is the author of several articles including "Citation of Canceled Matter in United States Patent Files Prior Art," 20 IDEA 121 (1979).

***This case is now terminated because the applicants have expressly abandoned their claim to the microorganism *per se* in the U.S. Patent & Trademark Office. See *Diamond v. Bergy,* U.S. , 204 U.S.P.Q. (B.N.A.) (1980).

"NRRL 8037" is defined in the specification as follows:

> The Microorganism
>
> The novel actinomycete used according to this invention for the production of lincomycin is Streptomyces vellosus. One of its strain characteristics is the production of lincomycin without the concomitant production of lincomycin B. Another of its strain characteristics is the production of comparable titers of lincomycin at a temperature of 28 degrees C. A subculture of this living microorganism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession number in this repository is NRRL 8037.[2]

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[2] *In re Bergy*, 563 F.2d at 1032, 195 U.S.P.Q. (B.N.A.) at 346.

The Examiner's Rejection of the Bergy Application

The Examiner's sole ground for rejection of the Bergy claim was that it was directed to non-statutory subject matter. Statutory subject matter is set forth in Section 101 of Title 35, United States Code, which reads as follows:

> Inventions Patentable
>
> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Examiner based the rejection on his classification of the claimed subject matter as a "product of nature." The "product of nature" rejection is derived from, among others, Justice Douglas' opinion in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[3] In that case, the U.S. Supreme Court said that "[the claimed bacteria's] qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."[4]

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[3] 333 U.S. 127, 76 U.S.P.Q. (B.N.A.) 280 (1948). U.S. Patent No. 2,200, 532, issued to Bond, was held invalid. The Bond patent claimed "]a[n inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium,* said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific." The term "inoculant" was used to describe a laboratory-produced bacteria culture which has been placed in a powder of liquid base and packaged for sale to agriculturists for the inoculation of seeds of leguminous plants. Certain bacteria of the genus *Rhizobium* infects the roots of leguminous plants, causing the growth of root nodules which enable the plants to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds. Prior to the invention of Bond, each inoculant contained only one strain of the *Rhizobium* bacteria and was intended for use only for a specific legume or group of legumes. The invention disclosed in the Bond patent was an effective mixed culture inoculant for legumes. To produce such a culture, it was necessary to experimentally determine a mix of bacteria which did not produce an inhibitory effect on one another when mixed in a common base. The opinion of invalidity was based on the finding of the court that Bond's inoculant was not a discovery or invention within the meaning of the patent statutes since that would require allowing a patent to issue on "the discovery of the natural principal itself." *Id.* 333 U.S. at 132, 76 U.S.P.Q. at 282.

[4] *Funk Bros Seed Co. v. Kalo Inoculant Co.,* 333 U.S. at 130, 76 U.S.P.Q. (B.N.A.) at 281. See also Moxon, "Products of Nature: The New Criteria," 20 Cath. U.L. Rev. 783 (1971).

The applicants responded by submitting to the Examiner affidavits of three other microbiologists showing that the subject microorganism does not exist in nature as a biologically pure culture. The applicants asserted that the biologically pure culture recited in claim 5 was a "manufacture" since it was the "product of a microbiologist." The Examiner adhered to the rejection and an appeal was taken.

The Board of Appeals Decision in the Bergy Case

The Board of Appeals upheld the Examiner's rejection under Section 101, but substituted a new reason[5] in place of the Examiner's "product of nature" rationale. The Board held that, since it is a living organism, a microorganism could not be a "process, machine, manufacture or composition of matter, or any new and useful improvement thereof," as required by Section 101. The Board asserted that Section 101 must be strictly construed and that "only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of those categories listed."[6] In support of its conclusion, the Board cited *In re Arzberger*[7] which held that bacteria are not patentable as plants under the Plant Patent Act of 1930[8] which extended patent protection to the field of agriculture. Furthermore, the Board reasoned that allowing microorganisms to be patented would logically require new types of insects and animals produced by selective breeding to be patentable, a result which, according to the majority, was clearly beyond the scope intended by Congress of the present patent laws.

One Board member dissented, stating that solely because microorganisms were alive did not preclude patentability under Section 101 and that, even if the microorganism in question was considered a "product of nature," when extracted and concentrated in a purified form, it would be patentable. Applicants appealed the decision of the Board to the Court of Customs and Patent Appeals.

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[5] See Patent & Trademark Office Rule of Practice 196, 37 C.F.R. § 1.196 (1979).

[6] *Ex parte Bergy,* 197 U.S.P.Q. (B.N.A.) 78, 79 (PTO Bd. Apl. 1976).

[7] 112 F.2d 834, 46 U.S.P.Q. (B.N.A.) 32 (1940). An applicant's claim for "[b]acteria herein described and designated as *Clostridium saccharo-butyl-acetonium-liquefaciens*" was rejected.

[8] Pub. L. No. 245, 46 Stat, 376. In the 1952 revision of the patent laws, the Plant Patent Act was incorporated into 35 U.S.C. as Sections 161-164. See Federico, "Commentary on the New Patent Act," 35 U.S.C. 1, at 41 (1953).

Applicants' Arguments in Bergy I
Before the CCPA

Applicants, in the posture of appellants before the CCPA, made four arguments in support of their appeal. They first took the position that the biologically pure culture of claim 5 was within the statutory classes set out in 35 U.S.C. 101. They argued that there is ample precedent in other appellate decisions implying that living organisms are statutory subject matter. Relying on *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[9] and the dissenting opinion of the Board of Appeals in the present case analyzing *Funk Bros.*, the applicants advanced the position that the Supreme Court had leaped the 35 U.S.C. 101 barrier in *Funk Bros.* and had decided the case solely on the basis of 35 U.S.C. 103, that is, as a question of the obviousness of the invention. Thus, applicants urged adoption of the Board's dissent and concluded that the bacteria culture in *Funk Brothers* was statutory subject matter.

Second, applicants cited two patents[10] whose claims included a living organism and a carrier as proof that the Patent & Trademark Office had in the past accepted bacteria cultures as patentable subject matter. Furthermore, the applicants pointed out that the Patent & Trademark Office had issued hundreds of patents having process claims wherein a living organism was the critical feature of the invention. Thus, applicants concluded, in rejecting the claims of their patent application, the Board had gone against established Patent & Trademark Office policy and settled rules of statutory interpretation.

Third, applicants brought to the attention of the Court three affidavits which had been submitted during prosecution of their application. The affidavits, each by a biologist employed by the Upjohn Company which was the assignee of the application, stated that a biologically pure culture of a specific microorganism, such as that recited in the applicants' claim 5, could not be found in nature. Thus, applicants concluded, the claimed invention was not a "product of nature".

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[9] See note 3, *supra*.

[10] U.S. Patent No. 3,632,747 claimed "The present bacterial fly larva-killing agent comprises spores of *Bacillus moritai* ATCC 21282 as an active ingredient and carrier." U.S. Patent No. 3,978, 211 claimed "A culture containing the microorganism strain *Actinoplanes dessanenis* ATCC 21938, said culture being capable of producing the antibiotic lipiarmycin in a recoverable quantity upon aerobic fermentation in an aquous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic salts."

Finally, the applicants argued that there was ample precedent for a claim directed to a pure material which was not "naturally occurring" They cited *In re Bergstrom,*[11] in which there was claimed pure PGE_2 and PGE_3; *Merck & Co. v. Chase Chemical Co.,*[12] purified vitamin B-12; *Kuehnsted v. Farbenfabriken of Elberfeld Co.,*[13] purified aspirin; *Parke Davis & Co. v. H. K. Mulford & Co.,*[14] purified adrenalin; *Ex Parte Yale,*[15] a compound purified with respect to a known but useless crude material; *Ex Parte Hillyer,*[16] a reaction product with purity limitations, purified with respect to a known crude product of the same reaction; and *Ex Parte Parke,*[17] a compound purified with respect to an old impure natural compound. The applicants argued that their claimed biologically pure culture was not naturally occurring and presented useful, statutory subject matter for patenting.

Solicitor's Arguments in Bergy I
Before the CCPA

In his brief to the CCPA, the Commissioner of Patents & Trademarks primarily limited his attention to the sole issue of whether living organisms are the kind of manufacture or composition of matter intended by Congress to be included within 35 U.S.C. 101. In support of his position that Congress did not so intend, the Solicitor for the Patent & Trademark Office argued legislative intent, judicial precedent, and other authority.

The Solicitor first reminded the court that not every invention is statutory subject matter for patenting. Examples of such excluded classes are printed matter, methods of doing business, purely mental steps, naturally occurring phenomena or laws of nature, and naturally occurring mathematical formula and their algorithms. The Solicitor cited the Board of Appeals' opinion that, as evidenced by the necessity for Congressional enactment of the Plant Patent Act of 1930,[18] Congress never intended to include living organisms within the scope of 35 U.S.C. 101. To support this argument, the Solicitor stated that a mere reading of the title of the Plant Patent Act, "A Bill to Provide for Plant

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[11] 427 F.2d 1394, 166 U.S.P.Q. (B.N.A.) 256 (C.C.P.A. 1970).

[12] 273 F. Supp. 68, 155 U.S.P.Q. (B.N.A.) 139 (D.N.J. 1967).

[13] 179 Fed. 701 (7th Cir. 1910), *cert. denied,* 220 U.S. 622.

[14] 189 Fed. 95 (C.C.S.D.N.Y. 1911), *aff'd,* 196 Fed. 496 (2d Cir. 1912).

[15] 119 U.S.P.Q. (B.N.A.) 256 (1958).

[16] 102 U.S.P.Q. (B.N.A.) 126 (1953).

[17] 64 U.S.P.Q. (B.N.A.) 335 (1964).

[18] See note 8, *supra.*

Patents", almost disposed of the issue. The Solicitor further emphasized the following language in a letter by Secretary of Agriculture Hyde appended to the reports of the Senate and House versions of the bill in 1930: "The purpose [of the bill] is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the time are understood to cover only inventions or discoveries in the field of inanimate nature."[19]

Regarding judicial precedent, the Solicitor stated that there was little guidance in the case law on the issue. The Commissioner reviewed the grounds presented in *Guaranty Trust Co. v. Union Solvent Corp.*,[20] *In re Arzberger*,[21] and the *Funk Bros. Seed Co.* case,[22] and interpreted some language in the case of *In re Mancy*[23] as implying that the CCPA had stated a claim directed to the microorganism *per se* would be unpatentable as a "product of nature." The Solicitor cited *Application of LeGrice*,[24] not discussed by the Board or the appellants, for the proposition that the result of the passage of the Plant Patent

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[19] S. Rep. No. 315, at 9-10, 71st Cong., 2d Sess. (1930); H. Rep. No. 1129, at 10-11, 71st Cong., 2d Sess. (1930).

[20] 54 F.2d 400, 12 U.S.P.Q. (B.N.A.) 47 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 U.S.P.Q. (B.N.A.) 237 (3d Cir. 1932). A patent claiming a process for making acetone and butyl alcohol using a particularly described bacteria was held valid. The court, in brief dictum, said: "Lastly the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented." *Id.*, 54 F.2d at 410, 12 U.S.P.Q. (B.N.A.) at 57.

[21] See note 7, *supra*.

[22] See note 3, *supra*.

[23] 499 F.2d 1289, 182 U.S.P.Q. (B.N.A.) 303 (C.C.P.A. 1974). The CCPA reversed a decision by the Patent Office Board of Appeals upholding the rejection of a claimed process for producing the antibiotic Daunorubicin by aerobically cultivating the microorganism *Streptomyces bifurcus*, strain DS 23, 219 (NRRL 3539), a new microorganism identified by the applicants. The court said in dicta: "Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature'." *Id.*, 499 F.2d at 1294, 182 U.S.P.Q. (B.N.A.) at 306.

[24] 301 F.2d 929, 133 U.S.P.Q. (B.N.A.) 365 (C.C.P.A. 1962). The CCPA decided that a particular printed publication describing applicant's novel "Rose Floribunda Plant" was not a bar to patentability under the Plant Patent Act, 35 U.S.C. § 161. The court held that "descriptions in printed publications of new plant varieties, before they may be used as statutory bars under 35 U.S.C. § 102 (b), must meet the same standards which must be met before a description in a printed publication becomes a bar in non-plant patent cases." *Id.*, 301 F.2d at 944, 133 U.S.P.Q. (B.N.A.) at 378.

Act was that the patent law, as shown by the committee reports, was extended to plant patents. Thus, the Solicitor surmised that certain forms of living organisms were extended the benefits of the patent system for the first time and were established as a wholly separate statutory class of patentable subject matter.

As other authority, the Solicitor presented a long list of quotations from text books and legal literature. None of the quotations was presented as being conclusive. Rather, the Solicitor stated that "there is a decided paucity of discussion . . . concerning the present issue, particularly in literature published before 1930."[25]

Finally, the Solicitor concluded:

> The discovery of hitherto existing but unknown living organisms, which have been deployed in various technological processes to produce useful results or products, has likewise proceeded apace for several decades. Methods for inducing mutations in those organisms have been found. The age of "genetic engineering" — creation of new living organisms by combining genetic material from different life forms — is now upon us. The question whether the patent laws should be extended to cover living organisms not already within the compass of 35 U.S.C. 161-164 and 7 U.S.C. 2321 et seq. is a policy matter which cannot, and should not, be deemed the proper subject for interstitial judicial legislation. Appellant's remedy is with Congress.[26] (Citations omitted.)

The First CCPA Decision in the Bergy Case

The court initially considered the issue before it "to involve the single question of whether the uncontroverted fact that the biologically pure culture, *as claimed,* is *alive* removes it from the categories of invention enumerated in Section 101." (Emphasis in original.)[27] The court, in a plurality opinion by Judge Rich joined by Judge Markey, stated its decision: "Our conclusion is that it does not."[28]

After stating that the issue was one of first impression, the court reviewed the closest precedents, *In re Mancy*[29] and the *Guaranty Trust Co.* case,[30] and found them inconclusive on the issue.

Since processes using living organisms are patentable, the court said that it is illogical to deny patentability solely because the claimed

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[25] Brief for the Commissioner of Patents & Trademarks at 14.

[26] *Id.* at 20.

[27] *In re Bergy,* 563 F.2d at 1035, 195 U.S.P.Q. (B.N.A.) at 348.

[28] *Ibid.*

[29] See note 23, *supra.*

[30] See note 20, *supra.*

culture contains a living organism. Examples of such processes cited by the court are the bacterial sewage treatment cases of *City of Milwaukee v. Activated Sludge, Inc.*[31] and *Cameron Septic Tank v. Village of Saratoga Springs.*[32] The court refuted the Board of Appeals' view that Section 101 requires a strict adherence to the recited categories of patentable subject matter. In the court's view, the statutory categories of "process, machine, manufacture, composition of matter or . . . improvement thereof"[33] are not rigidly defined and mutually exclusive, but are broad categories among which there is considerable overlap. The court was of the opinion that it was not necessary to decide whether the claimed biologically pure culture containing the microorganism was a manufacture or a composition of matter, finding it not intellectually profitable to do so. Furthermore, the court stated that, even if the harsh standards imposed by the Board were to be applied, the claimed microorganism does fall within the statutory categories as a manufacture or a composition of matter. In support of its decision, the court distinguished microorganisms from higher life forms such as insects, mammals and garden plants, stating that "[t]he nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents and catalysts than they are to horses and honeybees or raspberries and roses."[34] Thus, the court reasoned that the mere fact microorganisms are alive, as distinguished from chemical compounds which are inanimate, is a distinction without legal significance.

The court specifically limited its opinion to microorganisms. The court said that "we are not deciding whether living things in general, or at most, whether any other living thing other than microorganisms, are within Section 101."[35] The court stated that a case-by-case review was necessary to decide the patentability of other living things.

Finally, the court distinguished the case at bar from *In re Arzberger*[36] which held that bacteria are not patentable as plants on the ground that the *Arzberger* court did not have before it the issue of whether bacteria were included within Section 101.

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[31] 69 F.2d 577, 21 U.S.P.Q. (B.N.A.) 69 (7th Cir. 1934).

[32] 159 Fed. 453 (2d Cir. 1908).

[33] 35 U.S.C. § 101.

[34] *In re Bergy,* 563 F.2d at 1038, 195 U.S.P.Q. (B.N.A.) at 350.

[35] *Id.,* 563 F.2d at 1035, 195 U.S.P.Q. (B.N.A.) at 348.

[36] See note 7, *supra.*

Judge Kashiwa, sitting by designation from the Court of Claims, concurred only in the extremely limited holding of the plurality decision. He expressed the opinion that the position taken by the Solicitor regarding cases of patenting higher life forms was not supported by the plurality decision and that such cases must be decided on their own facts.

Judges Miller and Baldwin dissented on the grounds that microorganisms are not within the scope of 35 U.S.C. 101 because plants, as living things, were clearly not within the scope of 35 U.S.C. 101 when Congress passed the Plant Patent Act of 1930. The dissent argued that, otherwise, the 1930 Act was unnecessary. The dissent cited the passage of the Plant Variety Protection Act of 1970[37] as further support for its proposition that Congress would not enact needless legislation if living matter, such as plants, was already considered to be patentable.

The dissent pointed out that, although methods of using an algorithm in a system may constitute patentable subject matter, the algorithm itself is not patentable. Comparison was invited with the case of *In re Flook*.[38] The dissent took the position that, although methods of using microorganisms in a process may constitute patentable subject matter, the microorganism itself should not be patentable.

The dissent then commented that Judge Rich's statement concerning the public interest involved in allowing the patenting of microorganisms was irrelevant.

The dissent concluded by attacking Judge Rich's comment that the "product of nature" issue was without merit as unwarranted because the court did not have before it the views of the Board of Appeals.

Subsequent Proceedings

The CCPA decision was handed down on October 6, 1977. On October 27, 1977, the Commissioner of Patents & Trademarks petitioned the CCPA for either a rehearing of the case or a modification of the decision. In the petition the Commissioner urged that the court's interpretation of the scope of the statutory classes was too broad and that Congress had never intended to include living organisms in the terms "manufacture" and "composition of matter" in 35 U.S.C. 101. The petition was denied by a memorandum decision on November 23, 1977. The CCPA decision was appealed to the Supreme Court on a writ of certiorari which was granted. In a per curiam ruling, the judgment

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[37] 7 U.S.C. 2321 *et. seq.*

[38] 559 F.2d 21, 195 U.S.P.Q. (B.N.A.) 9 (C.C.P.A. 1977), *reversed sub nom., Parker v. Flook,* 437 U.S. 584, 198 U.S.P.Q. (B.N.A.) 193 (1978).

of the CCPA was vacated[39] and the case was remanded to the court for further consideration in light of *Parker v. Flook.*[40]

Part II

Background of the Chakrabarty Case

Chakrabarty, a microbiologist employed by the General Electric Company, genetically engineered a particular type of microbe so that a new strain was created with the capacity for simultaneously degrading several different components of crude oil. A patent application was filed in which an illustrative claim read as follows:

> 7. A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.[41]

A "plasmid" and a "degradative pathway" are defined in the specification as follows:

> *Extrachromosomal element* . . . a hereditary unit that is physically separate from the chromosome of the cell; the terms "extrachromosomal element" and "plasmid" are synonymous . . . .
>
> *Degradative pathway* . . . a sequence of enzymatic reactions (e.g. 5 to 10 enzymes are produced by the microbe) converting the primary substrate [i.e., oil] to some simple common metabolite, a normal food substance for microorganisms.[42]

The Examiner's Rejection of the Chakrabarty Application

The Examiner rejected the 12 Chakrabarty claims because they were allegedly directed to subject matter not covered by 35 U.S.C. 101.

The Examiner based the rejection on the grounds that the claimed subject matter is a product of nature and that the claims are directed to live organisms. The applicant asserted that the bacterium recited in the rejected claims was a "manufacture" and a novel "composition of matter" covered by 35 U.S.C. 101. The Examiner did not change his position and, therefore, the applicant appealed.

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[39] *Parker v. Bergy,* 438 U.S. 932, 198 U.S.P.Q. (B.N.A.) 257 (1978).

[40] *Parker v. Flook,* 437 U.S. 584, 198 U.S.P.Q. (B.N.A.) 193 (1978).

[41] *In re Chakrabarty,* 571 F.2d 40, 41-42, 197 U.S.P.Q. (B.N.A.) 72, 73 (C.C.P.A. 1978), *cert. dismissed,* 439 U.S. 801.

[42] 571 F.2d at 41; 197 U.S.P.Q. (B.N.A.) at 73.

The Board of Appeals Decision in the Chakrabarty Case

The Board of Appeals reversed the Examiner's first ground for rejection and ruled that the claimed bacterium was not naturally occurring and, therefore, could not be a product of nature. However, the Board unanimously ruled that Congress could not have intended Section 101 to include any living thing because, if it had, it would not have passed the Plant Patent Act of 1930. The Board pointed out that, if new bacteria were within Section 101, then all new life forms would be included. Such a conclusion was not believed by the Board to be within the scope of the present patent laws and, therefore, the Board ruled that no living thing could be patented. An appeal was subsequently taken to the CCPA.

Chakrabarty Arguments Before the CCPA

In his brief to the CCPA, counsel for the assignee of the Chakrabarty application argued that there was an explanation for the action of Congress in passing the Plant Patent Act of 1930. It was the position of the appellant that the reasons for the law were threefold:

> (1) enabling disclosure could never be made to satisfy [the patent law as codified at that time];
> (2) there was serious doubt as to whether an applicant for a patent on a plant, even a new variety, would fall within the definitions of "inventor" or "discoverer" adhered to by the courts; and
> (3) no reliable protection could be granted . . . because to "make" would not apply to the development of plants.[43]

Consequently, the appellant argued that the Plant Patent Act of 1930 did not affect the scope and meaning of 35 U.S.C. 101 as now interpreted by the courts.

The appellant pointed out that hearings were conducted in 1906 on a bill with the same objective and that there was no objection on the part of the committee members in attendance that the patent law provides for the patenting of living things. For example, it was noted that the famous legal commentator, Albert H. Walker, author of "Walker on Patents," testified in response to questions posed by the congressmen that the first person to cross-breed a horse and an ass would have been entitled to a patent on a mule. The hearing report does not indicate that the listeners objected to his opinion.[44]

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[43] Brief for Appellant at 7.

[44] *Id.*, at 11.

The appellant also pointed out that the Supreme Court itself twice ruled on patents covering living matter and in neither case was there any indication that living things were unpatentable simply because they were alive. The first such Supreme Court case was *American Fruit Growers, Inc. v. Brogdex Co.*[45] which dealt with fresh fruit having borax added to the rind as a protective film. The second case was the *Funk Bros. Seed Co.* case[46] discussed *supra.* This latter case arose after the passage of the 1930 Plant Patent Act. Although the patent, like the patent in the *American Fruit Growers* case, was declared invalid because the Supreme Court was of the opinion that the claims were directed essentially to products of nature, the patents were not declared invalid because the claims covered living matter per se.

Finally, the appellant attacked the argument made by the Board of Appeals that a patent on a new bacteria created by genetic engineering would necessarily require the Patent & Trademark Office to issue a patent on a human clone also created by genetic engineering, if and when the time ever arrived. It was the appellant's position that the clone would be a human being and, therefore, would be entitled to enjoy all basic freedoms guaranteed in the Constitution. Thus, the Thirteenth Amendment abolishing involuntary servitude and the Fourteenth Amendment securing due process and equal protection of the laws would bar a patent on a human clone.[47]

On the other side, the Solicitor argued that the Board correctly decided the claimed subject matter is neither a manufacture nor a composition of matter within the definition of 35 U.S.C. 101. After a recitation of the Board's reasoning that the Plant Patent Act of 1930 was necessary because previous congressional intent allegedly did not allow the patenting of living things, the Solicitor attempted to make a statutory construction. He determined that the specific terms of 35 U.S.C. 161 relating to plant patents are the sole and exclusive provisions controlling the types of living things that may be patentable and that such provisions are not supplemented by the general terms of 35 U.S.C. 101 relating to manufactures and compositions of matter.[48]

The Solicitor then attacked the Appellant's analysis of the legislative history behind the Plant Patent Act of 1930 and cited specific passages from the hearings, letters, and memoranda that tended to

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[45] 283 U.S. 1, 8 U.S.P.Q. (B.N.A.) 131 (1931).

[46] See note 3, *supra.*

[47] Brief for Appellant at 22.

[48] Brief for the Commissioner at 6.

support his position that the predecessor statute[49] to 35 U.S.C. 101 did not include living organisms per se. The Solicitor added that, if 35 U.S.C. 101 did indeed cover living things, then it would not have been necessary for Congress to pass the Plant Variety Protection Act of 1970.[50]

Turning his attention to judicial precedent, the Solicitor discussed the language in the cases of *Guaranty Trust, Arzberger, Kalo Inoculant, Mancy,* and *LeGrice,* which had been also cited and analyzed in his brief submitted in the *Bergy* case,[51] as compelling authority that Congress did not intend "manufacture" and "composition of matter" in 35 U.S.C. 101 to encompass living things.[52]

The Solicitor then argued that a British patent obtained by the appellant on the same subject matter was irrelevant under the authority of one of the CCPA's own earlier cases.[53]

The Solicitor concluded by reciting passages from several works by various legal and scientific scholars tending to support the proposition that living matter is not patentable even though perhaps it should be.[54]

The appellant submitted a reply brief in which he took the position that the brief for the Commissioner, in asserting a finding of Congressional intent, failed to establish that Congress had omitted living organisms from 35 U.S.C. 101. In support of its position, the appellant challenged the Solicitor's application of statutory construction as faulty because it was allegedly improper to construe the Congressional intent in passing the Consolidated Patent Act of 1870[55] and the predecessor statute of 35 U.S.C. 101 by consulting the later Congressional intent in passing the Plant Patent Act of 1930. The appellant reiterated its belief that the Plant Patent Act of 1930 merely provided a mechanism for avoiding the disclosure requirements necessary under the Patent Act of 1870 in force at the time that the Plant Patent Act was passed. The appellant concluded by attempting to clarify several points raised by the Solicitor in his brief for the Commissioner. In particular, the appellant relied upon the opinion released shortly beforehand by the CCPA in the *Bergy* case for the proposition that

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[49] R.S. 4886, Act of March 3, 1897, c. 391, sec. 1, 29 Stat. 692.

[50] See note 37, *supra.*

[51] See notes 20-24, *supra.*

[52] Brief for the Commissioner at 21.

[53] *In re Larsen,* 292 F.2d 531, 130 U.S.P.Q. (B.N.A.) 209 (1961).

[54] Brief for the Commissioner at 23-28.

[55] Act of July 8, 1870, c. 230, 16 Stat. 198.

living microorganisms are covered by 35 U.S.C. 101.[56]

The Solicitor submitted a two-page supplemental brief in which he argued that the holding in the *Bergy* case was "historically unsound and at variance with manifest congressional intent."[57] However, in his conclusion, the Solicitor took the position that he was unsure if the *Bergy* decision had any effect on the *Chakrabarty* appeal.[58]

The First CCPA Decision in the Chakrabarty Case

A majority ruled for the appellant Chakrabarty but the court splintered badly. There were four separate opinions written by the five judges sitting on the case.

Judge Rich, ruling for the appellant, wrote for himself and Judge Lane. The appellant also won over Chief Judge Markey who filed a concurring opinion. Judges Baldwin and Miller both dissented in separate opinions.

After giving a brief background of the case, Judge Rich focused on claim 7 directed to the genetically engineered bacterium. He analyzed both the rejection of the Examiner and the decision of the Board of Appeals.

Judge Rich disposed of the PTO's contention that, because the new bacterium is alive, it is not statutory subject matter within the meaning of Section 101. In reaffirming its earlier decision in the *Bergy* case, Judge Rich said the following:

> We do not consider the differences between the claims here and the claim in *Bergy* to be of any significance on the issue before us. In both cases the claims are directed to microorganisms and in both the *only* asserted objection to their patentability is that the microorganisms are alive and, for that reason *alone*, not within the § 101 categories of inventions which may be patented. We dealt fully with that identical issue and with the identical PTO arguments in *Bergy*. Nothing in the facts of this case requires that we add anything to what we there said. *Bergy* is, in this court at least, a controlling precedent.
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> The decision of the board is *reversed*.[59] (Emphasis in original.)

Chief Judge Markey concurred and added some remarks in defense of the plurality opinion against the attacks by Judges Baldwin and Miller. The Chief Judge simplified the sole issue by dividing manufactures and compositions of matter into two kinds by their sources: God or Nature and man. Since the new manufacture in this case was

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[56] Appellant's Reply Brief at 13.

[57] Supplemental Brief for Commissioner at 1, note 1.

[58] *Id.*, at 2.

[59] *In re Chakrabarty*, 571 F.2d 40, 43, 197 U.S.P.Q. (B.N.A.) 72, 75 (C.C.P.A. 1978).

made admittedly by man, the subject matter of the application was covered by Section 101. The Chief Judge would not allow the PTO to read the word "dead" into the statute before the words "manufacture" and "composition of matter."[60] He dismissed the Plant Patent Act of 1930 and the Congressional intent in passing the law as irrelevant and concluded by pointing out that the administrative difficulties of the PTO "should not frustrate the constitutional and statutory intent . . . in areas on the forefront of science and technology."[61]

In his dissent, Judge Baldwin criticized the characterization of the issue by both Judges Rich and Markey as "ambiguous" and "broad", respectively.[62] He considered the real issue to be whether "applicant's modification of a clearly unpatentable living organism is sufficient to render the resulting living organism statutory subject matter."[63] He was of the opinion that the modified living organism in the present case was analogous to the borax-impregnated orange in the *American Fruit Growers* case.[64] He felt that the modification of the unpatentable living organism was insufficient to change it into patentable and statutory subject matter because, like the orange that was impregnated with borax in the *American Fruit Growers* case, the basic nature of the living organism was not changed.

Judge Miller, in his dissent,[65] apparently accepted the arguments of the PTO that living organisms were not intended by Congress to be covered by 35 U.S.C. 101 and that the extension of patent protection to living plants by Congress with the enactment of the Plant Patent Act of 1930 supported this conclusion. He delved briefly into the legislative history and referred all readers back to his dissenting opinion in the *Bergy* case for all other points raised by Judges Rich and Markey.

Subsequent Proceedings

The CCPA decision in the *Chakrabarty* case was handed down on March 2, 1978. On May 26, 1978, Chief Justice Warren Burger granted a request made by the Solicitor General for an extension of time to file a petition for a writ of certiorari. The petition was eventually filed on July 26, 1978, and shortly thereafter the Commissioner of Patents & Trademarks, through his Solicitor, petitioned the CCPA to vacate its

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[60] 571 F.2d at 44, 197 U.S.P.Q. (B.N.A.) at 75.

[61] 571 F.2d at 44, 197 U.S.P.Q. (B.N.A.) at 76.

[62] *Ibid.*

[63] *Ibid.*

[64] See note 39, *supra.*

[65] 571 F.2d at 45-47, 197 U.S.P.Q. (B.N.A.) at 76-78.

decision, recall its mandate and reverse itself in the *Chakrabarty* case because of the Supreme Court's summary vacation of the CCPA's judgment in the *Bergy* case which was remanded to the CCPA for further consideration in view of *Parker v. Flook*.[66] The CCPA vacated its judgment on August 11, 1978, and the Supreme Court dismissed the writ of certiorari on August 25, 1978. Thus, the stage was set for a combined rehearing on both the decisions in the *Bergy I* and the *Chakrabarty I* cases.

Part III

Background for the Combined Bergy II and Chakrabarty II Cases

Before any discussion is undertaken of the combined case, it is necessary to review the decision in *Parker v. Flook* to discover what may have prompted the Supreme Court's summary remand of the *Bergy I* case.

Flook's invention related to a method for updating alarm limits. The only novel feature of the method was an algorithm or mathematical formula. After the solution to the formula was calculated, conventional post-solution steps were recited in the method claims. The issue was whether the invention claimed by Flook in his patent application was statutory subject matter under 35 U.S.C. 101. Thus, the *Flook* case involved the same statute as the *Bergy* and *Chakrabarty* cases.

In a 6-3 split decision, the Supreme Court ruled that the post-solution activity could not change an unpatentable principle into a patentable process. Since the algorithm discovered by Flook was a law of nature within the meaning of *Gottschalk v. Benson,*[67] it was non-statutory subject matter under Section 101.

The majority concluded that "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."[68] Since the patenting of live microorganisms was probably an area wholly unforeseen by Congress in 1952 for the extension of patent rights, perhaps it was this statement that the Supreme Court wanted the CCPA to keep in mind when considering the *Bergy* case on remand.

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[66] 437 U.S. 584, 198 U.S.P.Q. (B.N.A.) 193 (1978).

[67] 409 U.S. 63, 175 U.S.P.Q. (B.N.A.) 673 (1972).

[68] *Parker v. Flook, supra,* 437 U.S. at 596, 198 U.S.P.Q. (B.N.A.) at 200.

Appellants' Arguments in Bergy II
Before the CCPA

Counsel for the assignee of the Bergy application argued in a short brief that *Parker v. Flook* does not address the sole issue of the appeal taken in this case because the subject matter sought to be patented by Bergy and his co-inventors differed completely from that in the *Flook* case. Thus, it was the position of the appellants that "there is no basis for applying *Parker v. Flook* to this appea."[69]

Appellant's Arguments in Chakrabarty II
Before the CCPA

Counsel for the assignee of the Chakrabarty application argued in an extensive brief that certain language in the opinion in *Parker v. Flook* emphasized that, in the absence of a clear and certain signal from Congress, the Supreme Court does not propose to overrule its earlier precedents in order to hold in favor of patentability in cases in which patent rights are in areas wholly unforeseen by Congress. It was the opinion of the appellant that the Chakrabarty appeal does not involve an unforeseen area because Congress is familiar with human-directed recombination of DNA and living things produced by such experiments. Thus, although the appellant concluded that "*Parker v. Flook* has no negative effect on this appeal"[70], he nevertheless suggested that his application be remanded to the PTO so that he could amend the claims. He wanted to recite that the patentable aspect of his invention was that his genetically engineered Pseudomonas bacterium was stabilized by fusing together. As the claims stood on appeal, they recited simply that the bacterium contained at least two stable energy-generating plasmids. In a second short brief prepared in response to questions raised by the court during oral arguments, the Chakrabarty appellant concluded that the decision in *Bergy I* "appears to be controlling precedent favorable to appellant."[71]

Solicitor's Arguments in Bergy II
Before the CCPA

In his brief to the CCPA, the Solicitor argued for the Commissioner of Patents & Trademarks that Congress has given no clear and certain signal that any living organisms are patentable subject matter under 35 U.S.C. 101. The Solicitor quoted from the decision in *Deepsouth*

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[69] See Supplemental Brief for Appellants Bergy et al. at page 3.

[70] See Supplemental Brief for Appellant Chakrabarty at page 22.

[71] See Brief for Appellant In Question Raised by the Court at page 5.

Packing Co. v. Laitram Corp.[72] wherein the Supreme Court disapproved "the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public use narrower, than the courts had previously thought."[73] This same language had been quoted in *Parker v. Flook*. The Solicitor took the position that this quotation reached the heart of the matter and quickly concluded the following:

> The *thrust* of the Supreme Court's opinion in *Parker v. Flook*, coupled with the *fact* of remand of this case to this Court for further consideration in light of *Parker v. Flook*, should be dispositive of the issue here . . . .[74] (Emphasis in original.)

According to the Solicitor, the rationale for this conclusion was that the collective mind of Congress was never turned in the direction favoring patent protection for microorganisms.

Solicitor's Arguments in Chakrabarty II Before the CCPA

In his other supplemental brief to the CCPA, the Solicitor argued on behalf of the Commissioner of Patents & Trademarks the same position that it took in its *Bergy* brief with the identical language. However, the Solicitor added a page of rebuttal argument to the appellant's position by taking issue with the description of the genetically engineered microorganisms as "man-made". It was pointed out by the Solicitor that, during the consideration of the Plant Patent Act of 1930, the Senate and House committee reports both regarded it as "obvious that nature originally creates plants" although man sometimes "aids" or "directs" growth and, thus, has "facilitated nature in the creation of a new and desirable variety."[75]

Finally, in response to the appellant's offer to amend the claims to recite that the genetically engineered bacterium was stabilized by fusing together rather than to recite that the bacterium contained at least two stable energy-generating plasmids, the Solicitor took the position that the suggestion amounted "to a request for an advisory opinion on a matter not considered by the Board [of Appeals]"[76] and, therefore,

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[72] 406 U.S. 518, 173 U.S.P.Q. (B.N.A.) 769 (1972).

[73] *Id.*, 406 U.S. at 531, 173 U.S.P.Q. (B.N.A.) at 774.

[74] Supplemental Brief for the Commissioner of Patents and Trademarks at 4.

[75] S. Rep. No. 315 (accompanying S. 4015) and H.R. Rep. No. 1129 (accompanying H.R. 11372) (71st. Cong., 2d Sess., April 2 and 10, 1930, respectively).

[76] Supplemental Brief for the Commissioner of Patents and Trademarks at 6.

could not be reviewed under authority of the decision in *Application of Johnsen.*[77]

Amicus Curiae Arguments in Both Bergy II and Chakrabarty II

One brief amicus curiae was filed by attorneys for the Regents of the University of California which sponsors research in the field of microbiology out of which various inventions arise for patenting.

This amicus took the position that, to the extent the reasoning of *Parker v. Flook* applies, the decision of the Supreme Court shows the claims in both cases are directed to subject matter patentable under 35 U.S.C. 101. The amicus pointed out that the patent laws must be construed to promote progress in science and the useful arts by granting protection to any new and useful manufacture or composition of matter, whether living or non-living.[78] After giving their own analysis of the rationale of *Parker v. Flook* and arguing that manifestly different issues are raised in the *Bergy* and *Chakrabarty* cases, the attorneys for this amicus concluded the prior rulings made by the CCPA in both cases were correct and urged such rulings to be repeated.

Another friend of the court, the American Patent Law Association (hereinafter APLA), filed separate briefs for the appeals in each of the two cases. Claiming to represent over four thousand lawyers who comprise about half of the practicing patent attorneys in the United States, the APLA considered the purpose of the Supreme Court's remand of the CCPA decision in *Bergy I* to be "not altogether clear."[79] Nevertheless, in both briefs, the APLA argued the two cases do not involve an extension of patent rights because the inventions fall clearly within the definition of patentable subject matter and a determination of whether 35 U.S.C. 101 is satisfied does not involve an issue of "aliveness."[80] The APLA urged no prohibition against patenting in this technological area should be made but rather the making of inventions in the field should be encouraged by strengthening the patent system so that there is a reasonable protection of inventor's rights.

A third amicus was Genentech Inc., South San Francisco, California, a corporation engaged in technological research of recombinant DNA for making products used in medical and other fields. Directing its

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[77] 359 F.2d 905, 149 U.S.P.Q. (B.N.A.) 630 (C.C.P.A. 1966).

[78] Brief Amicus Curiae of the Regents of the University of California at 3.

[79] Brief on behalf of the American Patent Law Association, Amicus Curiae, in the Matter of the Application of Bergy et al., at 2.

[80] *Id.*, at 3-5. See also Brief on behalf of the American Patent Law Association, Amicus Curiae, in the Matter of the Application of Chakrabarty, at 7-12.

brief only to the *Chakrabarty* case, this amicus argued 35 U.S.C. 101 should be interpreted to encompass areas wholly unforeseen by Congress so inventions in new technological fields may be rewarded and so the patent system would not be reduced to a domain of gadgeteers in only old technical fields. Genentech also took the position that the controversiality surrounding the field of genetic engineering is a red herring and should be considered irrelevant because no resolution of the controversy will be accomplished and "no policy objective is served by denying patents on the microorganisms themselves, while continuing to grant patents on methods that employ them."[81] Finally, Genentech argued the legal fiction opposing the patenting of scientific principles *per se,* allegedly followed in *Parker v. Flook* by the Supreme Court, is inapplicable in the *Chakrabarty* case because the new microorganism claimed in the patent application was a concrete embodiment and not an abstraction of the underlying scientific principle leading to its manufacture.

The fourth amicus was a patentee and patent attorney named Cornell D. Cornish who filed his brief on behalf of himself and the village of Belle Terre, New York. Arguing only in regard to the *Chakrabarty* case, Cornish took a position favorable to the Patent & Trademark Office by concluding that the agency must have wide discretion in issuing patents and that the allowance of some claims and the rejection of others should be upheld as not an abuse of discretion within the administrative process of balancing competing social interests.

The CCPA Decision in the Combined Bergy and Chakrabarty Case

The Court, per Judge Rich, handed down a majority opinion that covered 27 printed pages, thus making it the longest opinion ever rendered to date by the CCPA. Judge Baldwin changed his previous position and wrote a concurring opinion. Judge Miller again dissented.

Judge Rich began by stating the issue as involving "the construction and application of 35 U.S.C. 101, more particularly the meaning to be given to the words 'manufacture' and 'composition of matter' in that section."[82] In effect, he inquired whether appellants could define their inventions in the claims of their patents as manufactures or compositions of matter comprising living organisms.

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[81] Brief Amicus Curiae of Genentech, Inc., in the Matter of the Application of Chakrabarty, at 13.

[82] *In re Bergy,* 596 F.2d 952, 955-56, 201 U.S.P.Q. (B.N.A.) 352, 357 (C.C.P.A. 1979).

The court reviewed the procedural background and summarized the present posture of the cases. It then briefly discussed the constitutional basis for the patent system and made a dissection of the anatomy of the patent statute. This lengthy part of the opinion appeared to teach some basic tenets of patent law and would seem unnecessary unless the court expected review by the Supreme Court.

The court proceeded to note its earlier decision in *Bergy I* was vacated and remanded for reconsideration in light of *Parker v. Flook*. In analyzing the *Flook* decision, the court found that the only common ground between the present cases and the *Flook* case is the involvement of 35 U.S.C. 101. The court noted the present cases did not involve the definition of a "process" under § 101 and no law of nature was involved. Thus, the court concluded "on the light *Flook* sheds on these cases, very simply, for the reasons we have stated, we find none."[83]

The court reviewed the inventions of Bergy and Chakrabarty and the rejections by the Examiners before making its decision: it adhered to the merits of its first rulings in both cases. The court considered the appealed claims within the statute and began by pointing out the court "*unanimously* believes it is not necessary that Congress shall have *foreseen* a new field of technology or useful arts to bring it within § 101."[84] (Emphasis in original.)

The court also considered the claimed living microorganisms "analogous in practical use to inanimate chemical compositions such as reactants, reagents, and catalysts used in chemical industry."[85] Because of the analogy, the court stated there is "no reason to deprive it or its creator or owner of the protection and advantages of the patent system by arbitrarily excluding it at the outset from the § 101 categories of patentable invention on the sole ground that it is alive."[86] The court continued by stating there is "no *legally* significant difference between active chemicals which are classified as 'dead' and organisms used for their *chemical* reactions which take place because they are 'alive'."[87] (Emphasis in original.)

The court criticized the Solicitor's characterization of the issue in its writ for certiorari in the *Bergy I* case as overly broad because the

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[83] *Id.*, 596 F.2d at 967, 201 U.S.P.Q. (B.N.A.) at 366.

[84] *Id.*, 596 F.2d at 973, 201 U.S.P.Q. (B.N.A.) at 371.

[85] *Id.*, 596 F.2d at 975, 201 U.S.P.Q. (B.N.A.) at 372-73.

[86] *Id.*, 596 F.2d at 975, 201 U.S.P.Q. (B.N.A.) at 373.

[87] *Ibid.*

petition presented the issue as "[w]hether a living organism is patentable subject matter under 35 U.S.C. 101."[88] The court was of the opinion that the issue should have been set forth as follows: "Is a man-made, biologically-pure culture of a microorganism . . . excluded from the terms 'manufacture' and 'composition of matter' in 35 U.S.C. 101 because the microorganism is alive?"[89] By making an analogy to yeastcake as a manufacture in which yeast is alive, the court implied the answer to the Solicitor's question is affirmative and the answer to its own question is negative. Both answers, of course, favor the appellants Bergy and Chakrabarty.

The court then dealt with *In re Mancy*[90] and the *Guaranty Trust* case[91] which contained dicta the Solicitor relied upon for a suggestion that living things are not patentable. Apparently not being able to completely resolve the differences favorably to the *Bergy* and *Chakrabarty* appellants, the court dismissed its own dictum in the *Mancy* case as "ill-considered" and that of the court in the *Guaranty Trust* case as "a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no opinion was expressed."[92]

The court then attacked the Solicitor's contention that, because Congress found it necessary to pass the Plant Patent Act of 1930 in order to grant special protection to horticulturists for developing new varieties of living plants, Congress must not have intended to encompass any living organisms in the predecessor statute to 35 U.S.C. 101 which lists general statutory subject matter.

First, the court declared the Solicitor made a mistake by looking at the legislative history of the 1930 Plant Patent Act in order to ascertain the intent of Congress in passing the predecessor statute to 35 U.S.C. 101 in 1874. Such interpretation of earlier congressional intent by reliance upon legislative history of later congressional acts constituted improper statutory construction.

Second, the court declared the Solicitor had gone astray in his analysis of the Plant Patent Act because he had failed to consider the express purpose of the bill to "remove the existing discrimination between plant developers and industrial inventors"[93] by eliminating the

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[88] *Id.*, 596 F.2d at 975-76, 201 U.S.P.Q. (B.N.A.) at 373.

[89] *Id.*, 596 F.2d at 976, 201 U.S.P.Q. (B.N.A.) at 373.

[90] See note 23, *supra.*

[91] See note 20, *supra.*

[92] *In re Bergy, supra,* note 82, 596 F.2d at 977, 201 U.S.P.Q. (B.N.A.) at 374.

[93] S. Rep. No. 315, 71st Cong., 2d Sess. (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess. (1930).

judicial interpretation that plants were not statutory subject matter because they were products of nature and by modifying the statutory requirement that an invention, such as a plant, must be described in writing in "full, clear, and concise terms".[94]

Thus, the court said the Solicitor had erred in concluding that, because the Plant Patent Act of 1930, as well as the Plant Variety Protection Act of 1970, were passed specifically to allow the grant of patents on living plants, Congress must have intended in earlier legislation to exclude the grant of patents on all other living organisms.

The court stated its decision did not extend the patent laws to encompass life itself because the Patent & Trademark Office has regularly issued patents claiming living matter. In support of its statement, the court listed ten exemplary patents drawn to living organisms and singled out an eleventh patent[95] issued to Louis Pasteur in 1873 for yeast. The court belittled the Solicitor's opinion that the CCPA was engaging in wholesale judicial legislation by characterizing the Solicitor as Chicken Little crying: "The sky is falling, the sky is falling!"[96]

The court analyzed the claims considered by the Examiners in both cases and noted the allowed claims in the Bergy application defined a process dependent upon the living microorganism while the allowed claims in the Chakrabarty application covered the living microorganism in combination with a carrier. The court could not see the logic of allowing claims on a process or a combination including the new microorganism while denying claims on the new microorganism itself.

In reversing the decision of the Board of Appeals in both cases, the court reached the following conclusion:

> We look at the facts and see things that do not exist in nature and that are man-made, clearly fitting into the plain terms "manufacture" and "compositions of matter." We look at the statute and, plainly, it appears to include them. We look at its legislative history and are confirmed in that belief. We consider what the patent statutes are intended to accomplish and the constitutional authorization, and it appears to us that protecting these inventions, in the form claimed, by patents will promote progress in very useful arts.[97]

In a long concurring opinion, Judge Baldwin agreed with the result reached by the majority but disagreed with the conclusion that the *Flook* case had no bearing on these appeals. Judge Baldwin considered

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[94] 35 U.S.C. § 112.

[95] U.S. Pat. No. 141, 072.

[96] *In re Bergy, supra,* note 82, 596 F.2d at 984, 201 U.S.P.Q. (B.N.A.) at 381.

[97] *Id.,* 596 F.2d at 987, 201 U.S.P.Q. (B.N.A.) at 383.

the *Flook* decision to reiterate the policy behind a line of cases that held a patent may not be obtained on an abstract principle or a law of nature. In discussing that line of cases,[98] Judge Baldwin carefully reviewed the claims allowed in each patent in issue and determined the inventions involved in the *Bergy* and *Chakrabarty* appeals did not preempt any natural laws because their patent applications "recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results."[99] After this review, Judge Baldwin stated he did not consider the patenting of microorganisms as extending Section 101 because the scope of the patents sought by appellants did not exceed bounds prohibited by the Supreme Court. He concluded the Plant Patent Act was passed, not because the patent laws previously precluded the patenting of live plants, but rather because the patent law requirement that every invention be described in writing needed to be relaxed so that plants could be patented.

Judge Miller dissented again. He did not agree with the majority that the *Flook* decision shed no light on these cases. He stated Section 101 should not be broadly construed *"where there is a basis for substantial doubt over the intent of Congress."*[100] (Emphasis in original.) Judge Miller considered such substantial doubt to exist regarding the patenting of life forms because of the passage of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. He expressed the opinion that "Congress did *not* intend that *any* organisms (which would include microorganisms), other than the plants covered by those Acts, be within the scope of 35 U.S.C. 101."[101] (Emphasis in original.) In Judge Miller's opinion, to say otherwise was to say that "Congress — not once, but thrice — enacted needless legislation."[102] The dissent also attacked the majority's view that the Plant Patent Act of 1930 was passed to overcome the written description requirement of the patent laws. It was Judge Miller's view that the act was passed in order to

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[98] *O'Reilly v. Morse,* 56 U.S. (15 How.) 61 (1853); *Le Roy v. Tatham,* 55 U.S. (14 How.) 156 (1852); *Tilghman v. Proctor,* 102 U.S. 707 (1880); *Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45 (1923); *Mackay Radio & Telegraph Co. v. Radio Corp. of America,* 306 U.S. 86 (1939); *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948).

[99] *In re Bergy, supra,* note 82, 596 F.2d at 997, 201 U.S.P.Q. (B.N.A.) at 391.

[100] *Id.,* 596 F.2d at 999, 201 U.S.P.Q. (B.N.A.) at 392.

[101] *Id.,* 596 F.2d at 999, 201 U.S.P.Q. (B.N.A.) at 393.

[102] *Id.,* 596 F.2d at 1000, 201 U.S.P.Q. (B.N.A.) at 393.

limit the types of plants which could be patented to particular kinds. He concluded the matter of patenting any organisms should be left to Congress. In so concluding, Judge Miller considered the issuance of the ten patents on organisms pointed out by the majority to be the result of administrative error and not to be the result of any consistent policy of granting patents on life forms.

Subsequent Proceedings

The CCPA decision in the combined *Bergy II* and *Chakrabarty II* cases was handed down on March 29, 1979. On July 27, 1979, the Acting Commissioner of Patents & Trademarks petitioned the Supreme Court for a writ of certiorari to present the question: "Whether a living organism is patentable subject matter under 35 U.S.C. 101."[103] Although the assignees of the applications of both Bergy and Chakrabarty filed briefs arguing against the writ, the Supreme Court granted certiorari on October 29, 1979.

Part IV

Potential Impact of the Decision – Applications to Genetic Engineering

The combined *Bergy* and *Chakrabarty* decision has profound implications in all fields of technology, particularly in the biological, chemical, pharmaceutical, medical, and agricultural arts. The biochemical arts are currently poised on the threshold of achievements of breathtaking scope. Basic discoveries in deciphering the genetic code of living organisms and the subsequent achievements in the field of genetic engineering[104] point towards ways in which researchers may create and manipulate life forms to perform functions which man has heretofore found impossible or extremely expensive. The current path which research is taking to exploit these achievements is the use of recombinant DNA techniques.

Recombinant DNA is the process by which segments of the DNA characteristic of one organism are removed or synthesized and "grafted" either onto the laboratory isolated DNA characteristic of another organism or onto the DNA of a living organism. The "cutting" and "grafting" tools are the restriction enzymes which have been found to break down or heal the DNA molecule at specific sites. By combin-

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[103] Petition for a Writ of Certiorari to the United States Court of Customs and Patent Appeals by the Acting Commissioner of Patents & Trademarks at 2.

[104] Cohen, "The Manipulation of Genes," 233 *Scientific American* 24 (July 1975).

ing the correct type of restriction enzymes in the correct order, the particular DNA segment of interest can be "cut." Transfer of the cut segment to the DNA of another organism may also be effected by a new technique through the use of plasmid vectors, virus-like entities which carry the subject genes into the host.[105]

There are a couple examples of experiments which display some areas in which practical applications of recombinant DNA techniques may be possible. One example is an experiment performed by a research team in the Department of Biochemistry and Biophysics at the University of California, San Francisco (hereinafter UCSF), in which the rat insulin gene was synthesized *in vitro* in bacterial plasmids.[106] The bacterial plasmids were then cloned, i.e., asexually reproduced, in order to manufacture relatively large quantities of the complementary DNA of the insulin gene. One purpose of this experiment was to investigate the possibility of the synthesis of insulin, the life-saving drug for diabetics, by bacteria.[107]

A second example involves a research team which manufactured somatostatin at the same laboratory. Somatostatin is a human brain hormone which helps to regulate the pituitary gland, the "master gland" that controls many body functions.[108] The research team manufactured a somatostatin-producing gene and transplanted it into a colony of bacteria, which made a quantity overnight equivalent to that obtained by grinding up nearly a half-million sheep brains.

Even more dramatic possibilities than these experiments may be hypothesized. For example, if the insulin-producing gene were to be grafted onto a microorganism which could survive the human body's

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[105] Wade, "Recombinant DNA: NIH Rules Broken in Insulin Gene Project," 197 *Science* 1342, 1343 (September 30, 1977).

[106] Ullrich et al., "Rat Insulin Genes: Construction of Plasmids Containing the Coding Sequences," 196 *Science* 1313 (June 17, 1977).

[107] Microorganisms such as the plasmid bacteria created by the UCSF research in this insulin gene experiment are basically different entities than the microorganisms claimed in *Bergy* but are similar to the microorganisms claimed in *Chakrabarty*. The *Bergy* microorganisms are purifications in that they are isolated from nature. While a biologically pure culture of the *Bergy* microorganism cannot exist in nature, the microorganisms themselves actually do exist in nature. However, microorganisms created by the techniques of genetic engineering, such as the bacterial plasmids of the UCSF experiment and those in the *Chakrabarty case,* are true "manufactures." They do not exist in nature. In fact, nature has built in natural barriers which normally prevent the exchange of genetic material from one microorganism to another.

[108] Cohn, "An Artificial Gene Makes Exact Copy of Brain Hormone," *The Washington Post,* November 3, 1977, at A9.

defensive immunity mechanisms such as the strain of E-coli bacteria which are found in the stomach and which aid in the digestion of food, a new microorganism could conceivably be introduced and localized at the proper place in a human suffering from diabetes, thus effecting a cure for the diabetic. One group of commentators[109] has suggested that genetic and cellular manipulations may produce the following achievements within 5-10 years: production of designed organisms for industrial and environmental processes such as waste degradation and synthesis of methane; production of plant cells with transplanted nitrogen-fixing capability; modification of the protein composition of food strains for cereal and cattle feed; gene transfer and cloning of agriculturally desirable crop strains; use of microorganisms, cell systems, fixed enzymes, and cell mutants to produce genes, hormones, pharmaceutical products, and foodstuffs in volume; and transplantation of genes into crop plant strains for antibiotic resistance to bacteria. Within 10-20 years, this same group of commentators hypothesizes that large-scale tissue and organ cultures may be modified for synthesis of transplantable parts, such as bones and pancreas into humans; synthetic "new animals" and "new plants," such as chloroplast-bearing yeasts, may be created; and mutant insect viruses functioning as pesticides may be manufactured. In short, the possibilities are mind-staggering.

Industry has already recognized the potential of recombinant DNA and is attempting to exploit it. For example, six major pharmaceutical companies, Hoffman-La Roche, Upjohn, Smith Kline and French, Eli Lilly, Merck, and Miles Laboratories, are actively engaged in studying recombinant DNA as a possible means of mass-producing rare drugs such as insulin.[110] Two smaller companies, Genentech and Cetus Corporation, have established relationships with microbiologists who pioneered genetic engineering techniques. Genentech is working with Herbert Boyer of the UCSF Department of Biochemistry and Biophysics, while Cetus has an arrangement with Stanley Cohen of the Stanford University School of Medicine.[111]

If the validity of patents on microorganisms are upheld, such patents will almost certainly prove to be extremely valuable. Under the umbrella of such protection, industry will be stimulated to apply these

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[109] Hoskins et al., "Application of Genetic and Cellular Manipulations to Agricultural and Industrial Problems," 27 *BioScience* 188 (March, 1977).

[110] Gwynne, "Caution, Gene Transplants," *Newsweek* at page 57, March 21, 1977.

[111] See Wade, *supra* note 105 at 197.

scientific discoveries for the benefit of mankind rather than go the trade secret route and guard them jealously, thus resulting in unnecessary duplicative work and the waste of inventive effort.

Part V

Patent Practice – Introduction

Now that the CCPA has reiterated that microorganisms *per se* are suitable subject matter for patent protection, the practitioner should not hesitate to submit claims directed to microorganisms which meet the standards of patentability, that is, where the microorganisms are useful,[112] novel,[113] and not obvious.[114] Such claims may be made in new patent applications, in patent applications which are currently pending in the U.S. Patent & Trademark Office by routine amendment,[115] and in issued patents which are less than two years old by applying for a reissue patent.[116] By these latter two methods, care should be taken to insure that an adequate description of the microorganism has been made in the originally filed application and that no new matter is added either by the amendment or by the reissue application.[117] Specifically, patent practitioners should not hesitate to include such claims out of fear that the entire patent will be declared invalid because *each* claim of a patent, whether in independent or dependent form, is presumed valid *independently* of the validity of other claims in the same patent.[118] Thus, even if all claims to microorganisms itself are invalid, all other claims in the patent are still presumed to be valid. Delay by the patent practitioner out of caution can only result in the loss of patent rights to which the inventor and any assignee are entitled.

Drafting the Application

In drafting the claims of the application it is advisable to follow, as closely as possible, the language of the claims which were allowed in *In re Bergy,* and in *In re Chakrabarty,* particularly in the present period in which such claims are unfamiliar to Examiners in the Patent &

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[112] 35 U.S.C. § 101.

[113] 35 U.S.C. § 102.

[114] 35 U.S.C. § 103.

[115] 35 U.S.C. § 132.

[116] 35 U.S.C. §§ 251, 252.

[117] 35 U.S.C. §§ 112, 132, 251.

[118] 35 U.S.C. § 282.

Trademark Office. For example, looking at claim 5 of the *Bergy* application, two points should be noted.

First, the *Bergy* claim included the language "A biologically pure culture of (the specific microorganism) . . ." This language enabled the CCPA to find that the claimed subject matter was a "manufacture" and not a "product of nature" since a biologically pure culture of the microorganism cannot exist in nature. Accordingly, it is advisable to include this or substantially similar language in a claim in order to insure that the passage of the application through the Patent & Trademark Office is smooth. Precedent for this type of claim is available to overcome an Examiner's rejection because of the *Bergy* case. Even though a patent practitioner may be of the opinion that this language is either unnecessary, excess verbiage, or mere semantics, it is still advisable to include it, since Examiners have been known to insist upon allowed formats, thus costing the patent practitioner undue time, effort, and expense.

Furthermore, such logic should also be extended to the *Chakrabarty* situation in which the microorganism is novel *per se,*[119] for example, where the applicant has produced a mutated microorganism by irradiation or chemical treatment. Thus, where the form of claim is as follows[120]:

> 2. The microorganism Streptomyces bifurcus, strain DS 23, 219 (NRRL 3539).

an applicant should consider using the form:

> 2. A biologically pure culture of the microorganism Streptomyces bifurcus, strain DS 23,219 (NRRL 3539).

Second, the claim in the *Bergy* application included the language "said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen, and inorganic substances." Such language is functional and does not limit the scope of the claim. Accordingly, the practitioner should not hesitate to incorporate it since it may also facilitate allowance of the claim by the Examiner.

In addition to claims directed to the novel microorganism *per se,* it is appropriate to include claims directed to the process of making the product of the microorganism. Such claims have been held to be prima

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[119] Wegner, "Patent Protection for Novel Microorganisms Useful for the Preparation of Known Products," *Int'l Rev. Indus. Prop. & Copyright L.* 285, at 290-291 (1974).

[120] *Id.* 285, at 190-291 (1974).

facie non-obvious in the *Mancy* case.[121] *Mancy* held that such processes were prima facie non-obvious even if the microorganism is a novel strain of a known organism which produces the product of the claimed process.

An applicant should also consider submitting product-by-process claims[122] directed to the product, i.e., the antibiotic, enzyme, hormone, etc., produced by the novel microorganism. This is a particularly useful claim where there is a possibility that the product may be manufactured abroad by a competitor, using the microorganism, and then imported into the United States. In this situation, a patent claiming only the microorganism would be ineffective in preventing importation of the product made by the microorganism. Accordingly, to gain the full measure of protection to which the applicant is entitled, process and product-by-process claims should be included.

In drafting the specification, applicants must comply with the requirement that "[t]he 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 . . . to make and use the same . . . ."[123] In applying this requirement to applications claiming novel microorganisms, the description in the specification must be drawn with great particularity and must include as much detail as possible regarding taxonomy, where and how the microorganism was discovered or produced, the laboratory methods by which the microorganism was isolated, cultivation of the microorganism, and any special characteristics either of the strain or its cultivation. Particular care should be exercised to include as much detail as possible, particularly until the Patent & Trademark Office gains more experience in handling applications claiming such microorganisms *per se*.

Deposit of the Microorganism

A deposit of the microorganism in a suitable depository must be made to satisfy the requirements of 35 U.S.C. 112. The deposit of a microorganism is required in applications in which the microorganism is not known and readily available to the public. An applicant must presume that, where an application claims a culture of a new microorganism, a deposit will be required by the Patent Examiner. The sufficiency of the deposit has been the subject of much controversy so

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[121] See note 23, *supra*.

[122] *Ex parte Hartmann*, 186 U.S.P.Q. (B.N.A.) 366 (Pat. Off. Bd. App. 1975).

[123] 35 U.S.C. 112.

the Patent & Trademark Office has consequently already established a procedure for the deposit of microorganisms. The procedure is set forth at 886 O.G. 683 (April 29, 1971) and in the Manual of Patent Examining Procedure (hereinafter MPEP) at Section 608.01(p). The procedure requires that a culture of the microorganism be placed in a depository affording permanence of the deposit and ready accessibility by the public upon grant of the patent. The culture must be made available during the pendency of the application to those entitled to access by the Commissioner of Patents & Trademarks. In determining who should have access, the Commissioner applies 35 U.S.C. 122 which requires that patent applications be held in confidence by the Patent & Trademark Office. The deposit must be made by the effective filing date of the U.S. application. This requirement means that, in order to obtain the right of priority from a previously filed foreign application, the deposit must be made as of the filing date of the previously filed foreign application.[124] Restrictions on access to the culture by the public must be irrevocably removed upon grant of the patent. Generally, these requirements are met by specific provisions in the contract between the applicant making the deposit and the depository. The contract should state that the culture is being deposited in connection with the filing of a patent application in the United States, should call attention to and require adherence to Rule 14[125] of the Patent & Trademark Office Rules of Practice, and should provide for permanent deposit and ready accessibility of the culture to the public if a patent issues. The depository may have an established procedure for receiving and maintaining deposits made in connection with the filing of a U.S. patent application and, consequently, may have a standard contract or letter agreement. An example of one such agreement is with the American

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[124] This expresses the Patent & Trademark Office guidelines set forth in M.P.E.P., Section 608.01(p). These guidelines do not necessarily have the force of law. There is some case law, such as *In re Fouche*, 439 F.2d 1237, 169 U.S.P.Q. (B.N.A.) 432 (C.C.P.A. 1971), *Feldman v. Aunstrup, infra*, note 128, and the concurring opinion of Judge Baldwin in *In re Argoudelis, infra* note 126, which would indicate that the deposit may be made at anytime prior to the issuance of the U.S. patent. However, there is no authority directly on point. Accordingly, applicants are cautioned to make the deposit before filing the priority application, whenever possible. Alternatively, applicants should not feel bound to accept the Patent & Trademark Office requirement where it proves to be impossible, or perhaps where it has been inadvertently not done. Nevertheless, applicants are cautioned that a court test may be necessary to establish the right to deviate from the Patent & Trademark Office guidelines if the requirement is not fulfilled.

[125] 37 C.F.R. § 1.14, sets forth the rules for preserving the secrecy of applications in accordance with 35 U.S.C. § 122.

Type Culture Collection (ATCC), located in Rockville, Maryland. To complete the deposit requirements, the application must identify the deposit by accession number, name and address of the depository, and must contain as complete a taxonomic description as is possible. The application must also aver, by oath or declaration, that the applicant has provided assurance of unlimited availability of the culture to the public through a depository "affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted" under the conditions satisfying the depository contract. The Patent & Trademark Office may require that a copy of the contract be submitted as evidence that the applicant has complied with these requirements, but the contract need not be submitted unless specific demand by the Patent & Trademark Office is made.

It is recommended practice in the filing of an application to make the oath or declaration of deposit together with the inventor's oath or declaration required by 35 U.S.C. 115 in order to insure that all the necessary formalities have been observed. If it is convenient, the oath or declaration of deposit should be incorporated in the body of the inventor's required oath or declaration accompanying the application, thus insuring that the formalities will be met as a routine matter. A separate oath or declaration is not defective, however. It should be noted that the proper party to make the oath or declaration regarding the deposit of the microorganism may be someone other than the inventor since, for example, the patent agent or attorney may be a proper party to the contract with the depository. Whoever assumes the responsibility to insure that the necessary conditions of deposit are met may be the proper party to execute such an oath or declaration. Of course, the determination of the proper party will depend on the structure of the organization in which the invention is made.

Using a Depository

The basis for the MPEP Section 608.01(p) guidelines is the case entitled *Application of Argoudelis*.[126] The applicants claimed the antibiotics sparsogenin and sparsogenin A, produced by the microorganism Streptomyces sparsogenes var. sparsogenes. The applicants had deposited, three months prior to the filing of the application, a culture of the microorganism in the culture collection of the U.S. Department of Agriculture depository located in Peoria, Illinois (NRRL). The applicants had imposed a secrecy requirement on the deposit, allowing access to the culture only by the Patent & Trademark Office. The

[126] 434 F.2d 1390, 168 U.S.P.Q. (B.N.A.) 99 (1970).

secrecy requirement was to be removed after issuance of the patent. The Patent & Trademark Office contended that the secrecy requirement rendered the application unavailable to the public, contrary to the requirements of 35 U.S.C. 112. The CCPA ruled against the Patent & Trademark Office position and held that the deposit satisfied the requirements of the statute, since the culture would be available to the public upon issuance of the patent.

The *Argoudelis* decision left several important questions unanswered, particularly for the foreign applicant. Could the deposit be made in a private depository which was not under the control of an agency of the U.S. government? More particularly, could the depository be located outside the United States?[127] These questions were answered in *Feldman v. Aunstrup.*[128] Feldman, the junior party in an interference in which both parties claimed the process of preparing a milk-coagulated enzyme using a laboratory-screened strain of the microorganism Mulchor miehi Cooney et Emerson, challenged the sufficiency of Aunstrup's deposit of the microorganism. The Aunstrup deposit had been made at the Centraalbureau voor Schimmelcultures (CBS), located in Baarn, Netherlands, fourteen days prior to Aunstrup's filing of a British provisional specification. Aunstrup's U.S. application, claiming priority of the British application, was filed eleven months later, within one year of the CBS deposit. Feldman, whose U.S. application was filed four months after Aunstrup's U.S. application, claimed that the CBS deposit was not adequate to satisfy the requirements of 35 U.S.C. 112 since CBS was a private depository which was not an agency of the U.S. government and was not located in the United States. The CCPA held that the Aunstrup deposit was adequate since the CBS was a depository of high standards and integrity which would insure the required permanence and ready accessibility to the public of the deposited culture. Accordingly, deposits of microorganisms in depositories of suitable high standards and integrity, whether such depositories are an agency of the U.S. government and whether such depositories are located within or outside the United States, may be used by applicants claiming novel microorganisms in U.S. applications.

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[127] Behr, "The Prescient Microbe Or Where to Deposit a Foreign Body," 57 J. Pat. Off. Soc'y 28 (1975).

[128] 517 F.2d 1351, 186 U.S.P.Q. (B.N.A.) 108 (C.C.P.A. 1975).

Patent Practice – Summary

The U.S. Court of Customs and Patent Appeals has held that patents may be obtained on microorganisms. Therefore, applicants should not hesitate to submit claims for microorganisms in new applications, to add claims to applications now on file, and to seek reissue patents claiming microorganisms on patents which are less than two years old. In applications directed to the *Bergy* type of microorganisms, it is advisable to claim biologically pure cultures and to include a functional description of the product of the cultivated microorganism in the claim. In all applications directed to any type of microorganism, the specification should include as much detail as possible regarding taxonomy, discovery or production, laboratory isolation, cultivation, and products of the microorganism. A deposit of the culture must be made in a suitable depository. The deposit should comply with the existing Patent & Trademark Office guidelines and may be made either in the United States or outside the United States in a depository of high quality and integrity.

Public Policy and Technological Risk

Kenneth T. Bogen

Abstract

Certain public policies, such as current federal radiation protection standards for the general public, accept various levels of technological risk. The criteria proposed in the literature on risk assesment and used by several agencies of the Federal government to justify the imposition of health risks upon the general public in accordance with acceptable risk policies will be reviewed and critiqued. Particularly, considerations of historically revealed risk preference, publicly (democratically) expressed risk preference, or economic cost-benefit analysis are shown to be insufficient to provide a basis for justifying the imposition of health risks upon the general public in a way that conforms to traditionally accepted mores of modern, common law nations whenever it is the case that such risks can reasonably be expected to result in definite injury or death. It is argued that this is true even when such risks can reasonably be expected to result in only a small, stochastically defined number of health effects within a much larger population exposed to the risks. Alternative, legitimate justifications for public risk acceptance policies are proposed which are based on (1) intent to reduce the net incidence of comparable health risks, (2) determinants of public necessity, and (3) the involvement of natural or traditional activities.

Public Policy and Technological Risk

Economic activity in the United States currently employs a number of technologies which impose health risks upon the general population. Automotive transport, jet transport, nuclear energy, chemical manufacture, and the use of certain fertilizers and pesticides are all examples of sources of technologically generated risk to life or limb which is or can be generally encountered by members of the popula-

tion. When a public policy is defined through laws or regulations controlling the use of a technology such that associated health risks to the public are limited, but not eliminated, government can be said to have adopted a policy which authorizes or embraces the risks associated with the regulated technology. Such public policy is, among other things, a policy of risk acceptance maintained by the government. Governmental risk acceptance decisions are of varying explicitness, refer to different types of risk, and are justified in various ways. This article will critique the criteria proposed in the literature on risk assessment and used by several agencies of the Federal government to justify the imposition of health risks in accordance with public policies of risk acceptance.

Types of Risk

In assessing risks and risk acceptance policies it is *important to distinguish between various types of risk.* There currently exists a substantial amount of literature in the field of risk assessment which addresses the problem of defining a useful taxonomy of risk types.[1]

For present purposes, *risks can be classified according to five basic characteristics: net importance, quality, probability, source, and target. The net importance of a risk is its subjective net magnitude,* i.e., the value that is placed on what is at risk. The phrase "at risk," of course, implies potential loss, damage, or destruction, and hence almost everything that is valued is constantly or is susceptible to being placed at risk. Note that by "net risk importance" only the ultimate subjective value of the actualized loss is being referred to. Net risk importance is thus to be distinguished from the overall significance or gross importance (the choice of words is admittedly arbitrary) of a given risk, the latter being a risk's net importance weighted by valuational factors associated with other characteristics and contexts of risk, to be described below. Often the net importance of risk is thought of in terms of the value of tangibles at risk, such as property, health, or

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[1] See Starr, Chauncey: "Social Benefit vs. Technological Risk," Science 165:1232-8 (1969); Starr, Chauncey: "Benefit-cost studies in sociotechnical systems," in National Academy of Sciences: *Perspectives on Risk-Benefit Decision Making,* pp. 17-42 (1972); Lowrance, W.W.: *Of Acceptable Risk* (Los Altos, Ca.: William Kaufman, 1976); Rowe, W.D.: *An Anatomy of Risk* (New York: John Wiley & Sons, 1977); Page, Talbot: "A generic view of toxic chemicals and similar risks," Ecology Law Quarterly 7:207-45 (1978); Slovic, P. and B. Fischoff: "How Safe is Safe Enough?: Determinants of Perceived and Acceptable Risk," in Gould, L. and C.A. Walker, eds.: Too Hot to Handle: *Social and Policy Issues in the Management of Radioactive Wastes* (New Haven: Yale University Press, *in press*).

life. But intangibles can also be placed at risk — a point neglected to a large extent by the risk assessment literature. The implementation of a new technology might have associated property and health risks, but it also may introduce risks to human freedom and dignity or, acknowledging behaviorist objections, to a valued sense of human freedom and dignity. Increased disregard for valued moral, cultural and political principles, attitudes, and traditions, as well as for valued symbols of these intangible values, can potentially have just as much individual or social disutility as increased rates of cancer.

The *quality* of a risk is a characteristic describing *how* something is at risk, as distinct from *what* is at risk. Typical distinctions in risk quality contrast whether a particular risk is incurred or expressed in a chronic or acute, personally controllable or personally uncontrollable (i.e., inevitable), isolated or multiple (catastrophic), immediate or delayed fashion.

The *probability* of a given risk with a given quality is, of course, necessary to be aware of in determining the gross importance of such a risk. A risk probability can be known to be nonexistent, low, or high, or it might fall within a range of values due to incomplete knowledge, or it might be known to be above zero but beyond that to be largely undefined.

The *source* of a risk refers to its mechanical etiology. Risks may be due to natural events, they may be entirely man-made, or their natural incidence may be enhanced by human activity or technology.

Finally, the *target* of a risk refers to those specific tangibles or intangibles that are threatened with loss, damage, or destruction. A risk target can be directly or indirectly threatened by a risk source. (Technology assessment is a form of policy analysis which attempts to predict risk targets whose vulnerability is, in many cases, the second or third order consequence of the action of a technological risk source.) Risk targets can be unknown, partially known, or exhaustively known, and, in addition, tangible risk targets can be known to be defined stochastically or by a particular distributive pattern.

Risks in Context

When analyzing the context of risk, of most concern is the subjective context with respect to persons bearing risk. Risks are, after all, threats to tangibles and intangibles held to be of *value* by people. Risk assessment should therefore properly describe and evaluate risks according to how the threatening context of threatened valuables affects a person's evaluation of a potential loss due to a given risk. One parameter of the subjective context of risk that has received

great attention in the literature on risk assessment is the degree to which a risk incurred is voluntary of involuntary. This contextual parameter might be described as the *teleological etiology* (to be distinguished from mechanical etiology) of risk, relating human purposes or intentions to the cause of a given risk. People can and often do purposefully subject themselves to a variety of risks that they are aware of. People are also subjected involuntarily to various risks. A risk can be involuntary due to a lack of awareness of the risk's existence on the part of the risk bearer, since one cannot be said to will that which one has no knowledge of, whether or not one *would* in fact will something if one *were* indeed to know of its existence. Involuntary risks can also be due to known natural hazards of the nonhuman, nontechnological environment to which a person is exposed. The inevitable health risks of the natural background level of ionizing radiation or of an approaching hurricane from which there is no escape are examples of the latter type of involuntary risk. Most germane to the assessment of justifications for risk acceptance policies are involuntary risks caused by human activity, either directly, or indirectly by means of an autonomous technology created by man. The context of involuntary, man-made risk can be further distinguished according to human purposes which may or may not be associated with such a risk context — a point greatly neglected by the risk assessment literature. An involuntary risk can be man-made and yet be entirely unassociated with human purposes (i.e., accidental, unintentional), such as the additional radiation risk borne by European miners during the 17th century who came into contact with elevated levels of radioactive radon gas, when ionizing radiation and its associated health risks were unknown. Man-made involuntary risks can, on the other hand, be directly associated with human purposes — purposes which can be benevolent with respect to the risk producer or others, malevolent with respect to the risk producer or others, disinterested with respect to the personal utility of the risk producer or others, or any combination of these attributes. The reason for drawing these teleological distinctions is that people can be expected to react differently to involuntary risk when different intentions are associated with risks imposed. Certainly, malevolently imposed risks will generate a far greater degree of reproach and hostility on the part of risk bearers and sympathetic observers than will unintentionally or benevolently imposed risks.

Related to the teleological etiology of risk, and particularly to the concept of "benevolently imposed risk" referred to above, is the notion of "the associated benefits of a particular risk." It is intuitive that

many risks are voluntarily borne with the expectation that enduring such risks will lead to the acquisition of benefits or positive reinforcements. Likewise, man-made risks which are borne involuntarily can be due to benevolence (benevolent, let us suppose here, with respect to the risk bearers) on the part of a risk imposer. But it is important to draw the distinction that the latter type of benevolent risk imposition can be either intentional or unintentional, depending on whether or not the risk imposer is aware of, knows about, or should reasonably expect that a particular risk to others will be generated as a result of particular benevolent (i.e., benefit-generating, or sincerely believed to be benefit-generating) activities engaged in. In the literature on risk assessment and social risk philosophy, statements like the following are sometimes made:

> When harm results [from a societally imposed risk], it is clearly unwanted and unintended. Risks and benefits are inseparable, not antithetical.[2]

From the considerations above it can be seen that the first part of the quoted statement is false whenever it is the case that risks are imposed *knowledgeably* (or in a way such that an impartial observer would be justified in claiming that the risk imposer should reasonably have known about or been able to foresee the risk-generating consequences of his activities). An imposed risk may be unwanted by a risk imposer, but clearly if the imposer is aware of the risk being imposed by an activity, then the voluntary pursuit of that activity implies that the resulting risk is intended. Of course, *both* benefits *and* risks can be intended at the same time by a knowledgeable risk imposer, as is the case with benevolent risk imposition when the risk imposer is knowledgeable of the risks being imposed, i.e., the case of *benevolently, intentionally imposed risks,* which shall hereafter be referred to as BENIM risks. (Bear in mind that risks are here being regarded as imposed or involuntary whenever they have not been knowledgeably embraced or consented to.) An example of BENIM risks would be the fallout risks imposed upon U.S. citizens from atmospheric atomic weapons tests carried out by the Department of Defense during the 1950s and early 1960s, since it can be assumed that these tests were sincerely believed to assist in providing U.S. citizens with a desirable component of national security. The increased chronic radiation risks allowed under the U.S. Federal Radiation

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[2] Maxey, M.M.: "Managing Low-Level Radioactive Wastes: Bioethical Concerns," in U.S. Environmental Protection Agency: "Low-Level Radioactive Waste Management, Proceedings of Health Physics Society Twelfth Midyear Topical Symposium, February 11-15, 1979," (EPA 520/3-79-002) 1979.

Council's 1960 Radiation Protection Guides (see ref. 4, *infra*) and under the U.S. Environmental Protection Agency's environmental standards for nuclear power operations (40 C.F.R. 190, effective 1 December 1979) are other examples of BENIM risks.

In considering the benefits associated with risks, the notion of *rationality* is often relevant. Rationality, it should be observed, is a concept that applies only to processes or means, not to ultimate goals or ends. The human goals of life, love, or happiness are given or built-in human attributes; they cannot be described as rational. Rationality (from the Latin *ratio,* meaning calculation, reason; akin to the Greek *arariskein,* meaning to fit) implies some form of calculation designed to optimally achieve some given goal. The voluntary assumption of known risks in order to achieve known benefits can be considered rational insofar as the probability of benefit acquisition offsets the probability of risk realization (i.e., the former probability is perceived in such a way as to induce the assumption of the latter probability). BENIM risks are, then, by definition, rationally imposed risks to the extent that the benefits outweigh the risks, as above, *in the mind of the risk imposer.* Rationally imposed BENIM risks might not seem rational at all to the risk bearers. BENIM risks will in fact be rational for both the risk imposer and the risk bearers only to the extent that the former and the latter have similar relevant goals or purposes which are similarly valued. To the extent that a number of people have similarly valued goals in common, it makes sense to generalize about "a reasonable person" in that group or about "rational behavior" for that group. In a pluralistic society such as the United States, generalizations about "the rational citizen" can only be made in specific contexts due to the presence of many dissimilar and even antithetical goals — political, economic, moral, and otherwise. When social realities in a democratic society necessitate a compromise between incompatible fundamental goals, the dictates of rationality cannot serve as a guide to the design of the compromise except insofar as even more fundamental goals are held in common by the disputants. Thus, when a political dispute arises over the definition of acceptable levels of governmentally authorized BENIM risks, recourse to arguments based on some "rational" perspective will not necessarily be useful in designing an appropriate solution.

The benefits associated with risk might be classified according to a taxonomy similar to the one proposed for risks. For instance, benefits can be classified according to their net importance in order to provide a basis of comparison between the benefits associated with a particular risk, e.g., a BENIM health risk that a government agency is

considering to allow on a population-wide basis. Okrent and Whipple have in fact proposed that for the purposes of regulating risk, the importance of associated benefits can be described according to whether they are (1) essential to society (e.g., food, water, energy at sufficient levels), (2) beneficial or advantageous to society (e.g., most manufacturing), or (3) not generally beneficial to society.[3] The context of benefits associated with risks is an especially important parameter in appraising public attitudes toward various risks they assume, particularly attitudes concerning the justification of BENIM risks incurred. In a society which values entrepreneurship governed by fair rules of free competition, sharp criticism can be expected from people bearing the brunt of BENIM risks whose associated benefits they (1) do not care for, (2) only marginally care for, or (3) are denied. In such situations the risk burden can be unfair, such that those who reap a given portion of the benefits do not incur a proportional amount of risk.

The last context of risk to be considered at this point is the degree to which a given risk is avoidable. Certain risks assumed can often be avoided, like participating in dangerous sporting activities. Of course, the rational person will avoid known risks that are avoidable to the extent that they do not provide compensatory benefits, when the costs of risk avoidance are taken into consideration. But many risks, both voluntarily and involuntarily incurred, are unavoidable. Unknown risks incurred are *ipso facto* unavoidable, as are many types of risk intrinsic to the environment and to human nature. Many risks are also unavoidable to the extent that benefits associated with them are considered necessary for the fulfillment of fundamental life goals, i.e., those akin to the highest order of benefits as outlined by Okrent and Whipple.

Acceptability of BENIM Risks

One basic guide to the design of acceptable levels of socially imposed risks that has frequently been used by policy makers is that of *"accepted" risks.* One class of comparable risks that has been attractive as a guide for acceptable risk criteria is the background rate of natural risks to which people are constantly subjected. For example, the natural background guide has been widely advocated for use in designing standards for acceptable levels of technologically enhanced ionizing radiation. The 170 mrem/yr limitation for average (non-

[3] Okrent, D. and C. Whipple: "An Approach to Risk Acceptance Criteria and Risk Management," University of California at Los Angeles (UCLA-ENG-7746) 1977.

medically) technologically enhanced radiation dose to the general population contained in the 1960 FRC Guides was based partly on the comparability of 170 mrem with the annual natural background level of exposure for the reason that "the farther we get from this level, the less confidence we have that any effects will be similar in kind and quantity to those that the population has experienced in the past."[4] A similar appeal to a natural background index is present in Maxey's recently suggested "bioethical principles for setting criteria and standards for radiation health protection," which contain the following provision:

> Any involuntary risks imposed by social policies for radiation protection must be congruent with, must not be in excess of, and may be reasonably less than, those involuntary risks imposed by the wide variations in naturally occurring toxic elements and harmful effects from our natural environment.[5]

Along the same lines is the suggestion an acceptable BENIM radiation risk level can be defined to be a risk of increased mortality or morbidity from malignant neoplasms which is within the limits of the statistical error of the index of mortality or morbidity from "spontaneous" neoplasms, used by Turkin, et al., to develop population standards for radiation releases from nuclear power plants in the

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[4] See Report of the Ad Hoc Committee of the National Committee on Radiation Protection and Measurements — May 6, 1959 (reprinted in *Science,* February 19, 1960), which states that "The committee recommends . . . that maximum permissible doses for the general population should be related to the average natural background level of radiation . . . . The farther we get from this level, the less confidence we have that any effects will be similar in kind and quantity to those the population has experienced in the past." Cf. also U.S. Federal Radiation Council: Minutes and Record of Actions (U.S. National Archives), 22 December 1959; containing Crow, J.F. (member NCRP subcommittee on Environmental Contamination by Radioactive Materials): "The Problem of Whole Population Radiation Protection Standards." A summary of Crow's presentation includes the following: " . . . a maximum permissible exposure cannot be an exposure below which there is virtually no hazard and above which there is appreciable hazard. . . . The soundest approach would appear to be to link radiation protection standards with factors above natural background since the human race has developed in a radiation environment of this level." Cf. also Federal Register, 18 May 1960, pp. 4402-3 ("Radiation Protection Guides"), and U.S. Federal Radiation Council: *Report No. 1: Background Material for the Development of Radiation Protection Standards,* 13 May 1960.

[5] *Supra* note 2.

Soviet Union.[6] With respect to technological risks in general, Starr has recommended that the risk of death from disease should serve as a "natural yardstick" with which to derive acceptable risk values, and has further suggested that a generally acceptable level of low-level or "negligible" risk should be equal to the average person's mortality risk from natural hazards such as earthquakes, floods, hurricanes, tornados, etc., calculated by Starr to be about 10^{-6}/yr.[7]

One problem with using a natural risk index to justify an acceptable level of technological risk is that the health risks from natural hazards like disease or floods are rarely, if ever, voluntarily accepted by people. In fact, it is often the case that people tolerate the existence of these risks by either ignoring them or by believing that *they* will never be victims, thereby eliminating cause for worry. Denying or ignoring a risk is not identical to accepting or embracing a risk. Natural hazards are never really accepted in the sense of *consenting to a discretionary imposition of risk,* for natural hazards are, by definition, never *imposed by choice,* they are rather inherent in nature. Natural risks therefore lack the human motivational context of known technological risks, rendering these two types of risk incommensurate for the purpose of extrapolating justifiable risk acceptance levels that might be used by a government regulatory agency seeking to define what, if any, technologically induced mortality or morbidity risks it ought to allow. Now, it may be argued that natural risks do have a human motivational context, not by human action, but by human omission. Since certain natural risks can be avoided by human intervention, it might be argued that all failures to intervene are just as much in need of justification as all impositions of BENIM risks in addition to the background of natural risks. This argument might go on to assert that to the extent that natural risks are not alleviated by, e.g., government, government may justifiably impose BENIM risks upon society at large. But this argument overlooks the point that government did not create natural risks (often referred to as acts of God) and therefore is not necessarily morally or legally responsible for their consequences, whereas government is necessarily responsible for the BENIM risks it imposed upon

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[6] Turkin, A.D., et al.: "Some Approaches to the Problem of Determining Standards for Population Irradiation Due to Radioactive Releases from Atomic Power Stations," (in Russian) presentation at the International Conference on Nuclear Power and Its Fuel Cycles, Salzburg, Austria, 2 May 1977; International Atomic Energy Agency (CONF-770505-111) 1977.

[7] Starr, *supra* note 1.

society since it is the author of these risks.[8] When government (or a person) has sufficient knowledge and power to easily control a natural risk to life, a moral responsibility to do so is generally assumed. But a BENIM risk *imposer* is always responsible for the consequences of risks imposed *regardless* of the ease with which the adverse consequences can be mitigated, given the decision to proceed with the risk imposition. A second problem, then, with using natural risk levels as an index for acceptable BENIM risk levels is that this index is irrelevant to considerations of justification, since BENIM risk imposers are responsible for their imposition but not for nature's hazards. Just because a population has historically been exposed to a certain level of natural risk, how does this justify the knowledgeable imposition upon that population of additional risks "similar in kind and quantity to those that the population has experienced in the past?" The approach of Turkin, et al., similarly begs the question of justification by assuming that all BENIM radiation risks are justified so long as their admitted impact is not perceivable on an epidemeological basis.

Another approach to basing acceptable risk levels on comparable normally incurred risks has focused on historically incurred technological risks. This approach considers the level of historically incurred technological risks to be a "revealed risk preference," in that this level indicates the degree of risk which society has tolerated in the past. An analysis of revealed risk preference in the United States by Starr was intended to address the question of how safe is safe enough regarding the imposition of technological risks in order to derive social benefits.[9] By relating historically revealed risks to some measure of associated benefits, Starr concluded that the acceptability of risk is approximately proportional to the third power of the asso-

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[8] Cf. *Vincent v. Lake Erie Transportation Co.*, 109 Minn. 456, 124 N.W. 221 (1910), wherein the Court held: "The situation was one in which the ordinary rules regulating property rights were supended by forces beyond human control, and if, without the direct intervention of some act by the one sought to be held liable, the property of another was injured, such injury must be attributed to the act of God, and not to the wrongful act of the person sought to be charged.... But here those in charge of the vessel deliberately and by their direct efforts held her in such a position that the damage to the dock resulted, and having thus preserved the ship at the expense of the dock, it seems to us that her owners are responsible to the dock owners to the extent of the injury inflicted." Using the reasoning of *Vincent,* it would follow that an agent imposing BENIM risks is legally and morally responsible for the consequences of those risks, and in so doing is so potentially guilty of, metaphorically speaking, saving the ship of social progress at the expense of the dock of human dignity.

[9] Starr (1969), *supra* note 1.

ciated benefits, and that the acceptability of voluntary risks has been about 1000 times greater than the acceptability of involuntary risks (see figure 1). Rowe has elaborated Starr's revealed risk preference methodology to derive an array of "risk conversion factors" which are intended to enable the calculation of acceptable levels of various risk types that government may justifiably impose in various contexts (see table 1).[10] Rowe observes that the "evaluation of anticipated risks [of governmental action] is relatively new in government and is practiced primarily in the regulatory agencies of the executive branch."[11] Government, Rowe contends, can efficiently and justifiably evaluate BENIM risks being considered for imposition by adopting the position that:

> Acceptable levels of risk for society can be obtained through examination of historic societal reactions to existing risks (when risks are known) as an external referent, and comparisons of new risks against existing societal behavior for similar risks by preestablished methodologies.[12]

Such a position, however, is subject to objections similar to those made regarding the use of natural risk indices for establishing criteria for acceptable levels of BENIM risks for society. Why should technological risks tolerated in the past serve to justify the imposition of current BENIM risks upon society? The revealed preference approach assumes that by trial and error society has arrived at some optimal balance between technological risks and their associated benefits. But, as Slovic and Fischhoff point out, in a world of changing values it is dubious to assume that past behavior is a valid indicator of present preferences, and that using this assumption is politically conservative in that it enshrines traditional economic and social arrangements.[13] And if, indeed, past preferences were a valid indicator of the present preferences of a majority of society, would this fact suffice to justify the BENIM imposition of risk upon society at levels similar to those historically incurred as a result of technology? To this question we now turn.

Besides comparable risk indices, guidance and justification for the imposition of BENIM risks upon society has been sought in current attitudes of the public regarding risk preference, i.e., in public perceptions of acceptable risk. This expressed risk preference approach

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[10] Rowe, *supra* note 1.

[11] *Id.* p. 55.

[12] *Id.* p. 432.

[13] Slovic and Fischhoff, *supra* note 1.

has had a growing appeal within the risk assessment literature and within government regulatory agencies, particularly with the growing popularity of "public participation" in regulatory processes. Advocating this approach, Slovic recommends that

> We need to develop a model of risk acceptance that would be useful to systems designers and policy makers. Such a model should not dictate what risks society should accept, but instead should reflect the public's considered values and preferences .... [Psychological research on the topic of perceived and acceptable risk] demonstrates that management of hazards needs to be based on an understanding of the ways in which people think about risk and uncertainty.[14]

Yet Slovic points out that perceived risk tends to be distorted by the imaginability and memorability of a given hazard, and thus that "we cannot assume that intelligent citizens have valid perceptions about the frequency of hazardous events to which they are exposed."[15] Similarly, Maxey notes a "need for correctives in public perception" because of the existence of "public misconceptions about safety."[16] These advocates of the expressed preference approach evidently qualify its validity upon the extent to which public perceptions are "distorted" or "irrational." But even assuming that public perceptions about various types of risk do accurately reflect their actual frequency and severity (or gross importance, as defined above), it still is not apparent why a given public risk preference should dictate and serve to justify the imposition of a corresponding level of risk upon society as a whole, which may include members who would not willingly subject themselves to the particular BENIM risk in question in order to attain the associated benefits desired by the majority. The expressed preference approach is predicated on the legal and ethical validity of democratically determined levels of acceptable BENIM risks to life and health. This assumption is not without sizeable problems, and it shall be the focus of attention after an investigation of a third basis upon which acceptable risk determinations have been made, that of cost-benefit analysis.

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[14] Slovic, P.: "The Psychology of Protective Behavior," *Journal of Safety Research* 10:58-68 (1978). See also Slovic, P., et al.: "Rating the Risks," *Environment* 21:14-39 (1979); and Slovic, P., et al.: "Images of Disaster: Perception and Acceptance of Risks from Nuclear Power," in Goodman, G., ed." *Impacts and Risks of Energy Strategies: Their analysis and role in management* (New York: Academic Press, *in press*).

[15] Slovic (1978), id.

[16] Maxey, M.M.: "Radwastes and Public Ethics: Issues and Imperatives," *Health Physics* 34:129-35 (1978).

Balancing costs and benefits has by far been the most popular and emphasized approach to making acceptable risk decisions in the context of public policies regarding technologically induced or enhanced risk to public health. Its popularity as a conceptual tool in approaching questions of public policy sprang from a dramatic development and refinement of cost-benefit analytic techniques in the field of economics following World War II. The economic tool of cost-benefit analysis has been growing in use within both the private business and governmental sectors of society, and within the latter context it is in vogue with the legislative, judiciary, and executive branches, including and especially government regulatory agencies.

The development of radiation protection philosophy, guides, and standards by the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), the FRC, and the EPA has been based on notions of balancing health costs with "compensatory benefits". This cost-benefit balancing approach has been controversial ever since it was first applied to the design of population-wide standards for technologically enhanced low-level ionizing radiation. This use of cost-benefit balancing continues to be both vigorously defended and vigorously opposed. Current proponents of the cost-benefit approach to justifying acceptable levels of risk from man-made radiation and from other sources of chronic technological risk use much the same reasoning as did the Federal Radiation Council when it provided its rational for its 1960 Guides, although this reasoning has been refined to some degree since then. Many members of the health physics community currently advocate the traditional ICRP and NCRP position that "the acceptance of risk should be evaluated in the context of offsetting benefits" in order to arrive at "objective" societal judgments about radiation risk acceptance.[17] The fact that such a position is controversial is certainly recognized by the health physics community, although the validity of objections may remain unrecognized. For example, Maxey, in addressing the Health Physics Society, recently maintained:

> The fact that our tools for balancing economic costs against risks to human life are not morally or ethically objectionable does not amount to saying that they are psychologically easy and acceptable to the general public. Far from it. The task of public education in this matter is monumental.[18]

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[17] See, e.g., Hull, A.P.: "Criteria for Risk Acceptance: A Health Physicist's View," research supported by the U.S. Energy Research and Development Administration, (NTIS document no. BNL-22363) 1977.

[18] *Supra* note 2, p. 406.

With respect to technological risk acceptability in general, Starr's incipient study on risk acceptability was intended to demonstrate a "means of providing the insight on social benefit relative to cost that is so necessary for judicious national decisions on new technological developments."[19] Expanding upon Starr's techniques, Rowe devised a methodology for fashioning societal risk acceptance decisions based upon the following initial premise:

> A major philosophical question with practical implications is: should risks and risk-causing activities be regulated, and, if so, when? To answer this double-pronged question, we must balance the costs and benefits.[20]

Okrent and Whipple have gone so far as to propose that acceptable mortality risk levels for the individual should be set at 1 to 2 x 10^{-4}/yr for "essential" technologies, 10^{-5}/yr for "beneficial" technologies, and 2 x 10^{-6}/yr for technologies not generally beneficial to society, all at a 90% confidence level of statistical accuracy.[21]

There are many problems, both theoretical and philosophical, with using some form of cost-benefit analysis, or rationales based on cost-benefit balancing, such as "as low as reasonably achievable" criteria, to justify acceptable risk levels for society.[22] An obvious problem lies in the definition of the "costs" and "benefits" that feed into this analytic process. Merely identifying the real, pecuniary, direct, indirect, tangible, and intangible costs and benefits resulting from the implementation of a given technology or technological change is difficult enough, let alone trying to rank the values of these costs and benefits. As was pointed out above in discussions on risk types and on rationality, the mere definition of the costs and benefits associated with a given BENIM risk is inextricably related to the goals, pur-

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[19] Starr (1969), *supra* note 1.

[20] Rowe, *supra* note 1, p. 58.

[21] *Supra* note 3. It is interesting to note that the acceptable risk scheme of Okrent and Whipple could only be an *ex post facto* standard in that it could only be used as a design criterion, rather than an enforcement criterion. Their scheme allows for no individual redress for technological transgressions, since, even if a particular case of "technogenic" mortality could be discerned from background mortality, it could never be discerned (1) whether or not a particular case was in the "allowable" fraction of an exceeded technogenic mortality rate, or (2) whether or not a particular case was statistically excluded from expectation at a 90% confidence level.

[22] For a general economic treatment of some of the theoretical problems with the use of cost-benefit analysis in environmental policy decision-making, see Mishan, E.H.: *Cost-Benefit Analysis* (New York: Praeger, 1971); Williams, A.: "Cost-Benefit Analysis: Bastard Science? and/or Insidious Poison in the Body Politick?" *Journal of Public Economics* 2:199-220 (1972); and Pearse, D.: "The Limits of Cost-Benefit Analysis as a Guide to Environmental Policy," *Kyklos* 29:97-112 (1976).

poses, and values of the risk imposers and risk bearers. In addition, the proper cost-risk-benefit assessment of a given BENIM risk imposed to obtain specified benefits hinges upon choices covering the entire range of competing and exclusive alternative means of obtaining those benefits. With respect to the assessment of policies concerning technological risks associated with energy production, Lovins concludes that cost-benefit analysis has no useful role in deriving energy policy for the reason that:

> Often the range of choices is too narrow because of promotional zeal or lack of imagination or understanding. This narrowness, more than a poor choice among artifically constrained alternatives, is a central problem of cost-benefit analysis.[23]

Even if it is assumed that the costs and benefits of a proposed BENIM risk are properly identified and appropriately valued, a further problem arises in that in order for the logic of cost-benefit balancing to be consistent for the purpose of justifying the proposed BENIM risk, it must be assumed that subsequent to the risk's imposition, the "offsetting" or "compensatory" benefits will *in fact* be used to mitigate or compensate for associated costs actually incurred. Thus, as Fischhoff points out, the proper use of cost-benefit analysis in designing and justifying acceptable risk levels must entail the identification of the risk victims and the appropriate transaction that must be carried out to compensate them.[24] In the case of chronic technological risks, the identification of risk victims is a major problem, since they are, by the nature and design of such risks, often only a small, statistically defined fraction of a background of victims of similar, competing risks to life or health. Some suggest that this problem is of no consequence if the number of "technogenic" health risk victims is close to or statistically indistinguishable from the background of similar natural or "historically accepted" technogenic health risks.[25] It has also been suggested that the problem can be avoided if compensatory benefits are distributed widely enough to reach all potential victims, for example, through a reduction in taxes or a contribution to a national health insurance plan.[26] While such a "risk credit" scheme might serve to induce a majority of citizens to voluntarily take on a number

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[23] Lovins, A.B.: "Cost-Risk-Benefit Assessments in Energy Policy," *The George Washington Law Review* 45:911-943 (1977).

[24] Fischhoff, B.: "Cost-Benefit Analysis and the Art of Motorcycle Maintenance," *Policy Sciences* 8:177-202 (1977).

[25] See, e.g., *supra* notes 2-4, 6, 8, and 12, and accompanying text.

[26] See, e.g., *supra* note 3.

of BENIM risks, it fails to address the original problem of *actually* compensating a risk victim for losses *actually* incurred. Suppose the gross value of 100 technogenic cancers were determined to be equal to $100 million, and that this known risk were proposed to be distributed over a population of one hundred million people. Assume further that $100 million and 100 technogenic cancers correspond to the equilibrium point between appropriately defined marginal social costs and benefits for the technological enterprise in question. Even if society were to distribute the total benefit of $100 million to all the potential risk victims in the form of reduced taxes or health insurance benefits, this would amount to only one dollar per person. Now, one dollar, or fifty, or one thousand dollars might induce the average "reasonable" person to take on a 10^{-4} risk of contracting cancer, but these sums could never compensate the *actual* cancer victims by the very same logic of the initial cost-benefit analysis!

It may be argued that in using cost-benefit calculus it is intended that social costs be compensated for by social benefits *at a social level.* For example, Polinsky argues that this reasoning provides a justifying rationale for using cost-benefit balancing to design acceptable risk levels since, in the long run and on the average, the victims of a particular technogenic risk will most likely be the beneficiaries of numerous life-improvements made possible by the existence of other technologies whose risks they did not become victims of.[27] This notion of trading reciprocal risks — the notion that the imposition of BENIM risks by society is fair because "they all balance out in the end" — has been described as follows:

> No one escapes either the risks or the benefits of all aspects of a society. Indeed, they are often implicitly traded between individuals. I live below the dam that provides you with hydroelectric power in the summer while you live near the nuclear power plant that provides me with electricity in the winter.[28]

Of course, justifying rationales based on this notion of implicit trading of reciprocal risks must assume that (1) the risks are indeed reciprocal, (2) the risks do in fact all balance out in the end, and (3) that along with the implicit trading there is implied or expressed consent. The "reciprocity" of risks is a function of both their type and their gross importance, and the latter may vary widely among individuals. What about multiple victims who just seem to have poor luck with

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[27] Polinsky, A.M.: "Probabilistic Compensation Criteria," *Quarterly Journal of Economics* 86:407-25 (1972).

[28] Fischhoff, B., et al.: "Weighing the Risks," *Environment* 21:4:17-20, 32-8 (1979).

technology? Is their suffering justified by the fact that for every one of them there is most likely one or a thousand people who never succumb to the hazards of technology? And what about those involuntary victims who, although receiving the benefits of a technology, would not, if given the choice, voluntarily take on either the risks or the benefits of that technology? Do involuntary benefits necessarily reveal implied consent to a risk-benefit transaction, thereby justifying the imposition of involuntary risk? To the extent that the answers to these questions are affirmative, they depend on the legal and ethical validity of involuntary risk imposition by majority rule.

There are other theoretical problems with the cost-benefit balancing approach to justifying acceptable levels of BENIM risk, such as the problem of discounting social costs over time and the problem of the valuation of costs and benefits to future generations, but almost all of these theoretical problems are subsumed by underlying philosophical problems concerning the notion of compensating for loss of life or health. The cost-benefit balancing approach assumes that for a given technological enterprise with associated BENIM risks, social utility can be maximized by balancing health costs with social benefits such that the incremental costs (decrease in social benefit) of achieving greater health protection are just balanced by the incremental value of that greater health protection. At such a point, economic theory would have it, society would be justified in implementing the technology along with the corresponding level of health risk. Such a position is predicated on the assumption that the impaired health and lost life due to a particular BENIM risk can be measured in economic terms which can serve as a basis for compensating the victims or potential victims of the risk imposed. The use of cost-benefit analysis in this fashion is intended to instill private market rationality into public sector decision-making regarding tradeoffs between public health and the maintenance and progress of a technologically based economy.

A clear philosophical difficulty in this analytic process lies in the determination of economic values for intangible costs such as those due to health risks. Confronting this problem with respect to radiation health risks, the National Academy of Sciences' BEIR committee concluded that placing a tangible value on human life is routinely done in our society, and hence that this is not a serious obstacle to the use of cost-benefit analysis in the design of population-wide standards

for low-level ionizing radiation.[29] In a similar context, Maxey observed:

> Evidently, the public has yet to comprehend the fact that safety is not an intrinsic property, measured by zero risks. It is a subjective, relativistic evolving, shifting judgment based on each person's current value-priorities.... A human life is of infinite value only in abstract theory or religious piety. If we are to avoid excessively costly and destructive policy decisions made by regulatory agencies, which are in conflict with the common good of the many, the public must be reeducated to reallocate the financial and social costs of safety.[30]

With respect to technological risks in general, Fishhoff also observes that a value of human life is a necessary input into cost-benefit analyses attempting to define and justify acceptable levels of BENIM risks, commenting that in this day and age, public familiarity with statistics is essential in order for society to learn how to make advantageous technological "gambles."[31]

Despite these and other expressions of the need for valuation of human life so that "rational" policy judgments can be made on the basis of cost-benefit analysis, the actual economic valuation of life has remained problematic. Economists have used several methods to value the loss of life or health in economic terms.[32] Most of these

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[29] See U.S. Environmental Protection Agency: "Consideration of Health Benefit-Cost Analysis for Activities Involving Radiation Exposure and Alternatives, "report of the Advisory Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences (EPA 520/4-77-003) 1977, pp. 26-8, 69-70, wherein it is stated that "At some low levels for any deleterious agent, the probabilities of effects may be so low that *society is willing to accept them and is justified in this acceptance if the effects are more than compensated by the associated benefits* of the activities that produce the agents.... The quantitative benefit-cost evaluation implies the willingness to accept a certain level of risk of death of injury in exchange for a sufficiently large benefit, biological or financial or other. This also implies a willingness to place tangible value on human life. Such judgments are routine in our society.... this concept... [of using] monetary values... does not imply insensitivity to the concept that individual life is priceless.... The evident fact that the risk perspective of an individual may differ from that of a social group creates a problem in a democratic political system.... Weighting factors should be applied to those terms [in cost-benefit equations used to determine acceptable levels of risk which may be undervalued by market place economics.... The values of the weighting factors used have to be established by society in general, whether through the political process, public survey, or other means." [Emphasis added.]

[30] *Supra* note 16.

[31] *Supra* note 24.

[32] See Mishan, E.J.: "Evaluation of Life and Limb: A Theoretical Approach," *Journal of Political Economy* 79:687-705 (1971).

methods revolve around deriving an "imputed value" or "shadow price" of life or health lost, i.e., a value in dollars ascertained by indirect means in order to reflect a true market price where no such price exists. Economists have long made these calculations in the context of deriving optimal business operation parameters (e.g., in the life insurance industry). Recently, with the growth of environmental economics, economists have begun to produce and apply these calculations in the context of public sector decision-making. One method used, called the "gross output" approach, estimates the loss of potential future earnings of a risk victim.[33] The "net output" approach would estimate the value of life or health lost to be the present discounted value of all economic losses over time accruing to others only as a result of death or injury. Implicit values of human life have also been derived from the calculation of social expenditures on public health, and from the amount that people are willing to pay for life or medical insurance. However, those considering these methods for use in risk acceptability determinations have generally recognized certain ethical problems, particularly the lack of input from potential victims into calculations based on these models. Advocates of the cost-benefit balancing approach have therefore generally recognized that some form of public participation is appropriate in order for this approach to properly justify acceptable BENIM risk levels. The BEIR II report, for example, concludes:

> In decisions that have a component that depends on human values, we propose the following: (i) The terms on both sides of the [cost-benefit balancing] equation be given a monetary value based on the market place, public survey or other appropriate means .... (ii) Weighting factors should be applied to those terms which may be undervalued by market place economics .... (iii) The values of the weighting factors have to be established by society in general, whether through the political process, public survey, or other means.[34]

Fischhoff has similarly advocated "democratic cost-benefit analysis" which would provide a formalized role for public input on value variables, perhaps under the auspices of a government cost-benefit oversight agency having multidisciplinary review panels and public defenders.[35] A poll of American attitudes toward health risk accep-

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[33] See, e.g., Ridker, R.G.: *Economic Costs of Air Pollution* (New York: Praeger, 1967).

[34] U.S. Environmental Protection Agency: "Considerations of Health Benefit-Cost Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives," report of the Advisory Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences (EPA 520/4-77-003) 1977, pp. 69-70.

[35] *Supra* note 24.

tance issues such as the valuation of human life has in fact been recently conducted by Etzioni, who concluded:

> Far from seeking a risk-free society, most favor a safer, cleaner, and healthier America — as long as the costs are not excessive and, above all, do not undermine economic progress.[36]

Etzioni goes on to advocate the use of democratic cost-benefit analysis in the context of risk acceptance decisions and the incorporation of explicit valuations of life in such analyses.

In pointing to the reasonableness of giving human life an economic valuation, or to the commonality of this procedure, or to its popular support, advocates of the cost-benefit balancing approach to acceptable risk problems have missed the point of certain objections to such valuation as part of a justifying rationale for the imposition of BENIM risks. What these advocates have failed to give due consideration are objections to BENIM risk imposition based not merely on an aversion to risks in general, but rather on an ethical judgment that certain types of risk *in certain human motivational contexts* are unequivocally opprobrious and unjustifiable. In placing a market value on human life, the cost-benefit balancer places life on the market, to be traded along with other commodities. As many of the advocates of the cost-benefit balancing approach have taken pains to point out, that life is on the market is neither anything new nor anything deserving opprobrium. Daily people buy insurance and get paid to take on risky jobs. However, the valuation of life in terms of BENIM risk-benefit balancing goes farther than merely placing life on the market, it perforce places *all* lives on the market — in effect, transforming life into currency or legal tender which society is of right free to collect, like taxes, in order to pay off its technological debts.

The arguments of those advocating and those oppugning the cost-benefit balancing approach for the reasons stated above are in fact based on two competing systems of political ethics which give rise to two concepts of value applicable to valuations made in the context of cost-benefit balancing. Pope has summarized these two concepts of value as follows:

> These two concepts of value — the individual and the social — represent two competing systems of political ethics. One goes back to John Locke. The purpose of government is to guarantee individual rights. Individuals own property, and exchange it freely in markets. These transactions are voluntary; buyer and seller must agree on a price. That price is the *value* of the good exchanged. One of the rights which is protected is the right not to sell, if agreement is not reached on a price. Society's concern is simply

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[36] Etzioni, A.: "How Much is Life Worth?" *Social Policy* 9:4-8 (1979).

> to make sure that the transactions are in fact voluntary .... The *social* concept of value in the United States derives from Jeremy Bentham and utilitarianism. Bentham was concerned not with maximizing individual rights, but with increasing the social good. Benthamites are thus concerned with the outcomes of transactions, as well as their voluntariness.[37]

According to the Lockean concept of value, the economic value of life or health possessed by a person is the minimum amount that person would be willing to sell the loss of life or health for. Of course, there may be people who would be unwilling to accept any price for a loss, or an increased risk of loss of life or health. Others may hold out for very high, in effect, monopolistic prices. Such positions should not be discounted as unreasonable or inconsistent with other market attitudes maintained by the same people. Increased health risks may in some situations have their selling price for some people, and indeed, they may have a legitimately defined shadow price for all people. But for some people the particular case of increased health risks due to intentionally imposed, involuntarily assumed risks (in the context of government policy, BENIM risks) may have no selling price, or, in effect, an infinite price. What is not given due consideration by the advocates of the cost-benefit balancing approach is that such an infinite selling price is not intended to represent the value of a health loss per se, but rather is intended to represent the value of not compromising the Lockean principle that an individual has a right not to sell. Thus, a cost that has traditionally been excluded from cost-benefit analyses regarding the justification of BENIM risks has been the cost of compromising a valued principle of political ethics.

The competing, Benthamite concept of value holds that the economic value of a health loss or risk of loss due to a BENIM risk is the maximum amount society (or, indirectly, an individual) would be willing to pay to avert such a loss or risk of loss. Advocates of the cost-benefit balancing approach adhere to this Benthamite concept of value, for it denies the opportunity for recalcitrant Lockeans to impede the imposition of BENIM risks. How is society to choose between these competing concepts of value so that acceptable risk policy decisions can be made? The advocates of democratic cost-benefit analysis would have the matter put to a vote or submitted to public scrutiny by means of an opinion survey.

Democratic allocation of technological risk has had a growing ap-

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[37] Pope, C.D.: "The Problem of Symmetry in Assessing Toxic Substance Risks: Bentham vs. Locke," paper presented at the Technical Information Project, Inc., conference on "Toxic Substances: Decisions and Values." Washington, D.C., 19-20 February 1979.

peal both in the literature on risk assessment and in the context of regulatory agency decision-making. The expressed preference approach to acceptable risk determinations is essentially the embodiment of democratic risk allocation. A key step in the cost-benefit balancing approach, the valuation of lost health or life, also requires democratic input according to many advocates of this approach. Central, then, to the acceptability of these two proposed approaches is whether or not the democratic allocation of technological risk is justifiable on the basis of political and legal principles which provide the fabric upon which our technological society has woven its history.

A democratically defined level of acceptable BENIM risk has intuitive appeal, for such an approach is in line with a time-honored principle of our society, that of democratic decision-making. However, the democratic approach systematically compromises another traditional value in our society, that of protecting minority rights. BENIM risks, such as technologically enhanced ionizing radiation, are increasingly being imposed by society in order to obtain moderate, population-wide benefits, such as nuclear generated electricity. The BENIM health risks are always quite low for any given individual. For example, the operation of the nuclear fuel cycle or the application of toxic pesticides on a national scale is expected to result in health risks to the individual on the order of 10^{-4}-10^{-6}. Many rational personal utility maximizers might take on such small, known risks in order to take advantage of the known benefits. This reasoning is in fact the basis of the position, maintained by advocates of democratic cost-benefit balancing, that the valuation of human life in the context of acceptable risk decisions is aproblematic. The cornerstone of this position is embodied in an economic study by Mishan in which the loss of life is surmized to be evaluable in economic terms when the loss occurs in the context of a Pareto improvement — a situation in which no people are made worse off and at least one person is made better off in an economic transaction. To get around the problem of the recalcitrant Lockean in the context of a democratic cost-benefit analysis, Mishan maintained:

> It is never the case, however, that a specific person, or a specific number of persons, can be designated in advance as being those who are certain to be killed if a particular project is undertaken. All that can be predicted, although with a high degree of confidence, is that out of a total of n members in the community an additional x members per annum will be killed (and, say, an additional ten x members will be seriously injured) .... And it is this fact of the complete ignorance of the identity of the potential victims that transforms the calculation. Assuming universal risk aversion, the relevant sums to be subtracted from the benefit side [of the democratically weighted cost-benefit equation] are no longer those which

> compensate a specific number of persons for their certain death but are those sums which compensate each person in the community for *the additional risk* to which he is to be exposed. [emphasis in original][38]

Mishan captures perfectly the situation created by chronic technological risk. He claims that in such a situation a Lockean system of value does not obtain, for no one exercises a right to market life, only a risk of its loss — and a small one at that. The Benthamite concept of value, Mishan implies, is the only one that is "reasonable" in such a situation. Democratic risk allocation will thus always lead to a Pareto improvement whenever projects undertaken are determined to bring about net benefits, given democratically weighted health costs. Mishan's conclusion is, of course, tautological, since the people involved are all assumed to be rational utility maximizers according to a Benthamite concept of utility. But this conclusion does reflect social reality in that a majority of people would, confronted with certain chronic technological risk options, perhaps not object to risk acceptance policy fashioned in accordance with a Benthamite value system. If the democratic determination of acceptable BENIM risk levels is enough to *justify* those levels of imposed risk, then it is of little consequence that some members of the community would rather behave "irrationally," or rationally according to a Lockean concept of value.

When *is* society justified, however, in refusing to recognize the recalcitrant Lockean? In accepting chronic technological risks society will generally face this problem, since, as Mishan points out, even though the marginal cost to the individual members of the society bearing an additional, BENIM risk will be an "insignificantly" increased risk of mortality or morbidity, the marginal social cost will with a high degree of certainty be a quite tangible increase in actual mortality or morbidity, albeit perhaps undetectable on an epidemiological basis. This situation, which will be referred to as the *marginal cost paradox,* will generally be a characteristic product of acceptable risk determinations based on a Benthamite concept of value. If a risk averse minority exists in society, and BENIM risks are imposed despite their objections, the possibility arises that the BENIM risks imposed might result in involuntary victims. Can society justify such a possibility?

Consider the following situation:

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[38] Mishan, *supra* note 32. Mishan's article is cited in, *inter alia,* the BEIR II report, *supra* note 34.

> *RANDOM JETTISON:* There are three men stranded in a lifeboat at sea. Chances for rescue or encounter with land are unknown. One week has gone by and the remaining food supply is low. Rather than risk the chance that all three might starve within another week's time, two propose that one of the group be eliminated by means of a random selection process. Over the coming days, it is proposed, the person to be jettisoned will be determined by rolling a die twice every hour. Each man, at the outset, is to choose one out of the six numbers on the die; if, after any pair of throws, a man's number comes up twice, he is to be jettisoned. The advocates of this plan stress that, if carried out faithfully, their plan ensures that the identity of the potential victim of the BENIM risk of jettison will never be known in advance. Further, each man would only have a probability of 1/36 of being jettisoned at each rolling, the probability that *any* man would be jettisoned at each rolling would be only 1/12, and no matter how many rollings take place, it would by no means be *absolutely certain* that any man's number would ever come up twice at any one rolling, and hence that any man would ever be jettisoned. The two advocates meet with the dissent of the third man, who maintains that while the suggested process seems fair, it is immoral, and that no one has the right to impose such a plan on people who do not consent, or indeed, whether or not people consent. A vote is taken, and the plan is implemented. It so happens that the dissenter's (assigned) number comes up twice upon the first rolling, and he is jettisoned.

Was the majority in this case justified in implementing their random jettison plan? Clearly, one human jettison was in the interest of the general welfare of the majority as defined by the majority, viz., a decrease in the likelihood of human starvation. But if the jettison victim had been involuntarily selected by means of a nonrandom process, such as by virtue of the fact that the victim was disliked by or weaker than the other two men, the jettison would appear to be immoral and unjust.[39] Does the mere fact of randomness and the lack of absolute certainty of jettison make the actual jettison in the case above any less unjust? Regarding the issue of certainty, while it is true that in the random jettison case each pair of rolls produced only a 1/36 chance of mortality for each of the three men, after seven days of faithful rolling there would be a probability *greater* than 99% that one of the men would have been jettisoned. Thus, the marginal cost paradox holds for this case. Is randomness, then, to be the key to

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[39] Cf. *United States v. Holmes*, 26 F. Cas. (No. 15,383) (C.C.E.C. Pa. 1842), and *Regina v. Dudley and Stephans*, 14 Q.B.D. 273 (1884). In the former case, the defendant was a crew member on a passenger boat transporting Irish immigrants to the United States. The boat hit an iceberg, and survivors escaped to two small, overloaded lifeboats. With little chance of rescue foreseen, the defendant instigated the "human jettison" of 14 of the immigrants and subsequently was convicted of manslaughter on that account. In *Regina* the defendants and a youth were cast away in a small boat with practically no food and little hope of rescue. Both defendants killed the youth and lived on his body until saved some days thereafter; subsequently, the defendants were convicted of murdering the youth.

justifying a democratically decided policy of random jettison? A policy of random enslavement of a minority of society would certainly be no more acceptable in our society today than a policy of discriminatory enslavement, and there is no reason why homicide should be considered any less reprehensible a deprivation of liberty than enslavement.

The 1960 FRC Radiation Protection Guides and the random jettison case described above have in common the fact that they both involve the imposition of the same type of risk: a BENIM risk. In the former case the BENIM risk is a chronic technological risk, whereas in the latter case the risk is due to purely human activity. But in both cases the risks have associated net benefits according to a Benthamite concept of value. Why is the random jettison case so evidently morally suspect, whereas the 1960 FRC Guides appear to be perfectly acceptable to many people? The quantity of risk imposed provides the distinguishing characteristic of the two cases that renders the one politically acceptable and the other politically unacceptable within the context of democratic policy formulation. In the random jettison case, the votes case in favor of the policy of BENIM risk imposition carried with them an acceptance of improbable individual harm and a probable social cost of the mortality of one third of the population at risk. Votes that might be cast in favor of the 1960 FRC Guides, however, would carry with them an acceptance of improbable individual harm and a probable social cost of approximately one one hundred-thousandth of the population at risk. Is such a quantitative difference sufficient to justify a qualitative difference in the way such policies should be morally judged? The advocates of democratic risk allocation would have it so. Certainly, such reasoning leads one to conclude, the random jettison case cited appears to involve immoral activity, but the policy implemented becomes perfectly moral, completely justified, in fact, exemplary of policy analysis that recognizes the modern imperative for society to take gambles in order to maximize its utility, merely by increasing the size of the lifeboat and the number of its occupants. Such a position is a forgery of morality, for it preys upon the human propensity to lose touch, in contexts involving large numbers of people, with the root of moral sentiment: the human capacity to empathize or commiserate with fellow human beings, and the corresponding capacity to feel guilty upon cause of human suffering. The majoritarian or unanimous democratic acceptability of BENIM technological risks can thus be due to the dehumanization of numbers, which cannot rightfully serve as a justifying rationale for the imposition of such risks. If one homicide out of one is considered morally reprehensible, then one

similar homocide out of 200 million can be no less morally reprehensible without opening the door to condoning a form of moral reasoning devoid of consistency, inescapably arbitrary, and callous toward the human sentiments in respect of which flows its purpose.

BENIM risk acceptance policies must be assessed within a legal, as well as moral context, for ultimately it is the law which provides an operational definition for the justifiability of government action. But the law is not exclusive of judgment in the determination of justice. Whether or not a justifying rationale provided by a regulatory agency for a risk acceptance policy meets a legal standard of justice depends on the validity or appropriateness of judgments regarding the relative importance of relevant legal principles. It is a recognized common law principle that "every person has a right to complete immunity of his person from physical interference of others, except insofar as contact may be [in the spirit of pleasantry or] necessary under the general doctrine of privilege," regardless of whether such interference if motivated by benevolent intentions.[40] Under what circumstances, however, is government privileged to adopt risk acceptance policies that authorize or result in intentional homocide or assault?

Fletcher has observed that two paradigms of liability have obtained in tort theory: one based on a doctrine of fairness and the other based on a doctrine of utility.[41] The more traditional paradigm, based on the fairness doctrine, grows out of the concept of reciprocity of risk as a determinant of whether a risk victim is entitled to recover and whether a risk imposer ought to pay damages. The more recently used paradigm grows instead out of a Benthamite concept of reasonableness as a determinant of social utility maximization. Fletcher argues that the paradigm of reasonableness is inadequate as a test for justifying the creation of (BENIM) risks, and that the more sound paradigm of reciprocity should be maintained, even though society is increasingly incurring technological risks of various kinds. To accomplish his recommendation, Fletcher suggests that:

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[40] *Mohr v. Williams,* 95 Minn. 261, 104 N.W. 12 (1905). This case involved a doctor who performed ear surgery on an unconscious patient. The patient had consented to surgery on one ear, but during surgery the doctor recognized a problematic condition in the other ear, and this ear was operated on as well. Upon suit for punative damages for an intentional (BENIM) tort, the doctor was held liable for assault and battery on grounds that there existed no expressed or implied consent to surgery on the second ear.

[41] Fletcher, G.P.: "Fairness and Utility in Tort Theory," *Harvard Law Review* 85:537-73 (1972).

> By providing compensation for injuries exacted in the public interest, the tort system can protect individual autonomy by taxing, but not prohibiting, [risky] socially useful activities.[42]

But with respect to chronic technological risks, Fletcher's proposal is contradictory on two grounds. First, it is impossible to make whole or compensate a victim who cannot be identified individually. Second, "individual autonomy" presupposes individual (healthy) existence, the loss of which cannot be compensated for in a way which maintains the automony of the involuntary risk victim. In denying the legal possibility of enjoying BENIM risks *solely* because society deems them useful, Fletcher's proposal is in essence no different from one based on the paradigm of reasonableness which he seeks to replace. To be true to the doctrine of fairness, if the *ex post facto* claim is justified that recovery is entitled because a risk was wrongfully imposed which, with a high degree of certainty, was forseen to cause injury, then this must give rise to the validity of the *ex ante* equitable claim that, given such a situation, an injunction against the imposition of such risk is entitled. However, the question of when a risk is wrongfully imposed is equivalent to the question of when the imposition of a risk is excusable under the doctrine of privilege. The answers to these questions are ultimately determined by the concept of justice that is employed.

In his treatise on justice, Rawls prefaces the development of his theory of justice as fairness with the assertion that "in a just society the basic liberties are taken for granted and the rights secured by justice are not subject to political bargaining or to the calculus of social interests."[43] The nature of basic liberties in our society is addressed by Dworkin as follows:

> The Constitution, and particularly the Bill of Rights, is designed to protect individual citizens and groups against certain decisions that a majority of citizens might want to make, even when that majority acts in what it takes to be the general or common interest. . . . Of course, a responsible government must be ready to justify everything it does, particularly when it limits the liberty of its citizens. But normally it is a sufficient justification, even for an act that limits liberty, that the act is calculated to increase what the philosophers call general utility — that it is calculated to produce more overall benefit than harm. . . . When individual citizens are said to have rights against the Government, however, . . . that must mean

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[42] Id. Cf. the similar proposal presented in Katz, M.: "The Function of Tort Liability in Technology Assessment," *U. Cincinnati Law Review* 38:587-662 (1969).

[43] Rawls, J.: *A Theory of Justice* (Cambridge: Harvard University Press, 1971) p. 28.

> that this sort of justification is not enough. Otherwise the claim would not argue that individuals have special protection against the law when their rights are in play, and that is just the point of the claim."[44]

Do citizens in the United States have rights *against* their government, as Dworkin suggests? Article I, Section 8 of the Constitution provides that "The Congress shall have the Power To . . . provide for the common Defense and general Welfare of the United States . . . And To make all Laws which shall be *necessary and proper* for carrying into Execution the foregoing Powers . . ." The Fifth Amendment goes on to delimit the propriety of governmental action by stipulating that "No person shall . . . be deprived of life, liberty, or property, without due process of law, nor shall private property be taken for public use, withouth just compensation." Note that the Constitution does not state that life *should not* be deprived, or that life shall not be deprived without just compensation. The Framers of the Bill of Rights were, of political necessity, quite specific and quite deliberate in specifying *absolute* limitations on governmental power.[45] At the time, American colonials were sensitive to arbitrary abuses of governmental power and they made wide use of the rhetoric of "the rights of Englishmen" and "natural rights"; thus, "It was the philosophy of Locke ('constitutionalized natural law,' . . .) rather than that of Bentham that prevailed on this side of the water."[46] The phrase "without due process of law" in the Fifth Amendment had its roots in the phrase "per legem terrae" ("by the law of the land") in the Magna Carta, whereby King John agreed in 1215 to feudal rights insisted upon by the barrons of Runnymede. In chapter 39 of that charter, King John promised:

> No free man shall be taken or imprisoned or disseized or outlawed or exiled or in any way ruined, nor will we go send against him, except by the lawful judgment of his peers or by the law of the land.

In the 1354 reissue of the Magna Carta under Edward III, the original promise was restated (28, chapt. 3):

> No man of what state or condition he be, shall be out of his lands or tenements, nor taken, nor imprisoned, nor disinherited, nor put to death, without he be brought to answer by due process of law.

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[44] Dworkin, R.: *Taking Rights Seriously* (Cambridge: Harvard University Press, 1977) pp. 133, 191.

[45] See Brant, I.: *The Bill of Rights: Its Origin and Meaning* (New York: Bobbs-Merrill, 1965).

[46] Pennock, J.R. and J.W. Chapman, eds.: *Due Process* (New York: New York University Press, 1977) p. xvff.

Some centuries later the common law of England was analyzed by the famed commentator, Blackstone, who was read by and was very influential upon the Framers of the Constitution of the Bill of Rights. In Blackstone's *Commentaries* he describes three "absolute rights of individuals" for the protection of which the State's existence is justified. "These rights," comments Blackstone, "consist in . . . that *residuum* of natural liberty, which is not required by the laws of society to be sacrificed to public convenience . . ."[47] The first of these rights, according to Blackstone, is:

> The right of personal security [which] consists in a person's legal and uninterrupted enjoyment of his life, his limbs, his body, his health, and his reputation.[48]

Blackstone asserts further that this first right includes the "preservation of a man's health from such practices as may prejudice or annoy it," and that "no suitable atonement can be made for the loss of life or limb."[49] This, then, is the jurisprudential heritage in light of which the due process clause of the Fifth Amendment must be interpreted. It is a quite uncompromising heritage, and one which supports the claim that, indeed, the Constitution does guarantee rights *against* the government.

The imposition of new BENIM risks through government policy, in light of the accepted legal principles reviewed, cannot be justified solely by virtue of public convenience, democratic decision, or reference to natural or historically incurred levels of risk. Judicial decisions in the United States give support to the contention that BENIM health risks due to technology do indeed give rise to standing to sue for injunctive relief. In granting injunctive relief against prospective mining operations that threatened to destabilize a cliff overhanging a section of railway, the 6th Circuit Court of Appeals held that:

> It may be that . . . disaster could occur only upon concatenation of circumstances of not too great probability . . . It is common experience, however, that catastrophies occur at unexpected times and in unforseen places . . . . A court of equity will not gamble with human life, at whatever odds, and for the loss of life there is no remedy that is in an equitable sense adequate.[50]

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[47] Blackstone, Sir William: *Commentaries on the Laws of England* (Philadelphia: W.B. Young & A. Small, 1803) pp. 128-9.

[48] Id., p. 129

[49] Id., pp. 134, 130.

[50] *Harris Stanley Coal & Land Co. v. Chesapeake and O. Ry.*, 154 F.2d 450, 453 (6th Cir.), cert. denied, 329 U.S. 761 (1946). Cf. Also *Stevens v. Rockport Granite Co.*, 216 Mass. 486, 104 N.E. 371 (1914); and *Smith v. Staco Milling Co.*, 18 F.2d 736 (2d Cir.) 1927.

More recently, in *Reserve Mining Co. v. Environmental Protection Agency* (1975) an injunction was sought ordering the Reserve Mining Co. to cease discharging potentially carcinogenic taconite tailings from its iron ore processing plant in Silver Bay, Minn., into the ambient air of Silver Bay and the waters of Lake Superior. The court held in this case:

> The public's exposure to asbestos fibers in air and water creates some health risk. Such a contaminant should be removed .... the existence of this risk to the public justifies an injunctive decree requiring abatement of the health hazard on reasonable terms as a precautionary and preventative measure to protect public health.[51]

Even more recently it was recognized by the U.S. Supreme Court that

> ... the emission of nonnatural radiation into appellees' environment would also seem a direct and present injury, given our generalized concern about exposure to radiation and the apprehension flowing from the uncertainty about health effects and genetic consequences of even small emissions like those concededly emitted by nuclear power plants.[52]

These judicial findings are inconsistent with the view that society has the right to impose marginal detriment upon its members without showing of just cause or excuse. Surely, regulatory agencies responsible for controlling technology and protecting human health and the environment must justify the restrictions of liberty which they impose upon citizens. Surely, the legitimate design of "acceptable" levels of technological risk need not be justified in ways which offend the legal rights, the proper expectations, and the moral sensitivities of citizens. And surely, justifying rationales for legitimate BENIM risks can be fashioned in a way which upholds the principles of justice which our nation strives to protect and implement.

Toward Technological Responsibility

The power of modern technology necessitates responsibility in its use. This responsibility, in the context of regulating technology, must include the requirement for government to provide a legitimate justification for every instance in which it knowledgeably authorizes or effects the deprivation of liberty or of the life and health upon which liberty is predicated. To the extent that authorized levels of technological risk imposed upon the general population can reasonably be

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[51] 514 F.2d 492, (8th Cir.) 1975.

[52] *Duke Power Co. v. Carolina Environmental Study Group,* 438 U.S. 59, 74 (1978). Original appellees' standing to sue was upheld, but the original suit, based on the claim that the Price-Anderson Act limiting liability of licensed private nuclear power plant owners for nuclear accidents is unconstitutional, was dismissed.

expected to result in the inevitable loss of life or health, such risk imposition must also be legitimately justified. This responsibility of government is required not merely to pander to mistrust of technology, obsessive preoccupation with risk, or vain emotionalism on the part of the public. It rather is an *obligation,* flowing from the nature and context of the risks imposed. In his book, *An Anatomy of Risk,* Rowe maintains that "Certain kinds of risk consequence have the potential to be valued emotionally rather than rationally."[53] The people who emotionally object ("squawks," as Rowe refers to them) to having their lives or health intentionally placed at risk are not necessarily behaving in an unreasonable or unwarranted fashion. On the contrary, in the context of unjustified or improperly justified BENIM risks, such "irrational emotionalism" is called for for the very reason that the principles of justice and political ethics at stake are fundamentally irrational and emotional.

In his 1620 treatise on the new method of inductive scientific reasoning, Francis Bacon observed that "Human knowledge and human power meet in one; for where the cause is not known the effect cannot be produced."[54] Moral responsibility is generated by the power of modern technology insofar as knowledge about the effects of technology on people exists of should reasonably be available. Technological risks are BENIM risks to the extent that risk imposers are or should reasonably be aware of risks being imposed. The moral and legal responsibility generated by BENIM risks is that of ensuring that the imposition of such risks is justified. However, in the literature on risk assessment, arguments are often made suggesting that the type of knowledge that predicates the existence of a BENIM risk is indistinguishable from knowledge regarding *ex post facto* probabilities of injury occurrence, and that therefore all technological risks are tantamount to probabilities of accidental injury, from which it is improper to derive *ex ante* moral obligations. Such an argument, for example, would claim that for the same reason that government is not obligated to revoke all aircraft operating licenses or to adhere to stringent grounds for justifying the issuance of these licenses merely because an average of X number of people on the ground throughout the country are killed per year due to the crashing of those licensed aircraft, the government is similarly without obligation regarding licenses for nuclear fuel cycle operations, despite the fact that an av-

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[53] Rowe, W.D.: *An Anatomy of Risk* (New York: John Wiley & Sons, 1977) p. 63.

[54] Bacon, F.: *The New Organon,* I:III (1620), in Spedding, J. et al., eds." *The Works,* vol. VIII (Boston, Taggard & Thompson, 1863) p. 39.

erage of X number of people per year throughout the country would be expected to contract cancer due to the planned release of radioactive materials into the environment associated with these operations allowable under 40 C.F.R. 190. But such an argument is fallacious, for it fails to recognize the special quality of the type of knowledge that predicates a BENIM risk in need of justification, which is that *ex ante* knowledge or reasonable availability of knowledge which (1) is able to establish intent or negligence on the part of the risk imposer, and (2) is able to establish that the presence of the risk imposed can indeed be reasonably expected to result in actual injury or death. Thus, BENIM risks in need of justification are, in actuality, BENIM health *costs* rather than merely BENIM health *risks*. Chronic technological risks authorized by government have been defined as those BENIM risks which *are* in need of justification because of the fact that the individual risks they impose do, when summated over the exposed population, satisfy both the first and second criteria stated above. The risk of airplane crashes, on the other hand, does not, in general, satisfy these criteria. Airplanes are not manufactured or flown with the intent that some of them will crash. Airplane crashes, and many other types of catastrophic technological risk, are most often accidental, as opposed to being "inevitable."

An understanding of the difference between the concept of "accidental" and the concept of "inevitable," as these concepts are applied to the expression of technological risks, is essential to understanding the nature of BENIM technological risks in need of justification. At the root of this difference is knowledge or the reasonable availability of knowledge. That plane and automobile crashes annually kill an average of X number of "innocent bystanders" (those who have not explicitly or implicitly consented to being subjected to the risk in question) does not establish that those deaths are the "inevitable" result of the use of the technologies in question, for "inevitability" must here be viewed in the context of (1) available knowledge regarding the technologies, (2) those aspects of human nature involved with the use of those technologies, and (3) certain reasonable standards of human conduct.

Regarding knowledge of technological hazards, it is true that failures can occur in any technological system and that these failures can result in injury or death. In trucking liquified gas, for instance, it is possible that a brand new tire can blow out for no apparent reason, causing a highway accident resulting in numerous deaths. The law regards the operation of potentially dangerous technologies, such as the trucking of liquified gas, as "abnormally dangerous activities" for

the results of which the performers of such activities are held strictly liable. But the law of equity does not grant the right for a person living along a highway (or for society in general, by a class action) to obtain an injunction against the passage of a liquified gas truck along the adjacent highway solely on grounds that such a truck might have a mechanical failure and run into the home of this person, given the fact that a few such accidents happen annually. Mechanical failures often occur, but where they are not reasonably expected, society allows the use of technology to go unhindered. Reasonable expectation should be thought of as being based upon a theory of causality sufficiently persuasive, in light of relevant evidence, to engender a conviction to act according to the expectation produced by the theory. Catastrophic events often involve the occurrence of a discontinuity in the action of a physical system that does not lend itself to prediction according to some causal model. When a particular catastrophic failure occurs with enough regularity to give rise to a convincing causal model for that failure (or grounds for believing that a convincing causal model *could* be developed), then for this case there can be said to exist the *ex ante* knowledge sufficient to generate the moral responsibility to provide for or avoid that failure. But causal models constituting the *ex ante* knowledge called reasonable expectation are lacking for most types of catastrophic technological failure, as implied by the word "catastrophe" (the Greek word for the downward turn of events that the Fates inflict upon the hero of a tragedy). Reasonable expectation is, however, present (by definition) in the case of chronic technological risk, and for this reason it is inappropriate to project onto this type of risk the rules governing injunctions against the execution of "abnormally dangerous activities," as these rules have been traditionally defined in the courts.

The growth of *ex ante* knowledge of or reasonable expectation of technologically induced harm implies, then, the growth of moral responsibility concerning such harm, including the moral obligation not to inflict or further it unjustifiably. This view is dissimilar to the one, implicitly advocated in the literature on risk assessment, that the growth of *ex ante* knowledge has reached the point where we should redefine our morals so that we can proceed or continue to kill people in formerly unjustifiable ways without feeling guilty about it. The former position recognizes that adherence to it may ensure that technological society shall become a much more costly and difficult enterprise, but it also recognizes that the latter position entails equal if not greater costs by opening the door to the promotion of inhumane

attitudes capable of ramifying in regrettable ways.[55] A correlate of the knowledge-begets-responsibility position advocated herein is that the harbingers of new technology have the responsibility to know about and recognize ignorance of associated hazards to the greatest extent feasible, lest ignorance become an excuse for the improper justification of technological hazards.[56] This correlate is implied by the notion of "reasonable availability of knowledge" referred to above.

It is clear that knowledge of those aspects of human nature involved in the use of technologies and some reasonable standards of human conduct must also figure in to the concept of "inevitability" as it applies to technological risks in need of justification. It is, for example, common *ex ante* knowledge that people can at times be expected to sneeze, and therefore if any proposed technology which must be operated by people is susceptible to catastrophic failure inflicting injury upon the general public simply because of the occurrence of a sneeze, the imposition of such a technological is clearly in need of a stringent form of justification. In addition to common human foibles, *ex ante* knowledge can pertain to common human capacities, including the capacity to avoid injury in certain situations. Many involuntary injuries due to automotive transport cannot be considered "inevitable" because they can properly be considered to be *reasonably avoidable,* in that avoidance is possible with only a minimal amount of requisite behavioral control on the part of potential victims. "Reasonable" avoidability implies that the time and effort required of the potential victim to avoid becoming an actual victim is not undue in relation to the magnitude of direct and indirect benefits associated with the risk to be avoided.[57] Government, it will therefore be maintained, can on utilitarian grounds require the forfeiture of a person's time and effort to a reasonable degree, but not the forfeiture of a person's health or life. Finally, responsibility is not necessarily engendered because a technology can be operated or abused in ways not

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[55] Bacon, in *The Great Instauration,* id. at p. 15, expressed a similar concern when he qualified his advocacy of modern scientific methodology with the following words: "Lastly, I would address one general admonition to all — that they consider what are the true ends of knowledge, and that they seek it . . . but for the benefit and use of life, and that they perfect and govern it in charity."

[56] See Jonas, Hans: "Technology and Responsibility: Reflections on the New Task of Ethics," *Social Research* 40:31-54 (1973).

[57] It should be noted that chronic technological risk, such as that due to technologically enhanced levels of ionizing radiation, is not normally "reasonably avoidable" as the latter term is defined in the text.

conforming to reasonable standards of human conduct. That some persons drive while drunk or while prone to epileptic fits should not be sufficient to require government to adhere to stringent grounds for justifying its subsidy of highway construction. Technologies are of necessity designed for use by people who conform to basic standards of reasonable conduct, and to require otherwise would simply stifle technological development in accordance with an untenable system of political ethics. Government is not capable of nor should it be obligated to guarantee that criminal, negligent, or dangerously unpredictable behavior will never come to pass; it should merely be required to endeavor to stop and limit the impact of such behavior to the greatest extent feasible.[58]

Bearing in mind the three caveats presented above regarding the intended meaning of "inevitable," it can be concluded that insofar as a governmentally imposed technological risk is a BENIM risk, and insofar as this risk is known to be of such a nature that the loss of health or life will "inevitably" result from its imposition, government is morally and legally obligated to provide a legitimate justification for the imposition of this risk. This justification must be based on criteria as stringent as the Constitutional demand for the preservation of the rights that such a justification seeks to balance. By this reasoning, it is proposed that the following three justifications be adopted by government as the only legitimate justifications for authorizing or executing the deprivation of life or health by means of the BENIM risks associated with a technology policy.

Justification Based on Intent to Reduce Net Comparable Risk

Risks leading to the deprivation of life or health may justifiably be authorized or imposed by government if the intent and reasonable expectation in so doing is to reduce the net total of comparable risk-induced injury. This justification is analogous to the common law principle that homicide may be privileged if it is necessary in order to protect other people from fatal harm. According to this rationale, government is justified in imposing health risks in order to eliminate or mitigate larger, preexisting health risks of similar importance,

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[58] It is recognized that certain technologies capable of producing catastrophic levels of injury engender a responsibility to take extraordinary precautions in order to provide for the extraordinary contingencies of criminal, negligent, or unpredictable behavior, such as sabbotage. When such extraordinary precautions result in substantial restrictions of liberty in order to achieve "reasonable avoidability" of the catastrophic risks imposed, it becomes legitimate to question a lack of adherence to a stringent standard of justifiability regarding the imposition of such risks.

thereby imposing "the lesser of two evils." It is this rationale which, for example, serves to justify mandatory vaccination programs which entail serious health risks to a small number of immunosensitive individuals, but which also protect a much larger number of people from infectious disease. Another example of public policy which might employ this rationale would be a policy of adopting a particular energy-producing technology on the basis of a comparative risk analysis which generates the reasonable expectation that the newly adopted technology will result in fewer BENIM risks than would a traditional energy-producing technology.[59] This example, however, begs the question of the justification of the original energy-production-related health risks, and therefore presumes that the following two justifications obtain.

Justification Based on Public Necessity

BENIM risks may justifiably be imposed on the general public if the benefits associated with these risks are determined, through the democratic political process, to be necessary for the preservation of fundamental liberties and the material base essential to secure those liberties. This justification is admittedly imprecise and, to some extent, arbitrary — but less so that a justification based solely on utilitarian principles. The justification based on public necessity is meant to be analogous to the common law principle that homicide may be privileged for reasons of public necessity — a rationale asserting that when peril threatens a whole community, the infliction of fatal risks is excused when their infliction is motivated to preserve the vital public interest. In time of Congressionally declared war, for instance, society is justified in requiring that its members risk their lifes in the interests of national security. Society might similarly determine that a certain level of energy-producing capacity is in the *vital* interests of national security or welfare. But if society were to make such a political determination, it is obligated to use all reasonably available knowledge to ensure that the technological path selected to achieve the necessary goal is the one that produces the fewest BENIM health risks. Thus, if society determines that an electricity-generating capacity of X gigawatts per year is vital to national security, and thereby justifies the operation of 100 nuclear power plants expected to result in Y number of additional health ef-

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[59] An example of the use of this justification is found in Inhaber, Herbert: "Risk of Energy Production," 3rd ed., Canadian Atomic Energy Control Board (AECB 1119/REV-2) 1978.

fects per year, it must argue and support the case that, energy conservation or alternative measures either (1) could not result in X GW/yr available capacity, (2) would, if implemented, result in greater than Y health effects per year, or (3) would, if implemented, result in some offsetting threat to vital national interests by a means other than (1) above. Such a determination of public necessity — that which is vital to the national interest — is not aproblematic, but it is certainly a more stringent and objective determination than one aimed at identifying merely what a majority of people desire in a given context. In the example above, for instance, it is likely that reasonable people will agree that energy *consumption* alone should not be a determinant of what is in the vital national interest, for any and every use of electricity cannot reasonably be considered a public necessity. What is a public necessity certainly changes as society and the technology it comes to depend on evolve. But for any given age, it should be possible for elected or appointed decision-makers to arrive at a consensus, or a series of provisional or interim consensuses, on what does or does not constitute a public necessity in a given context. Made on this basis, good-faith public policy decisions about technology policy options become politically accountable, in that they expose decision-makers' beliefs about the nature of public necessity to public scrutiny — as they should be in a democratic society.

Justification Based on Natural or Customary Activity

Lastly BENIM risks may justifiably be imposed upon the general public if this imposition is the result of natural or customary activity, the interruption of which either could not reasonably be expected or would result in severe and unmanageable social disruption. This justification is most pertinent to newly discovered health risks whose continued presence can be said to constitute a "newly generated" BENIM risk ("newly generated," that is, by the advent of new knowledge). With respect to natural activity, it is now known, for example, that people exude a certain amount of ionizing radiation, but on this account government ought not be proscribed from continuing to conduct its business with the public with the assistance of human federal employees. With respect to customary activity, it is now known that the operation of certain technologies and industries has detrimental health effects on the general population, for example, by means of carcinogenic pollution. The imposition of such BENIM risks may not be indefinitely justifiable on any basis, but a provisional or interim justification may be warranted to allow a reasonable period of time for the design and implementation of control measures or alternative

technologies serving to eliminate, or at least incrementally mitigate the original health risks. The customary activity basis for justifying BENIM risks is not intended to incorporate any sort of *economic* cost benefit balance, but rather a balance between the need to respect rights to life and health and the need to prevent reasonably and lawfully developed expectations dependent on newly challenged technological activities (e.g., expectations regarding employment, housing, or medical care) from being suddenly shattered in a context that could lead to severe and unmanageable social disruption.

It is recommended that these three justifications be used in the context of acceptable risk policies, such as those regarding low-level ionizing radiation, to replace extant or contemplated justifying rationales based strictly upon utilitarian cost-benefit balancing utilizing a Benthamite concept of value. It is *not* being recommended that economic cost-benefit balancing cease to play a role in the determination of socially acceptable levels of BENIM technological risk, but rather that it be used only subsequent to and not as part of the legitimate justification of the imposition of such risk.

PARKER v. FLOOK: A Formula to Cause Alarm

STEFAN BAUER-MENGELBERG*

On three occasions[1] the United States Supreme Court has had to decide whether a patent should issue on a computer program. All three of the patents were denied.

In each of these cases the Court went to considerable lengths to emphasize that it was deciding, not the general question whether computer programs fall into the class of patentable subject matter,[2]

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[1] *Gottschalk v. Benson*, 409 U.S. 63, 175 U.S.P.Q. (BNA) 673 (1972); we shall henceforth refer to this case as *"Benson"*. *Dann v. Johnston*, 425 U.S. 219, 189 U.S.P.Q. (BNA) 257 (1976). *Parker v. Flook*, 437 U.S. 584, 198 U.S.P.Q. (BNA) 193 (1978); we shall henceforth refer to this case as *"Flook"*.

[2] This class is sometimes referred to as the class of *statutory* subject matter, for patent rights are created entirely by statute, 35 U.S.C., enacted by Congress pursuant to the authority granted by Art. I, Sec. 8 (clause 8) of the U.S. Constitution. 35 U.S.C. §101 delimits the domain of patentable subject matter to new and useful processes, machines, manufactures, and compositions of matter, and new and useful improvements thereof. Since computer programs are not mentioned, the question of their patentability reduces, initially, to whether they can be fitted under any of these rubrics. "Process", perhaps the most likely candidate (at least for those programs that are generally termed "software"), is defined in 35 U.S.C. §100(b) as follows:

> The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

but only whether the program in the particular case was entitled to patent protection:

> [1] It is said that the decision precludes a patent for any program servicing a computer. We do not so hold. ... It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. Such is not our purpose.[3]
>
> Petitioner and respondent, as well as various *amici*, have presented lengthy arguments addressed to the question of the general patentability of computer programs. ... We find no need to treat that question in this case, however[.][4]
>
> [2] To a large extent our conclusion is based on reasoning derived from opinions written before the modern business of developing programs for computers was conceived. The youth of the industry may explain the complete absence of precedent supporting patentability. Neither the dearth of precedent, nor this decision, should therefore be interpreted as reflecting a judgment that patent protection of certain novel and useful computer programs will not promote the progress of science and the useful arts, or that such protection is undesirable as a matter of policy.[5]

All the same, it is clear that the policy question of the patentability in general of computer programs looms large in the background. It is the subject of dicta in both *Benson*:

> It may be that the patent laws should be extended to cover these programs, a policy matter to which we are not competent to speak.[6]
>
> [3] If these programs are to be patentable, considerable problems are raised which only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain. The technological problems tendered in the many briefs before us indicate to us that considered action by the Congress is needed.[7]

and *Flook:*

> Difficult questions of policy concerning the kinds of programs that may be appropriate for patent protection and the form and duration of such protection can be answered by Congress on the basis of current empirical data not equally available to this tribunal.
>
> It is our duty to construe the patent statutes as they now read, in light of our prior precedents, and we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress.[8]

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[3] *Benson,* 409 U.S., at 71; 175 U.S.P.Q. (BNA), at 676. To facilitate backward reference, certain passages have been identified by a numeral in square brackets. Reference to these passages will be by the same token.

[4] *Dann v. Johnston, supra* (footnote 1), 425 U.S., at 220; 189 U.S.P.Q. (BNA), at 258.

[5] *Flook,* 437 U.S., at 595; 198 U.S.P.Q. (BNA), at 199.

[6] 409 U.S., at 72; 175 U.S.P.Q. (BNA), at 676-677.

[7] 409 U.S., at 73; 175 U.S.P.Q. (BNA), at 677. Footnote omitted.

[8] 437 U.S., at 595-596; 198 U.S.P.Q. (BNA), at 199-200. Footnote omitted.

Benson in addition quotes three paragraphs from the Report of the President's Commission on the Patent System,[9] to the effect that the (then) current law in this area was uncertain, that, because of the lack of research files and the tremendous volume of applications that would be generated, the Patent and Trademark Office could not in fact deal with the applications for patents on programs, and that the absence of patent protection seemed not to have interfered with the substantial and satisfactory growth of the programming industry.

In the petition for a writ of certiorari in *Flook,* the acting Commissioner of Patents and Trademarks urged that the decision of the Court of Customs and Patent Appeals, which had ordered the patent to issue, would "have a debilitating effect on the rapidly expanding computer 'software' industry, and . . . require him to process thousands of additional patent applications."[10] The Supreme Court opinion in *Flook,* immediately after citing these arguments, continues:

> Because of the importance of the question, we granted certiorari, — U.S. —, 98 S.Ct. 764, 54 L.Ed.2d 780.[11]

Hence it is apparent that, in spite of the disclaimer quoted above,[12] the decision in *Flook* was intended to do more than dispatch the case at bench, at least in the negative sense of constituting a holding action to keep the floodgates from opening.

However, with the question of the patentability in general of computer programs formally left open,[13] it is to be expected that grants

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[9] "To Promote the Progress of... Useful Arts" (1966). The paragraphs quoted appear in 409 U.S., at 72; 175 U.S.P.Q. (BNA), at 677.

[10] 437 U.S., at 587; 198 U.S.P.Q. (BNA), at 196. Footnote omitted.

[11] 437 U.S., at 588; 198 U.S.P.Q. (BNA), at 196. The grant of certiorari is reported in 434 U.S., at 1033; 196 U.S.P.Q. (BNA), at 864.

[12] See [2].

[13] Indeed, there are currently patents outstanding on computationally implemented methods. See *Application of Freeman,* 573 F.2d 1237, 197 U.S.P.Q. (BNA) 464 (C.C.P.A. 1978) (system for typesetting alphanumeric information, using a computer-based control system with a phototypesetter of conventional design); *Application of Deutsch,* 553 F.2d 689, 193 U.S.P.Q. (BNA) 645 (C.C.P.A. 1977) (method of operating a system of manufacturing plants (oil refineries)); *Application of Chatfield,* 545 F.2d 152, 191 U.S.P.Q. (BNA) 730 (C.C.P.A. 1976), *cert. den.* (Oct. 3, 1977), 434 U.S. 875, 195 U.S.P.Q. (BNA) 465 (method for improving the efficiency of multiprogrammed computer systems).

The Court of Customs and Patent Appeals has, in fact, repeatedly pointed to [1] and [3], and the characterization of *Benson* as a "limited holding" in *Dann v. Johnston, supra* (footnote 1) [425 U.S., at 224; 189 U.S.P.Q. (BNA), at 259], as justifying the position that computer programs are not *per se* outside the domain of statutory subject matter. See *Application of Freeman, supra,* 573 F.2d, at 1244; 197 U.S.P.Q.

or denials of patents on computer programs will continue to be the subject of litigation, as indeed they have been since *Flook* came down.[14] *Flook* has already been variously referred to in the lower courts,[15] and it merits our close attention, because it may continue to be cited as a precedent: four days after deciding *Flook*, the Supreme Court remanded a case for reconsideration "in light of *Parker* v. *Flook*".[16]

In the opinion of the present author, *Flook* is not a reliable source of intellectual illumination.[16a] A thoroughly flawed decision, based on shoddy, superficial analysis, it can only serve to obfuscate. Our

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(BNA), at 470; *Application of de Castelet*, 562 F.2d 1236, at 1240; 195 U.S.P.Q. (BNA) 439, at 443 (C.C.P.A. 1977); *Application of Chatfield, supra*, 545 F.2d, at 155; 191 U.S.P.Q. (BNA), at 733. In *Chatfield* we actually find this passage:

> We join the Supreme Court's suggestion in *Benson* that those who seek to preclude the patenting of all software or "computer program" inventions submit an appropriate proposal to the Congress.

545 F.2d, at 156; 191 U.S.P.Q. (BNA), at 734. It attests to a rather startling reading, on the part of the Court of Customs and Patent Appeals, of [3].

[14] *Flook* was decided on June 22, 1978. 437 U.S., at 584; 198 U.S.P.Q. (BNA), at 193.

[15] *Application of Phillips*, 608 F.2d 879, 203 U.S.P.Q. (BNA) 971 (C.C.P.A. 1979) (case remanded earlier to the Patent and Trademark Office Board of Appeals for "a supplemental opinion that will provide the specifics of a detailed factual analysis," 593 F.2d 1021, at 1022; 201 U.S.P.Q. (BNA) 257, at 258 (C.C.P.A. 1979)); *Application of Diehr*, 602 F.2d 982, 203 U.S.P.Q. (BNA) 44 (C.C.P.A. 1979), *cert. granted sub nom. Diamond v. Diehr* (Mar. 17, 1980), 48 U.S.L.W. 3595, 3602; *Application of Bradley*, 600 F.2d 807, 202 U.S.P.Q. (BNA) 480 (C.C.P.A. 1979), *cert. granted sub nom. Diamond v. Bradley* (Mar. 17, 1980), 48 U.S.L.W. 3595, 3602; *CTS Corporation v. Electro Materials Corporation of America*, 469 F.Supp. 801, 202 U.S.P.Q. (BNA) 22 (S.D. N.Y. 1979); *Application of Gelnovatch*, 595 F.2d 32, 201 U.S.P.Q. (BNA) 136 (C.C.P.A. 1979); *Application of Johnson* and *Application of Parrack* (two cases under the latter name), 589 F.2d 1070, 200 U.S.P.Q. (BNA) 199 (C.C.P.A. 1978, *reh. den.* Feb. 15, 1979); *Application of Sarkar*, 588 F.2d 1330, 200 U.S.P.Q. (BNA) 132 (C.C.P.A. 1978, *reh. den.* Jan. 25, 1979); *Hirschfeld v. Banner*, 462 F.Supp. 135, 200 U.S.P.Q. (BNA) 276 (Dist. Ct. D.C., Civil Division, 1978).

[16] *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. (BNA) 257; below: *Application of Bergy*, 563 F.2d 1031, 195 U.S.P.Q. (BNA) 344 (C.C.P.A. 1977, *reh. den.* Nov. 23, 1977) (microbiological process for preparing an antibiotic using a biologically pure culture of a newly discovered microorganism).

[16a] [Footnote added in proof] This seems also to have been the opinion of the Court of Customs and Patent Appeals, at least as far as the remanded case is concerned (see footnote 16, *supra*). In the opinion on remand, which also deals with the application of Chakrabarty (see *infra*), Judge Rich wrote:

> We are redeciding these appeals, as directed, "in light of *Parker v. Flook*." . . . As might have been foreseen, the results are not helpful.

Application of Bergy, Application of Chakrabarty, 596 F.2d 952, at 964; 201 U.S.P.Q. (BNA) 352, at 364 (C.C.P.A. 1979). (We shall henceforth refer to this opinion as *"Bergy II"*.)

purpose here cannot, of course, be to propose a rehearing of *Flook;*[17] but we can hope to sterilize the fundamental errors in the Supreme Court's opinion by not allowing them to go unexposed, lest they infect future litigation in this area. If *Flook* is to cast a shadow, and to cast it forward, then at least let that shadow be short!

> To conclude on the light *Flook* sheds on these cases, very simply, for the reasons we have stated, we find none.

Id., 596 F.2d, at 967; 201 U.S.P.Q. (BNA), at 366. This is so although the court sought light not only in the *Flook* holding, but in the entire *Flook* opinion:

> Clearly, our assigned task is first to determine the bearing of *Flook*, if any, on these two appeals. This requires, as we see it, consideration not only of what was *decided* in *Flook* but examination of everything that was said in the opinion.

Id., 596 F.2d, at 958; 201 U.S.P.Q. (BNA), at 358. Emphasis original.

Application of Chakrabarty, 571 F.2d 40, 197 U.S.P.Q. (BNA) 72 (new strain of a microorganism, with new capacities to degrade several main components of oil, for use in oil spills), had originally been decided by the Court of Customs and Patent Appeals on March 2, 1978, after that court's decision in *Flook* (see footnote 33, *infra*) but before the Supreme Court's (see footnote 14, *supra*). After an extension of time had been granted by the Chief Justice, a petition for a writ of certiorari was filed on July 26, 1978; by this time, of course, the Supreme Court's decision in *Flook* had come down and *Bergy* had been remanded. Since *Bergy* and *Chakrabarty* "involve only the same single question of law" [*Bergy II*, 596 F.2d, at 955; 201 U.S.P.Q. (BNA), at 356], upon petition of the Commissioner of Patents and Trademarks, dated August 3, 1978, the Court of Customs and Patent Appeals vacated its earlier decision in *Application of Chakrabarty*, "because it was obviously necessary to give it the same reconsideration" [*Bergy II*, 596 F.2d, at 957; 201 U.S.P.Q. (BNA), at 358] as *Bergy*. On August 11, 1978, *Chakrabarty* was restored to the calendar of the Court of Customs and Patent Appeals, to be heard together with the remanded *Bergy* on November 6, 1978, although they were "separate appeals, not formally consolidated" [*Bergy II*, 596 F.2d, at 955; 201 U.S.P.Q. (BNA), at 356]. Thereupon the parties to *Chakrabarty* stipulated, pursuant to Rule 60(1) of the Supreme Court (Rule 60 governs "Dismissing Causes", Rules of the Supreme Court of the United States, 17 *U.S. Supreme Court Digest, Lawyers' Edition*, at 92), that the petition for a writ of certiorari be dismissed. *Cert. dismissed sub nom. Banner v. Chakrabarty* (Aug. 25, 1978), 439 U.S. 801, — U.S.P.Q. (BNA) —. After the decision on remand, the Supreme Court again granted certiorari (Oct. 29, 1979), — U.S. —, 204 U.S.P.Q. (BNA) 608. On January 14, 1980, *Bergy* was dismissed, upon motion of the respondents, as moot, because an amendment to the patent application abandoned all subject matter in controversy. 48 U.S.L.W. 3609. Judgment was vacated and the case remanded to the Court of Customs and Patent Appeals with directions to dismiss the appeal as moot. 48 U.S.L.W. 3451 [at 3449 the date is erroneously given as January 14, 1979]. *Chakrabarty* was heard *sub nom. Diamond v. Chakrabarty* on March 17, 1980, 48 U.S.L.W. 3609, 3613, and the patent was sustained, in a 5:4 decision, on June 16, 1980. 48 U.S.L.W. 4714.

[17] Indeed, it is a bit late for that, under Rule 58 ("Rehearings"), Rules of the Supreme Court of the United States, 17 *U.S. Supreme Court Digest, Lawyers' Edition*, at 89-90.

Flook leans heavily on *Benson,* and it will therefore be useful to begin our discussion with a brief summary of that case.[18]

The patent in *Benson* claimed a method for programming general-purpose digital computers to convert numerals from binary-coded decimal (BCD) notation into pure binary notation.[19] The claim was not confined to a specific computer, or even to a specific computer program, but covered any use of the method, which could control the writing of a computer program for some particular computer, or class of computers, to accomplish the desired transformation.

The Court framed the question in the case as "whether the method described and claimed is a 'process' within the meaning of the Patent Act",[20] and proceeded to answer it in the negative. This result was synthesized out of a finding that

> [4] [t]he mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed [i.e., if the patent issues], the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.[21]

and the long-standing, generally recognized principle that

> [5] a scientific truth, or the mathematical expression of it, is not patentable invention.[22]

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[18] We shall be concerned only marginally with *Dann v. Johnston, supra* (footnote 1), in which the computer program was held to be unpatentable on grounds of obviousness, under 35 U.S.C. §103. (According to *Graham v. John Deere Co.,* 383 U.S. 1, 148 U.S.P.Q. (BNA) 459 (1966), this section was enacted, in 1952, "merely as a codification of judicial precedents", 383 U.S., at 17; 148 U.S.P.Q. (BNA), at 466.)

In the earlier stages of *Dann v. Johnston,* other grounds were advanced for denying the patent. The examiner relied on 35 U.S.C. §§102 (prior art) and 112 (indefiniteness), and the Patent and Trademark Office Board of Appeals on 35 U.S.C. §101, in addition to §§103 and 112. (The Court of Customs and Patent Appeals reversed the Board in a 3:2 decision, 502 F.2d 765, 183 U.S.P.Q. (BNA) 172 (1974).)

[19] These are two systems of notation that are commonly used to represent numbers in computing machinery. The technical details need not concern us here; they are ably set forth in *Benson* [409 U.S., at 66-67; 175 U.S.P.Q. (BNA), at 674] by Mr. Justice Douglas, who seemed to be enjoying himself in working through them.

[20] 409 U.S., at 64; 175 U.S.P.Q. (BNA), at 674. A footnote to the passage quoted (footnote 2, *id.,* except that in 409 U.S. it runs over to p. 65) gives the text of 35 U.S.C. §100(b) (see footnote 2, *supra*) and §101.

[21] 409 U.S., at 71-72; 175 U.S.P.Q. (BNA), at 676.

[22] *Mackay Radio and Telegraph Co. v. Radio Corporation of America,* 306 U.S. 86, at 94; 40 U.S.P.Q. (BNA) 199, at 202 (1939). The quotation appears in 409 U.S., at 67; 175 U.S.P.Q. (BNA), at 675.

In the words of Mr. Justice Douglas,

> [6] Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.[23]

We now proceed to our examination of *Flook*. The patent in that case covered a method of updating alarm limits in the catalytic conversion of hydrocarbons. An alarm limit is a number chosen so that, if a given variable in the conversion process — temperature, say, or pressure — reaches or exceeds it, an alarm signal is triggered. The catalytic conversion of hydrocarbons, of course, is not new, nor is the monitoring of process variables, the use of alarm limits, the notion that they must from time to time be recomputed and adjusted during the conversion process, or the utilization of computers to this end.[24] The only feature of Flook's process for which novelty was claimed was a formula,[25]

$$B_1 = B_0(1.0 - F) + PVL(F),$$

which controls the updating adjustment.

In this formula, B_0 represents a current "alarm base" for the process variable being monitored. The current alarm limit is obtained by adding to the current alarm base a predetermined constant "alarm offset", K. B_1 represents the updated alarm base, and the updated alarm limit will be obtained by taking $B_1 + K$. Entering into the computation of B_1, besides B_0, are F, which may be any number between 0 and 1, and PVL, which is the "present value" — that is to say, the value at the time of updating — of the process variable. Thus B_1 is set equal to what is generally called a weighted average of B_0 and PVL, the relative weight accorded to each of these terms being controlled by the choice of F.[26] The patent application does not purport to indicate what, in a given case, the proper choice of the constants K and F would be,[27] nor does it indicate what the time interval between

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[23] 409 U.S., at 67; 175 U.S.P.Q. (BNA), at 675.

[24] 437 U.S., at 594; 198 U.S.P.Q. (BNA), at 199.

[25] The formula is given in the Appendix to the opinion, in 437 U.S., at 597; 198 U.S.P.Q. (BNA), at 200. We have, as good scientific style dictates, written it using subscripts, which the typographer has done his best to simulate. The versions in the reports employ baseline numerals, or a mixture of these and subscripts.

[26] See Claim 1, which is reproduced in the Appendix to the opinion, in 437 U.S., at 596-597; 198 U.S.P.Q. (BNA), at 200. (There are minor typographical differences between the version of Claim 1 that appears in the Supreme Court opinion and that which appears in the opinion of the Court of Customs and Patent Appeals, 559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10.)

[27] 437 U.S., at 586; 198 U.S.P.Q. (BNA), at 195.

updatings should be.[28] Lastly, it gives no indication how the alarm system is actually modified to reflect the newly-determined alarm limit.[29] "All that it provides is a formula for computing an updated alarm limit."[30]

Our understanding of the case will be facilitated if we briefly trace its progress from the Patent and Trademark Office to the Supreme Court.

The examiner rejected the application on the grounds that

> the mathematical formula constituted the only difference between respondent's claims and the prior art and therefore a patent on this method "would in practical effect be a patent on the formula or mathematics itself."[31]

Thus from the beginning the issue was joined under 35 U.S.C. §101.

The Patent and Trademark Office Board of Appeals sustained the examiner, holding that the novel element in the method

> [7] lay in the formula or algorithm described in the claims, a subject matter that was unpatentable under *Benson*.[32]

The Court of Customs and Patent Appeals reversed,[33] on the grounds that *Benson* controlled only claims that would *entirely* pre-empt a mathematical formula or algorithm, whereas Flook was only claiming the use of his method to update alarm limits in a process comprising the catalytic chemical conversion of hydrocarbons:

> [8] The court reasoned that since the mere solution of the algorithm would not constitute infringement of the claims, a patent on the method would not pre-empt the formula.[34]

This much of the history of the case is related in the Supreme Court opinion. Examination of the opinion of the Court of Customs and Patent Appeals,[35] however, reveals that other issues surfaced in the earlier stages. One, upon which the case might validly have turned, became a victim of infant mortality:

> [9] The examiner made a second argument which, to the extent that it is relevant to the §101 rejection, appears to state that inventions

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[28] 437 U.S., at 597; 198 U.S.P.Q. (BNA), at 200.

[29] 437 U.S., at 586; 198 U.S.P.Q. (BNA), at 195.

[30] *Ibid.*

[31] 437 U.S., at 587; 198 U.S.P.Q. (BNA), at 196. Footnote omitted. The language of the inner quotation, of course, tracks that of *Benson;* see [4].

[32] 437 U.S., at 587; 198 U.S.P.Q. (BNA), at 196.

[33] 559 F.2d 21, 195 U.S.P.Q. (BNA) 9 (1977).

[34] 437 U.S., at 587; 198 U.S.P.Q. (BNA), at 196.

[35] 559 F.2d 21, 195 U.S.P.Q. (BNA) 9.

> which replace human judgment with mathematical formulas are non-statutory. The board [Patent and Trademark Office Board of Appeals] did not discuss this argument and neither appellant nor the solicitor briefed it. We will, therefore, not consider it.[36]

In addition, the examiner, the Patent and Trademark Office Board of Appeals, and the Court of Customs and Patent Appeals discussed the import of *In re Christensen*[37] upon the present case. The passage from *In re Christensen* upon which both sides relied is:

> [10] The issue before us in the instant case is also a narrow one, namely, is a method claim in which the point of novelty is a mathematical equation to be solved as the final step of the method, a statutory method? We follow the Supreme Court in concluding that the answer is in the negative. Given that the method of solving a mathematical equation may not be the subject of patent protection, it follows that the addition of the old and necessary antecedent steps of establishing values for the variables in the equation cannot convert the unpatentable method to patentable subject matter.[38]

The examiner used this to support his view that Flook's method, while clearly useful within the technological arts, is nonstatutory, since its only non-conventional component was the algorithm, and this position was also adopted by the Board of Appeals. On rehearing, Flook argued that the language of *In re Christensen* applies only to cases in which the solution of the equation is the last step of the process, and that this was not true of his method.[39] Nonetheless,

> [11] the board expressly rejected appellant's position regarding the holding in *Christensen*. . . .The board held that appellant's focus on the "last step" condition is misplaced because whether or not there happens to be a step after solution of the algorithm is a mere matter of form.[40]

However, the Court of Customs and Patent Appeals — which does, of course, occupy a somewhat privileged position when it comes to interpreting its own decisions[41] — explained that the holding of *In re Christensen*

> [12] is expressly limited to claims directed to determining data used in an algorithm and solving the algorithm, that is, to claims in which nothing is done after solution of the algorithm.[42]

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[36] This is footnote 2 of the opinion of the Court of Customs and Patent Appeals, 559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10.

[37] 478 F.2d 1392, 178 U.S.P.Q. (BNA) 35 (C.C.P.A. 1973).

[38] 478 F.2d, at 1394; 178 U.S.P.Q. (BNA), at 37-38.

[39] 559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10.

[40] *Ibid.*

[41] Four of the five judges in the two cases, including the author of the *In re Christensen* opinion, Judge Lane, were the same.

[42] 559 F.2d, at 23; 195 U.S.P.Q. (BNA), at 11.

The *In re Christensen* court, we are told, read *Benson* as requiring that a claim, to be statutory, must

> [13] include a recitation which materially limits the claim to a scope less than the mere act of solving an algorithm. The court determined that this requirement of a limitative recitation is not satisfied by the recitation of data-gathering steps but implied that it may be satisfied by the recitation of some sort of post-solution activity. ... [T]he court did not need to reach the question of what sort of post-solution activity is required for statutory subject matter.[43]

Since in Flook's method the solution of the equation is not the last step, and since his claim would not "wholly pre-empt the mathematical formula",[44] neither *In re Christensen* nor *Benson* renders the claim unpatentable. Therefore the Court of Customs and Patent Appeals reversed.

The argument based on post-solution activity was further pressed by Flook in the Supreme Court. Obviously, it did not carry the day there;[45] indeed, as we shall see, it was disposed of in rather cursory fashion.

We now turn to the Supreme Court's analysis in *Flook,* which is to be found in the introductory paragraph and Section III of the majority opinion.[46]

The introductory paragraph, which contains the Court's statement of the problem, reads in relevant part:

> [14] The only novel feature of the method is a mathematical formula. In *Gottschalk v. Benson* ... we held that the discovery of a novel and useful mathematical formula may not be patented. The question in this case is whether the identification of a limited category of useful, though conventional, post-solution applications of such a formula makes respondent's method eligible for patent protection.[47]

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[43] *Ibid.*

[44] The language is that of *Benson,* see [4], and it is cited in 559 F.2d, at 23; 195 U.S.P.Q. (BNA), at 11.

[45] Thus was laid to rest the speculation, which had gained considerable currency in both the computing and the patent community after the decision of the Court of Customs and Patent Appeals in *Flook* (it came down on August 4, 1977), that a somewhat stable line could be drawn between patentable and unpatentable computer programs on the basis of the question whether the computation accomplished by the program was the end of the process (in which case the program would not be patentable) or whether the program formed an integral, non-final part of a larger process (in which case it might be). The lifetime of this illusion was slightly under eleven months. See, e.g., Robert J. Frank, "The patentability of software inventions", IEEE spectrum, vol. 15, no. 4 (April 1978), pp. 42-46, especially the section "A pattern emerges", at p. 46.

[46] Section I, which is devoted to a characterization of the claim, and Section II, the Court's (abbreviated) history of the case, have already been presented.

[47] 437 U.S., at 585; 198 U.S.P.Q. (BNA), at 195.

The Court's analysis, in Section III, begins with the bold assertion "This case turns entirely on the proper construction of §101 of the Patent Act,"[48] and at once proceeds to eliminate novelty and obviousness, which might have been issues under §§102 and 103, from the case. With respect to novelty, in particular, the Court posits:

> [15] For the purpose of our analysis, we assume that respondent's formula is novel and useful and that he discovered it.[49]

The Court also adopts — since Flook did not challenge it — the examiner's finding that the formula is the *only* novel feature of the method.

Section 101 of the Patent Act allows for the patenting of processes, and the claim in this case is undoubtedly on a process, but, since *Benson,* there is the additional question "whether the method described and claimed is a 'process' within the meaning of the Patent Act."[50] The Court recognizes the validity of Flook's contention that — precisely because he is claiming only the use of his formula in the catalytic conversion of hydrocarbons — the language of *Benson,* to the effect that "the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself", does not apply to his claims.[51] But it rejects his argument that the presence of post-solution activity distinguishes his process from that in *Benson* sufficiently so as to make it patentable, and it does so largely by characterization:

> [16] The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process *exalts form over substance.* A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean Theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.[52]

Indeed, the Court seems even to have second thoughts about the reasoning of *Benson:*

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[48] 437 U.S., at 588. The parallel passage in 198 U.S.P.Q. (BNA), at 196, has "Code" instead of "Act".

[49] 437 U.S., at 588; 198 U.S.P.Q. (BNA), at 196.

[50] See footnote 20, *supra,* for the citations in *Benson.* The quotation in *Flook* occurs in footnote 10, in 437 U.S., at 589; 198 U.S.P.Q. (BNA), at 197.

[51] 437 U.S., at 589-590; 198 U.S.P.Q. (BNA), at 197. The quotation from *Benson* is, of course, from [4].

[52] 437 U.S., at 590; 198 U.S.P.Q. (BNA), at 197. Emphasis added. Footnote omitted, but see immediately *infra.*

> [17] It should be noted that in *Benson* there was a specific end use contemplated for the algorithm — utilization of the algorithm in computer programming. . . . Of course, as the Court pointed out, the formula had no other practical application; but it is not entirely clear why a process claim is any more or less patentable because the specific end use contemplated is the only one for which the algorithm has any practical application.[53]

The Court hastens to explain, however, that

> [18] it is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm. See *Eibel Process Co. v. Minnesota and Ontario Paper Co.*, 261 U.S. 45, 43 S.Ct. 322, 67 L.Ed. 523; *Tilghman v. Proctor,* 102 U.S. 707, 26 L.Ed. 279.[54]

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[53] 437 U.S., at 590; 198 U.S.P.Q. (BNA), at 197. But for the elision, this is footnote 11, the footnote omitted from [16]. We shall have occasion to comment on this expression of doubt with respect to one ingredient of the *Benson* rationale when we have completed our analysis. See footnote 128, *infra.*

[54] 437 U.S., at 590; 198 U.S.P.Q. (BNA), at 197. In a footnote to this passage [footnote 12, 437 U.S., at 590-591; 198 U.S.P.Q. (BNA), at 197] the Court explains that the claim in *Eibel* was on an improvement on a paper-making machine, in which use was made of gravity to improve the flow of the product, but the patentee, of course, did not claim to have discovered the law of gravity. Similarly, in *Tilghman,* which concerned the manufacture of fat acids and glycerine from fatty bodies, the inventor claimed only a novel way of bringing about the union of elements of neutral fat with their atomic equivalents of water, and not the principle, which had been known, that it was necessary to do this.

These hoary cases — *Eibel* dates from 1923, and *Tilghman* from 1881! — seem to the present author to have little direct bearing on the problem in *Flook. Eibel* revolved entirely about the question whether there had been "invention", the precursor of non-obviousness (see footnote 18, *supra*). *Tilghman* did raise the question of statutory subject matter; it was granted that Tilghman claimed a process, but at the time the term "process" was not yet in the statute as the name of a statutory category. Its precursor was "art", and much of the argumentation in *Tilghman* concerned the question whether Tilghman's process could be accommodated under it. Another question — one that would have had more relevance to *Flook,* but was not discussed in that case — concerned the patentability of a process implemented by specific apparatus but presented in a claim that was not limited to that specific apparatus. The Court decided in favor of patentability and held the patent infringed by a use in which functionally equivalent apparatus was used.

With respect to the Court's use of these cases — to illustrate that a process which "contains a law of nature or a mathematical algorithm" is not, for that reason, unpatentable — it should be remarked, first, that no mathematical algorithm figured in either of them. Next, it is far from clear what "contains" means in this context. The processes in *Eibel* and *Tilghman* did depend quite directly upon fairly specific scientific principles. We shall argue that the process in *Flook* does not rely on any identifiable principle of empirical science, and that its reliance upon arithmetic is quite incidental.

The following quotations from earlier cases are cited with approval:

> [19] While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.[55]
>
> [20] He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[56]

The lesson extracted from these cases is that

> [21] [t]he process itself, not merely the mathematical algorithm, must be new and useful. Indeed, the novelty of the mathematical algorithm is not a determining factor at all. Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the "basic tools of scientific and technological work," see *Gottschalk v. Benson* [[6]], . . .it is treated as though it were a familiar part of the prior art.[57]

And, after the discussion of some other cases in which well-known scientific principles were put to practical use, this is reiterated:

> [22] We think this case must also be considered as if the principle or mathematical formula were well known.[58]

The Court thereupon proceeds to deal with the counter-argument made by Flook, to the effect that

> this approach improperly imports into §101 the considerations of "inventiveness" which are the proper concerns of §§102 and 103.[59]

This view is said to rest upon two fundamental misconceptions; the first is

> that if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of §101 and the substantive patentability of the particular process can then be determined by the conditions of §102 and §103.[60]

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[55] The passage is the one from which [5] was extracted, and the citations in footnote 22, *supra,* will serve for it as well. The quotation appears in 437 U.S., at 591; 198 U.S.P.Q. (BNA), at 198.

[56] *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, at 130; 76 U.S.P.Q. (BNA) 280, at 281 (1948). The quotation appears in 437 U.S., at 591; 198 U.S.P.Q. (BNA), at 198.

[57] 437 U.S., at 591-592; 198 U.S.P.Q. (BNA), at 198.

[58] 437 U.S., at 592; 198 U.S.P.Q. (BNA), at 198.

[59] *Ibid.*

[60] 437 U.S., at 593; 198 U.S.P.Q. (BNA), at 198.

This assumption is rejected as based upon a too narrow reading of *Benson,* one that would make patentability a matter of the draftsman's art and

> [23] would ill serve the principles underlying the prohibition against patents for "ideas" or phenomena of nature. The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of "discoveries" that the statute was enacted to protect.[61]

And, in a footnote to this passage, there is the additional explanation:

> [24] The underlying notion is that a scientific principle, such as that expressed in respondent's algorithm, reveals a relationship that has always existed.[62]

The second misconception is said to be that

> the fatal objection to his application is the fact that one of its components — the mathematical formula — consists of unpatentable subject matter.[63]

Rather,

> [25] [r]espondent's process is unpatentable under §101 not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention. Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.[64]
>
> [26] Respondent's application simply provides a new and presumably better method for calculating alarm limit values. If we assume that that method was also known, as we must . . ., then respondent's claim is, in effect, comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel.[65]

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[61] *Ibid.* Footnote omitted, but see immediately *infra.*

[62] 437 U.S., at 593; 198 U.S.P.Q. (BNA), at 198. Thus begins footnote 15, the footnote omitted from [23]. It continues by quoting from Peter D. Rosenberg, *Patent Law Fundamentals* (Clark Boardman Company, Ltd., New York, N.Y., 1975), which adduces Newton's formulation of the law of gravity as an example: "Such 'mere' recognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment. . . .Patentable subject matter must be new (novel); not merely heretofore unknown." *Op. cit.,*§4, at 13. The citations at the beginning of this footnote apply, except that in 198 U.S.P.Q. (BNA) the passage runs over to p. 199.

[63] 437 U.S., at 593-594; 198 U.S.P.Q. (BNA), at 198.

[64] 437 U.S., at 594; 198 U.S.P.Q. (BNA), at 199.

[65] 437 U.S., at 594-595; 198 U.S.P.Q. (BNA), at 199. Footnote omitted, but see immediately *infra.*

In a footnote there is further language concerning the notion "method of calculation":

> [27] [R]espondent's . . . process patent rests solely on the claim that his mathematical algorithm, when related to a computer program, will improve the existing process for updating alarm limits. Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under §101.[66]

And, as if the point had not yet been made with sufficient persistence, the following passage, from an opinion of the Court of Customs and Patent Appeals, is cited with approval:

> [28] [I]f a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.[67]

We shall consider the dissent later.

Before proceeding with an analysis of this, the Court's, argument, it will be well to elucidate, however briefly, the meaning or meanings of some of the terms that occur and recur in the various excerpts above, and, where there are several, to sort them out in a preliminary way.

Foremost among these terms — and no doubt the one least likely to be understood by a lay audience — is "algorithm". It made its appearance already in *Benson,* where we find the following:

> [29] A procedure for solving a given type of mathematical problem is known as an "algorithm".[68]

This explication is entirely adequate for the purposes of the *Benson* opinion, but it is not a satisfactory characterization in general. There are, indeed, profound problems connected with the definition of "algorithm",[69] but, fortunately, these need not impede our present

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[66] 437 U.S., at 595; 198 U.S.P.Q. (BNA), at 199. The passage is from footnote 18, the footnote omitted from [26].

[67] *Application of Richman,* 563 F.2d 1026, at 1030; 195 U.S.P.Q. (BNA) 340, at 343 (C.C.P.A. 1977). The quotation appears in 437 U.S., at 595; 198 U.S.P.Q. (BNA), at 199.

[68] 409 U.S., at 65; 175 U.S.P.Q. (BNA), at 674. Note that this statement does not, strictly speaking, purport to be an exhaustive definition of the term "algorithm". It can (and should) be taken as an assertion of class inclusion.

[69] See, generally, A.A. Markov, *Theory of Algorithms,* translated (from the Russian) by Jacques J. Schorr-Kon and PST [Program for Scientific Translations] Staff (The Israel Program for Scientific Translations, Jerusalem, 1961); Hans Hermes, *Aufzählbarkeit, Entscheidbarkeit Berechenbarkeit; Einführung in die Theorie der rekursiven Funktionen* (Springer Verlag, Berlin, Göttingen, Heidelberg, 1961); Martin Davis, *Computability & Unsolvability* (McGraw-Hill Book Company, Inc., New York, Toronto, London, 1958).

analysis. For our purposes, the notion will have been made sufficiently precise if we say that an algorithm

(1) consists of (or at least is expressible in) a statement of finite length in some language, such that

(2) it constitutes a set of deterministic instructions, which, if executed, will,

(3) in a finite number of performable steps,

(4) yield the correct answer to the problem to be solved.

That problem need not be a mathematical problem,[70] in the

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[70] As the Court of Customs and Patent Appeals well knew, even before it wrote its opinion in the *Flook* case; witness its wise footnote 5 in *Application of Chatfield, supra* (footnote 13), which was decided by the five judges who decided *Flook:*

> Over-concentration on the word "algorithm" alone, for example, may mislead. The Supreme Court [in *Benson*] carefully supplied a definition of the particular algorithm before it, i.e., "[a] procedure for solving a given type of mathematical problem." The broader definition of algorithm is "a step-by-step procedure for solving a problem or accomplishing some end." *Webster's New Collegiate Dictionary* (1976). It is axiomatic that inventive minds seek and develop solutions to problems and step-by-step solutions often attain the status of patentable invention. It would be unnecessarily detrimental to our patent system to deny inventors patent protection on the *sole* ground that their contribution could be broadly termed an "algorithm."

545 F.2d, at 156; 191 U.S.P.Q. (BNA), at 734. Emphasis original. This footnote is attached to the passage

> "It is a maxim, not to be disregarded, that general expressions, in every opinion, are to be taken in connection with the case in which these expressions are used." *Cohens v. Virginia,* 19 U.S. (6 Wheat.) 264, 398, 5 L.Ed. 257 (1821).

Ibid. The quoted words are those of Chief Justice Marshall. [Instead of "398", it should be "399", and the passage appears in 5 L.Ed. at 290.]

The Oxford English Dictionary (Oxford University Press, Oxford, 1971) does not recognize either the narrow or the broader meaning of "algorithm" discussed above. In vol. 1, at 218 (Compact Edition, vol. 1, at 55), it characterizes "Algorithm" as "erron. refashioning of ALGORISM", which is defined, *ibid.,* as "The Arabic, or decimal system of numeration; *hence,* arithmetic." Alonzo Church, in *Introduction to Mathematical Logic, Volume I* (Princeton University Press, Princeton, N.J., 1956), in footnote 118, at 53, writes of "algorithm": "This is the long established spelling of this word, and should be preserved in spite of any considerations of etymology." The etymology goes back to the name of the Arab mathematician al-Khowārazmī, "through the translation of whose work on Algebra, the Arabic numerals became generally known in Europe" *(Oxford English Dictionary,* vol. 1, at 217; Compact Edition, vol. 1, at 55).

conventional sense of the term; a deterministic routine for locating a given piece of information in a file, for example, would be an instance of an algorithm, as would one for sorting a long list of names into alphabetical order.[71]

The notion of determinism employed here is that, at any particular stage of the procedure, the algorithm must give precise and unambiguous directions as to what is to be done next, with no alternative allowed. The difficulties associated with the definition of "algorithm" are largely those of explicating what is meant by "performable", as in the third clause above.[72] It is, however, not at all difficult to give *examples* of performable steps: the addition or multiplication of integers, the representation (in some symbolic form) of the roots of a quadratic expression, and so forth. *Not* performable, in this sense, would be a step that could not be executed until a hitherto unsolved problem in mathematics were solved, e.g., "add 1 (to some previously computed number) if Fermat's last conjecture is true; add 2 if it is false".[73]

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[71] To be sure, the solution of such problems is often facilitated if they are first translated into mathematical problems, or modelled in some mathematical system. (For an example of such a translation, in which the original problem was a musical one, see Stefan Bauer-Mengelberg and Melvin Ferentz, "On Eleven-Interval Twelve-Tone Rows", Perspectives of New Music, vol. 3, no. 2 (Spring-Summer 1965), pp. 93-103.) At a deeper level of analysis, one can say that any problem for whose solution there exists an algorithm has a mathematical (and, in fact, an arithmetic) model; see the works listed in footnote 69, *supra*.

[72] The temptation is, of course, to say that those steps are performable for which there exists an algorithm. The resulting circularity is obvious.

[73] Fermat's last conjecture — more generally, but perhaps incorrectly, referred to as his last *theorem* — is to the effect that $x^n + y^n = z^n$ has no non-trivial solutions (i.e., solutions in which both x and y differ from zero) in integers with $n > 2$. Ferdinand Lindemann, *Ueber den sogenannten letzten Fermat'schen Satz* (Veit, Leipzig, 1909); Robert Karl Hermann Haussner, *Das letzte Fermat-Theorem* (W. de Gruyter, Berlin, 1943). Pierre de Fermat was a French lawyer who studied mathematics as an avocation; he claimed to have proved the conjecture enunciated above, but his proof, if such there was, is not known. Nor has anyone since been able either to prove or to disprove the conjecture (which indicates that, at present, no algorithm is known for doing so). Lest it be thought, however, that Fermat — like the wonderful folks who brought us *Flook* — was one of those lawyers who, while dabbling in science, get in beyond their depth, it should be noted that his achievements in mathematics were considerable. See Michael Sean Mahoney, *The Mathematical Career of Pierre de Fermat (1601-1655)* (Princeton University Press, Princeton, N.J., 1973).

One might, of course, say that the non-performability of a step depending upon whether Fermat's conjecture is true or not is a function of present limits on our knowledge, and that, if and when Fermat's conjecture is ever decided, the step will become performable. But not all presently unsolvable problems are subject to the expectation that they may, at some time in the future, be solved; there are

The expression "mathematical formula" can — and, in *Flook,* alas, does — mean various things. The examples that follow are by no means intended to be exhaustive.

By "mathematical formula" one means, first of all, an expression that is a provable result (i.e., a theorem) in some system of mathematics. Examples would be (in two-dimensional Euclidean geometry) the Pythagorean theorem and the assertion that the length of the circumference of a circle is given by $2\pi r$, where r is the radius of the circle, and (in ordinary arithmetic) the multiplication table.

Even within mathematics proper, however, some expressions may on occasion be termed "mathematical formulas" although they are not theorems. Examples are:

(1) Definitional statements, such as "Let u = (x + 1)/x". These assign meaning to, and therefore introduce into the system, hitherto undefined terms (in our example, "u"), and they are true, not because of any fact of mathematics, but because they embody decisions as to how we choose to employ the terms defined.

(2) Equations, such as "sin x = ½". These are not provable theorems, because it is not the case that they are true for all values of the variables occurring in them; rather, they constrain the range of possible values of these variables. (Hence the problem posed by such an equation is, in general, not to prove, but to *solve* it, which means discovering the values of the variables that will satisfy it.)

(3) Statements such as "Set x = 1.75", which assign a particular value to a given variable.

Used more loosely, the expression "mathematical formula" can mean any statement couched in the language, or symbolism, of mathematics. It is useful to distinguish, among such statements, between those that express the laws of some science[74] and those that do

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essentially, or inherently, unsolvable problems [see Martin Davis, ed., *The Undecidable, Basic Papers On Undecidable Propositions, Unsolvable Problems And Computable Functions* (Raven Press, Hewlett, N.Y., 1965) and the review of the first twenty-nine items in that anthology by Stefan Bauer-Mengelberg, The Journal of Symbolic Logic, vol. 31, no. 3 (September 1966), pp. 484-494], and, to the extent that a step in the solution of a given problem is designed so that its performability depends upon the solution of one of these, the step will be essentially non-performable.

[74] These are often popularly referred to as *laws of nature,* e.g., in *Flook:*

> Reasoning that an algorithm, or mathematical formula, is like a law of nature, *Benson* applied the established rule that a law of nature cannot be the subject of a patent.

437 U.S., at 589; 198 U.S.P.Q. (BNA), at 197. It should be noted that *Benson* does not employ the expression "law of nature" except in a quotation from another case. (The passage quoted is the same as [20], hence the citations to the original may be found in

not. In the former category would be, for example, the gas law, PV = kT, k a constant, which asserts that (as is true within a certain range) the product of the pressure and the volume of a gas is directly proportional to its temperature (measured in the Kelvin, or "absolute", scale), as well as, presumably, the law of gravitation, $F = mm'/d^2$, to use a formulation quoted in *Flook*.[75] These are, in general, confirmed (or at least not yet disconfirmed) empirical statements, which is to say, statements that can in some way be subjected to experiential tests. But a word of caution is in order here. There is little question that in most systems of physics the gas law would be taken to be an empirical statement; pressure, volume, and temperature are independently measurable, hence the equation is subject to confirmation (and, in principle at least, to disconfirmation) by experiment. But not all statements in a given science, however empirical they may look on first inspection, actually are what they appear to be; some, rather, are definitional in nature. Moreover, a given statement may *sub silentio* change its status in a particular science over time. An illustration will, perhaps, make this clear.[76]

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footnote 56, *supra*. The quotation appears in 409 U.S., at 67; 175 U.S.P.Q. (BNA), at 675.) Perhaps the *Benson* Court felt restrained by the words of Mr. Justice Frankfurter, in his concurrence in *Funk Brothers, supra* (footnote 56):

> It only confuses the issue, however, to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.

333 U.S., at 134-35; 76 U.S.P.Q. (BNA), at 283.

Another reason why the use of the term "law of nature" is not to be encouraged is that one never knows whether a presumed, or alleged, scientific law is in fact a law of nature; such laws function as hypotheses and are always subject to correction or rejection (or to change of status, as explained *infra*).

[75] The quotation is from Rosenberg, *op. cit.* footnote 62, *supra*, and appears in footnote 15, 437 U.S., at 593; 198 U.S.P.Q. (BNA), at 199.

[76] We have intentionally chosen a simple example readily intelligible to all. For an analysis of the fundamental Newtonian laws of physics from this point of view, which raises the question whether the relationship expressed in the equation "$F = mm'/d^2$" really existed before Newton (as the quotation in footnote 62, *supra*, alleges), see H. Poincaré, *Science and Hypothesis*, in *The Foundations of Science*, translated by George Bruce Halstead (The Science Press, Lancaster, Pa., 1946), especially Part III ("Force"), Chapter VI ("The Classical Mechanics"). In general, see Morton G. White, "The Analytic and the Synthetic: an Untenable Dualism", in *John Dewey: Philosopher of Freedom, A Symposium*, edited by Sidney Hook (The Dial Press, New York, N.Y., 1950), pp. 316-330.

Prior to the seventeenth century, European ornithologists would have been justified in adhering to the proposition "All swans are white" and in viewing it as a generalization from observed experience. (For the purpose of simplifying the continuation, we shall ignore the existence of the South American black-necked swans.) However, in the seventeenth century Australia was discovered, and it is the home of *chenopis atrata,* a bird that we now call the black swan. When confronted with evidence of the existence of this bird, European ornithology experienced a mini-crisis; the system required adjustment. The adjustment that was in fact made was the discarding of the "law" that all swans are white; it was treated as a generalization arrived at prematurely, on incomplete evidence, ultimately to be disconfirmed by newly discovered facts. That reaction to the mini-crisis was indeed the appropriate one if the generalization was to be taken as an empirical statement,[77] but it must be noted that the European ornithologists had another option: they could have denied that this troublesome Australian bird was a swan, on the basis that, since it was not white, it obviously *could* not be a swan! Had that alternative been seized upon, the proposition "All swans are white" could have stayed in the textbooks of ornithology, but it would, of course, have undergone a radical change of character. No longer would it represent a generalization from experience; rather, it would be a consequence of a decision — made, not in the realm of ornithology, but in that of semantics — not to employ the word "swan" to refer to any bird unless, *inter alia,* it was white. In short, the statement would henceforth be true, not because the ornithological universe was furnished in a certain way, but because we saved it by the manner in which we chose to modify the definition of the term "swan".

Yet other statements fall even more clearly into the realm of those that are true by definition. A prime example is "water at sea level boils at 100 degrees centigrade and freezes at zero",[78] which, of course, does not disclose any startling discoveries about the properties of water, but, rather, articulates a determination how the centigrade measure of temperature is to be scaled.[79]

In the empirical realm, too, we find statements, couched in mathematical terms, that express neither scientific laws nor definitional truths. "The temperature at location *A* exceeds that at

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[77] Indeed, one could maintain that it demonstrated that the generalization *was* taken as an empirical statement.

[78] As in the dissent in *Flook,* 437 U.S., at 598; 198 U.S.P.Q. (BNA), at 201.

[79] It is therefore not clear what the dissent means when it says, *ibid.,* that "[a] patent could not issue" on this fact "even though newly *discovered*" (emphasis added).

location *B* by 20° F." need not express an invariant truth but may simply be descriptively true at some particular time. Yet other statements function as *pre*scriptions. Two examples, chosen from the world of business, may make this clear. (1) A law firm may have the fixed policy of billing a certain class of its clients at an hourly rate equal, in dollars, to one tenth of the number specifying, *anno domini,* the year in which the service was rendered.[80] Clearly this is not a *provable* equation; the rate could have been set differently, and the rule may at some time be changed. Rather, it is a proposal how the rate is to be determined. (2) Similarly, a bank may adopt a "mathematical" formula by which to set (or adjust) its prime rate. Such a formula might call for adding a fixed number of percentage points to a moving average — whether weighted or not — of some other, empirically ascertainable rate (say that paid on certificates of deposit in large denominations) for the prior three weeks.[81] Once the bank has decided to employ this formula for determining its prime rate, the level of that rate will, of course, be controlled by it, but there is no law of "nature", or of economics or banking, that demands that this particular formula be chosen, nor is the notion of prime rate defined by it.[82] The formula must be understood, not as encapsulating the *discovery* what the prime rate *is* — as if it were a pre-existing number, which had been waiting about for someone to stumble upon it — but, rather, as a device that with each given use, as it were, brings the number into being. A formula of that kind represents a decision how a certain aspect of a business is to be managed. It may, to be sure, incorporate a judgment about the optimization of revenues in a given economic situation, but it is not a law of business science.[83]

Armed with these preliminary considerations, let us now analyze *Flook.* We shall argue, first, that the result in *Flook* is not mandated by

[80] Thus services rendered in 1979 would be billed for at $197.90 per hour. The rate would not be low, but it would be relatively inflation-proof, and in that sense — as well as, obviously, in others — the example is a highly artificial one.

[81] If the number of percentage points to be added, instead of being specified outright, were made dependent upon whether Fermat's last conjecture (see footnote 73, *supra*) is true or false, we would have a mathematical formula for determining the prime rate without being able to state an algorithm for its evaluation.

[82] The prime rate is generally taken to be the rate of interest charged by a bank on loans to its most creditworthy customers. A not untypical version of a definition is "an interest rate at which preferred customers can borrow from banks and which is the lowest commercial interest rate available at a particular time and place." *Webster's New Collegiate Dictionary* (G. & C. Merriam Company, Springfield, Mass., 1975), at 914.

[83] There is, of course, considerable room for doubt whether there *are* laws of business science. In general, those disciplines that find it necessary to use the word "science"

Benson. We may do so even though Flook's own attempts, before the Patent and Trademark Office Board of Appeals, the Court of Customs and Patent Appeals, and the Supreme Court, to wriggle out from under *Benson,* based principally on the fact of post-solution activity, were brushed aside by the Supreme Court as an exaltation of form over substance,[84] echoing language that, if the Court of Customs and Patent Appeals is to be relied upon as a reporter, had already been employed by the Patent and Trademark Office Board of Appeals.[85] The Supreme Court's refusal to accept this argument as a sufficient basis for distinguishing between the cases does not, of course, preclude the possibility that they should be distinguished on other grounds; it does not *per se* make *Benson* on point. This would be so even if the Court's holding on this matter were correct. Actually, we shall argue in due time, the Court's fundamental analytical error in *Flook* prevented it from seeing the proper significance of the fact of post-solution activity.

We observe, initially, that, while the method defined by the claims in *Benson* meets the conditions of our (stricter) characterization of "algorithm", as can readily be seen by an examination of Claims 8 and 13, both of which are reprinted in the Appendix to *Benson,*[86] the formula in *Flook* is certainly not an algorithm.[87] It would, however, not

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in their names — domestic science, library science, commercial science, military science, juridical science, and, alas, computer science — are somewhat suspect as sciences.

[84] See [16].

[85] See [11].

[86] 409 U.S., at 73-74; 175 U.S.P.Q. (BNA), at 677. Thus, while the explication of the term "algorithm" tendered in *Benson* ([29]) is somewhat specialized in scope (see footnote 70, *supra*) and insufficiently specific in its use of the term "procedure", no erroneous or even tendentious use of it was made in that opinion.

[87] Of course, Claim 1 of the patent, as it appears in the Appendix to *Flook* (see footnote 26, *supra*) has, as any description of a *method* is likely to have, an over-all form suggestive of an algorithm, but, since the precise sequence of steps to be followed in calculating the number determined by means of the *Flook* formula is not in fact specified, as we shall do immediately *infra,* the claim, just like the formula that it contains, falls short of meeting our conditions for an algorithm.

It is apparent from the entire text of the *Flook* opinion, however, that, when the Court uses the term "algorithm", it is not speaking of the claim as a whole, i.e., of the entire method of updating alarm limits, but only of the formula which plays a central role in the method. Indeed, the terms "algorithm" and "formula" are used quite interchangeably. The following is typical: "The only difference between the conventional methods of changing alarm limits and that described in respondent's application rests in the second step [of the four comprising Claim 1] — the mathematical algorithm or formula." 437 U.S., at 585-586; 198 U.S.P.Q. (BNA), at 195. See also the Court's account of the holding of the Patent and Trademark Office

be difficult to write an algorithm for the computation that it specifies. This might include the following steps:

(1) Subtraction of F from 1.0;

(2) Multiplication of B_0 by the result of step (1);

(3) Multiplication of PVL by F;

(4) Addition of the results of steps (2) and (3).

Board of Appeals, [7], and its exegesis of *Benson,* in the sentence quoted in footnote 74, *supra.*

The characterization of the formula in *Flook* as an algorithm goes back at least as far as the opinion of the Court of Customs and Patent Appeals:

> The issue in this case is whether a claim to a process which *uses* an algorithm to modify a conventional manufacturing system is statutory subject matter under *Gottschalk v. Benson* . . . and *Christensen* . . . .

559 F.2d, at 22-23; 195 U.S.P.Q. (BNA), at 10. Emphasis original. That the court is here not referring to the entire method, but only to the formula, is clear not only from the word *"uses",* in the passage just quoted, but also from the following:

> *Christensen's* [sic in 559 F.2d (there is no italicization in 195 U.S.P.Q. (BNA))] holding of nonstatutory subject matter is expressly limited to claims directed to determining data used in an algorithm and solving the algorithm, that is, to claims in which nothing is done after solution of the algorithm. . . .Thus, *Christensen* does not render the claims before us unpatentable, because these claims include recitation of post-solution activity, a step in which the solution is applied to a control system.

559 F.2d, at 23; 195 U.S.P.Q. (BNA), at 11. Were "algorithm" taken to mean the method in its entirety, there would be no activity after the "solution" of the algorithm. The passage makes sense only if we take "algorithm" to refer to the formula, and "post-solution activity" to refer to the adding of the alarm offset to the updated alarm base as well as the adjustment of the alarm limit to the updated value thus obtained, these being steps (3) and (4) of Claim 1. 559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10.

Whether the patent examiner in the case or the Patent and Trademark Office Board of Appeals used the term "algorithm" to characterize the formula in *Flook* the present author, who has had available to him only the opinions of the Court of Customs and Patent Appeals and the Supreme Court, is unable to determine with any certainty, since it is not clear whether, when the Court of Customs and Patent Appeals writes that the examiner rejected the application because "the only part of this claimed invention which is not conventional is the particular algorithm used to adjust the alarm value" [559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10], it is giving a faithful indirect quotation or freely paraphrasing (and introducing the term "algorithm" on its own). Similarly for its account of the reasoning of the Patent and Trademark Office Board of Appeals, [11].

These could be performed in a number of possible orders,[88] and, to obtain an algorithm, we would have to select a particular one. Several subsidiary decisions would have to be made, depending upon the form in which B_0, F, and PVL are initially given, about such matters as the representation of fractions, and, if decimals are to be used, the degree of precision with which they are to be stated, whether there is to be rounding or truncation, and the like. Only then would we have anything resembling an algorithm.

Even though one can assimilate *Flook* to *Benson* by supplying an algorithm for the computation of the value specified by the formula in *Flook,*[89] the fact that in *Flook* a formula was at issue, and in *Benson* an algorithm — would that they had been called that, without a cross-over in terminology! — is not without significance, for it points to a fundamental difference between the two cases. One generally speaks of an algorithm when the focus of discussion is on the details of computation,[90] and of a formula when the specification of a value is the significant point. To be sure, the *Flook* method was intended to be computationally implemented,[91] and that would not have been possible unless it could yield a derived algorithm, but the novelty, the invention, was not one of details of calculation; what was sought to be patented was not *how* a weighted average was to be computed, but *that* it was to be computed.

To point up this difference, let us suppose that disputes had arisen, first, in the billing department of our hypothetical law firm, about the best method of calculating the rate at which a given service should be billed, and, second, among the officers of our hypothetical bank, about how the prime rate ought to be set.

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[88] 1-2-3-4; 1-3-2-4; 3-1-2-4. Of course, if we were prepared to be somewhat less faithful to the notation of the *Flook* formula (see page 81, *supra*), the algorithm could also call for the multiplication of B_0 and F, followed by the subtraction of the product from B_0. (If these steps were to take the place of (1) and (2), in the text above, respectively, the resulting possible *sequences* of steps would remain the same.) There are obviously other variants, still less faithful to the notation of the original formula, that would lead to the same result.

[89] One notes — not without regret — that *Benson* also employs the term "mathematical formula" (see, e.g., [4]), even though the claims reproduced in the opinion (citations in footnote 86, *supra*) fail to contain a formula.

[90] It is not an accident that the theory of computability and the theory of algorithms are taken to be the same thing. See the works listed in footnote 69, *supra*.

[91] "Although the computations can be made by pencil and paper calculations, the abstract of disclosure makes it clear that the formula is primarily useful for computerized calculations producing automatic adjustments in alarm settings." 437 U.S., at 586; 198 U.S.P.Q. (BNA), at 195-196. Footnote omitted.

The billing clerks in the law firm operate within the guidelines established by the partners, which essentially dictate what the rate should be. The clerks are not at liberty to change the rate; for them the problem is merely that of discovering this abstractly predetermined number. Assume now that three different clerks make three different proposals how this should be done,viz.:

(1) Write down, in decimal notation, the number of the year A.D. in which the service was rendered. Place a decimal point before the last digit and append a trailing zero. Place a dollar sign before the first digit. The resulting expression will represent the hourly rate to be charged.

(2) Analogously, using long division by 10, correct to the second decimal place.

(3) Analogously, using multiplication by .10.

It is, of course, provable that each of these will give the identical, unique correct answer; from that point of view, none is superior to the others. But that does not prevent one or the other from being superior from the point of view of ease of calculation, say (1) for persons with low arithmetic skills doing it manually, or (3) for persons with a hand-held calculator of a certain type. The question which method of calculation is to be used, however, arises only *after* the policy decision as to what the rate is to be has been made.

Contrast that situation with one in which the officers of our hypothetical bank are proposing alternate formulas for setting (or adjusting) the prime rate. Suppose that the suggestion is made that the rate be set, not as specified above, but by adding a certain fixed number of percentage points to a weighted average of the Federal discount rate and the commercial paper rate. Unlike the dispute in the billing department of the law firm, which concerned the *better way of computing a number,* the dispute in the executive suite of the bank would concern the *way to compute a better number.* These are two vastly different matters; commutativity does not apply here. Nothing will show this more clearly than a moment's reflection on the fact that the meaning of "better", in the two expressions, is entirely different. In the former, "better" relates to computational methods; in the latter, to the prime rate determined.[92]

[92] I.e., the rate arrived at is better from the point of view of the scheme of values within which the organization — here the bank — operates. These may concern more than profitability: e.g., safety, staying within Federal and state banking regulations, and so forth.

We are now in a position to recognize that the two algorithms — the one actually in *Benson* and the one putatively in *Flook* — are basically of quite different types, and that it therefore does not automatically follow, from the fact that both may be termed algorithms, that they merit identical treatment under the patent laws.

The claim in *Benson* was clearly of the type "better way of computing a number". For, given a number expressed in binary-coded decimal notation, there is only one correct representation of it in pure binary notation. Hence, for any particular input to the process, the numeral that the method must yield — if it is to be the correct one — is already determined. The only open question is that of the technique to be used in arriving at that representation. To express it in another way: for a given number in BCD notation, there are not better and worse representations in pure binary notation (making it of interest to us to compute the better one); there is a unique correct representation, and what we should be interested in seeking is better ways of arriving at it. The relationship between the BCD representation and the pure binary representation of a given number is determined by a law of mathematics,[93] and in fact one can prove a theorem to the effect that the algorithm claimed in *Benson,* in either of the forms given

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[93] More precisely, perhaps, by a law of *meta*mathematics, the study that takes as its objects, not mathematical entities such as numbers or circles, but statements about and expressions denoting such entities. Thus metamathematics is the theory of mathematical theories. See, e.g., Stephen Cole Kleene, *Introduction to Metamathematics* (D. van Nostrand Company, Inc., New York, N.Y., 1952). Since the algorithm in *Benson* relates numerals, which are expressions, in given systems of notation, denoting numbers, it is not an algorithm in mathematics (e.g., about numbers), but in metamathematics (about representations of numbers in some system of notation). The subject of metamathematics is itself studied by means of techniques that are, in many cases, mathematical, and there is no reason to suppose that its theorems constitute subject matter for patents any more than do the theorems of mathematics.

There clearly was, in the Patent and Trademark Office itself, some awareness of the fundamental issue, for Stanislaw J. Soltysinski, in "COMPUTER PROGRAMS AND PATENT LAW: A COMPARATIVE STUDY", Rutgers Journal of Computers and the Law, vol. 3, no. 1 (1974), pp. 1-82, writes, with respect to *Benson:*

> In his arguments, the Commissioner of Patents asserted that Respondents' conversion theory followed automatically from the definitions of pure binary, decimal, and BCD numbers, and from the axioms for or definitions of addition and multiplication in the binary system and, therefore, did not embody the kind of discovery contemplated either by the Constitution or the Patent Act.

At 37. The footnote (no. 147) at the end of this passage reads "Brief for Petitioner at 15, 17-31" (referring, apparently , to additional quoted excerpts as well).

there,[94] will accomplish the correct transformation. The algorithm, therefore, is bottomed on, or guaranteed by, this theorem, and, as the case law clearly indicates, theorems are not statutory subject matter for patents. Thus the algorithm in *Benson* fails of statutory patentability on either of two grounds: what is essentially involved is either a (meta)mathematical theorem, or a better way of computing a number (more precisely, of arriving at a numeral) whose identity, so to speak, is determined by the (meta)mathematical theorem.[95]

The situation is quite different in *Flook*. If all that Flook had been seeking to patent were an algorithm — even a particularly elegant algorithm — for computing the value of B_1, *given that* the computation was to be in conformity with his formula,[96] then indeed his algorithm should fall under the proscription of *Benson*. In that case, what Flook would be proposing would be "a new and presumably better method for calculating"[97] a number in essence already determined by an anterior policy decision; he would, in effect, simply be providing a more convenient, efficient, or reliable way of *discovering* this number. But the *Flook* claim is quite indifferent to the question which method is used to accomplish the arithmetic operations called for by the *Flook* formula; from that point of view, the notion of algorithm plays a distinctly subsidiary role here. What Flook is asserting is that his formula can be used to update alarm bases; accordingly, he must be understood, not as claiming a "better method for calculating alarm limit values"[98] — in the sense, just discussed, of one that improves on the technique of calculation — but as *proposing* that the weighted average of the current alarm base and the present value of the process

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[94] The citations may be found in footnote 86, *supra*.

[95] Perhaps this clears up at least a part of the mystery spoken of by Judge Rich in his concurrence in *In re Christensen, supra* (footnote 37):

> "Algorithm" has been used in the sense of a "procedure for solving a given type of mathematical problem" and "formula" is used in the sense of a mathematical formula. The Supreme Court in *Benson* appears to have held that claims drafted in such terms are not patentable — for what reason remaining a mystery.

478 F.2d, at 1396; 178 U.S.P.Q. (BNA), at 39.

[96] E.g., if his invention had consisted in the discovery that one of the three sequences given in footnote 88, *supra*, for the computation was superior to the others (while acknowledging that all of them lead to the same result).

[97] The language is that of [26].

[98] The language is that of [26].

variable constitutes a better (or at least acceptable[99]) way of determining a new alarm base. What he is offering, therefore, is not of the type "better way of computing a number", but of the type "way to compute a better number".

The number B_1, the key ingredient of the updated alarm limit, is not determined, apart from and prior to the decision to employ the *Flook* formula, by any theorem of mathematics. For a given B_0 and PVL, there might — so far as mathematics is concerned — be a wide range of possible B_1's that would work, i.e., would be acceptable from the point of view of the operation of the system. The formula, garbed though it is in the language of mathematics, does not express a truth of mathematics, but, rather, a judgment about alarm limits and therefore, presumably, about the operating characteristics of a catalytic converter.

Now one might object that the catalytic conversion of hydrocarbons involves the laws of chemistry, of structural engineering, and so forth, and that the *Flook* formula in some way "expresses" these. But there is no evidence whatsoever that the alarm limit has as its sole purpose, say, the prevention of an explosion. For all we know, it may also signal deterioration of the quality of the product, entry into an uneconomic range of operation, and the like. The *Flook* opinion itself recognizes the possibilities both of inefficiency and of danger.[100] Certainly no known science contains laws that relate all of these notions.

Thus, whereas the *Benson* algorithm must be understood as essentially analogous to a method for ascertaining the billing rate, in the billing department of our hypothetical law firm, the adoption of the *Flook* formula represents a decision analogous to that made by our hypothetical bank, in setting its prime rate.[101] The *Benson* choice is

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[99] Whether the number computed in accordance with the *Flook* formula is actually better — from the point of view of the operation of the catalytic converter — than one computed otherwise is not clear from the opinion; it may well be that, as a compromise for the convenience of automation, fine-tuning has been sacrificed. This does not change the fact, however, that "better", in *Flook*, does not refer to arithmetic details.

[100] 437 U.S., at 585; 198 U.S.P.Q. (BNA), at 195.

[101] Nothing in our choice of these examples in the present context is intended to suggest that formulas for billing the clients of law firms, or for setting the prime rate of a bank, should be patentable. They are unpatentable, however, not because there are algorithms that will compute their output under given circumstances, but, rather, because methods of doing business — a category into which formulas of both kinds would clearly fall — have long been held to be unpatentable:

> [A] system of transacting business, apart from the means for carrying out such system, is not within the purview of section 4886, supra [35 U.S.C.A. §31, the precursor of 35 U.S.C. §101].

made within mathematics, the *Flook* choice within the industrial activity of operating catalytic converters.[102]

Let us now return to the matter of post-solution activity. It was presumably chosen as basis for an attempt to distinguish *Flook* from *Benson* because *In re Christensen* had left open the possibility that post-solution activity might have import different from that of

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In re Patton, 127 F.2d 324, at 327 (C.C.P.A. 1942, *reh. den.* June 12, 1942).

> It is a rule of universal application that an object is not patentable where its novelty consists wholly in an arrangement of printed matter or in a method or system of doing business.

Conover v. Coe, Com'r of Patents, 99 F.2d 377, at 379 (D.C. App. 1938).

The formula in *Flook,* however, is not a method of doing business; rather, it is a feature of a procedure for controlling a chemical process, and it therefore does not partake of the frailty of our examples, which should be understood as having been introduced purely for the purpose of making clear the distinction between arriving at, or deciding upon, a formula that will be used to control some activity (whether business or industrial) and the consideration of alternate ways in which the values of the output variable determined by such a formula for given values of the input variables may be computed. (The choice of a *formula* for the billing of clients, of course — rather than the choice of a *method* of computing the values determined by a formula already chosen — is one that is made, not within mathematics, but within the business of lawyering, and it is in principle quite analogous to the choice of a formula for setting the prime rate.)

That these notions were not foreign to the Court of Customs and Patent Appeals is indicated by the following passage from the dissent, by Judge Miller, with whom Judge Baldwin joined, in *Application of Bergy, supra* (footnote 16):

> However, this court has pointed out that claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not.

563 F.2d, at 1041; 195 U.S.P.Q. (BNA), at 353. Emphasis original. This passage was written after the court's opinion in *Flook* (indeed, *Flook* is among the cases cited immediately after it) but before the Supreme Court's.

[102] While one must be tolerant of varied usage of the term "mathematical formula", there is no reason to accept it in the case of the term "mathematical problem", which should be used only to refer to problems *in* mathematics. It is therefore pure self-deception for Mr. Justice Stevens to write, as he does in his footnote 1:

> We use the word "algorithm" in this case, as we did in *Gottschalk v. Benson,* ... to mean "[a] procedure for solving a given type of mathematical problem ... ."

437 U.S., at 585; 198 U.S.P.Q. (BNA), at 195. (The inner quotation is from [29].) *Flook* concerns, not a mathematical problem, or procedures for solving one, but a mathematical procedure for solving an industrial control problem, which is quite a different matter.

Again, the Court of Customs and Patent Appeals has shown itself quite aware of the point, as is shown by the following passage from Chief Judge Markey's opinion in *Application of Freeman, supra* (footnote 13):

pre-solution activity.[103] But the discussion of post-solution activity throughout *Flook* seems to have revolved entirely about its presence or absence, with no attempt made to delve into the question of the relationship of such activity to the type of algorithm or formula at issue. It should now be clear that, for a formula (or derived algorithm) of the *Flook* type, its very *raison d'être* is post-solution activity. One does not set a prime rate *except* to lend money at that rate (or to discourage potential borrowers who are not prepared to pay it). Similarly, one does not compute a value of B_1 by means of the *Flook* equation *except* to use it in the updating of an alarm limit. Determining a value of B_1 cannot conceivably have any other purpose. The transformation of binary-coded decimal notation into pure binary notation in *Benson,* however, represents the solution of a (meta)-mathematical problem in and of itself; this solution has intrinsic — even if "only" theoretical — value, and whether it is then applied, in the control of switching circuits, say, is irrelevant to an assessment of its correctness. Post-solution activity in the *Benson* case, in short, is frosting on the cake. In the *Flook* case it *is* the cake; it is certainly not "a mere matter of form".[104]

> As a bare minimum, application of *Benson* in a particular case requires a careful analysis of the claims, to determine whether, as in *Benson,* they recite a "procedure for solving a given type of *mathematical* problem."

573 F.2d, at 1245; 197 U.S.P.Q. (BNA), at 470. The inner quotation is, of course, again from [29], and the emphasis on the penultimate word was added by Judge Markey. Unfortunately the opinion goes on to list *Flook* among the cases that illustrate the following sentence:

> In some claims, a formula or equation may be expressed in traditional mathematical symbols so as to be immediately recognizable as a mathematical algorithm.

573 F.2d, at 1246; 197 U.S.P.Q. (BNA), at 471.

[103] See [10], [12], [13]. Indeed, when one reflects on the use of this argument and the heavy reliance on the disclaimer of pre-emption (see [8] and the text accompanying footnote 51, *supra*), one cannot help but get the impression that Flook's litigation strategy in avoiding *Benson* was framed much more by the desire to utilize the meager pickings yielded by the search for precedents than by an effort to develop analytically the particular features of his case. In fact, as we shall argue (see footnote 128, *infra*), the scope of the notion of pre-emption is quite different in the two cases.

[104] The language is that of [11].

The current box-score in our comparison of *Benson* and *Flook,* then, is this:

Benson	*Flook*
(1) Algorithm, but no formula;	Formula, but no algorithm;
(2) (Meta)mathematical theorem as underpinning;	No theorem (from any discipline) as underpinning;
(3) Indifferent to post-solution activity.	For the sole purpose of post-solution activity.

It is hardly a recipe for being on all fours, even if we admit that the first item in the comparison represents a "curable" distinction.[105]

We can now address the major question, whether the *irreconcilable* differences between the two cases — the unpleaded and undiscussed second item in the list above, and the apparently mispleaded and misunderstood third — should entitle the *Flook* claim to different treatment under the patent laws from that meted out to the *Benson* algorithm. In order to approach this question, we must ask whether, in the light of our analysis, what one might call the broader rationale of *Benson* applies to *Flook,* or, for that matter, whether the principles, precedents, and examples cited in *Flook* itself have any relevance.

It is our contention that *Benson* is not a precedent from which *Flook* can be reached by a small extension.[106] It is, in fact, almost entirely irrelevant to the problem in *Flook.* And, harsh though it may seem to say it, the same is true of most of the argumentation in *Flook* itself.

The underlying ideology of *Benson,* of course, is that science — whether empirical or mathematical — is not patentable,[107] and this is repeated often enough in *Flook.*[108] It is clearly a correct statement of the law, and the policy consideration that buttresses it — that scientific truths, those that are as yet undiscovered as well as those that have been discovered, are in some sense the common property of mankind — seems unexceptionable. While the patent law — wisely, no doubt — refuses to introduce or recognize a distinction between the notion of invention and that of discovery,[109] the common-sense distinction, to the effect that discovery is the uncovering of something that already exists, while invention is the creation or development of

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[105] Curable, but by no means irrelevant, for reasons stated and once more repeated: in *Benson,* quite properly, the mode of computation is the heart of the matter, while in *Flook* it is a side-issue — the invention resides in the number to be computed.

[106] As is suggested by [14].

[107] See [5].

[108] See [19], [20], [23], [24].

[109] See the definition of "invention" in 35 U.S.C. §100(a), and also 35 U.S.C. §101.

something that is new,[110] must be kept in mind; in its terms it is invention, not discovery, that may be rewarded by patent protection.[111] And scientific truths, in general, are discovered, not invented.

The *Flook* formula, however, is not "a scientific truth, or the mathematical expression of it."[112] It is not a truth at all. As a proposal, albeit in mathematical terms, for the management of an aspect of an industrial process, it is within the range, not of predicates such as "true" or "false", "correct" or "incorrect", but, rather, "wise" or "foolish", "practical" or "impractical", "sound" or "unsound", and the like. Thus it is nonsense to say that "a scientific principle, *such as* that expressed in respondent's algorithm, reveals a relationship that has always existed",[113] and there is no reason why the formula must be "treated as though it were a familiar part of the prior art",[114] or why "this case must also be considered as if the principle or mathematical formula were well known".[115] Accordingly, the assumption in [25] is undercut, and it no longer follows that the application "contains no patentable invention."

The examples of the multiplication table,[116] the Pythagorean theorem,[117] and the formula "$2\pi r$" for the circumference of a circle[118] (stated as a function of its radius) are completely beside the point. These are provable theorems (or restatements of the contents of provable theorems), laws of mathematics, necessarily true,[119] and in that sense analogues of the theorem underlying the *Benson* al-

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[110] The patent law, of course, requires newness for patentability (see footnote 2, *supra*), thus eliminating discovery, in the common-sense signification, from being patentable.

[111] "So fundamental is this technical distinction between 'inventions' and 'discoveries,' that only inventions are patentable — naked discoveries are not!" Rosenberg, *op. cit.* footnote 62, *supra*, at 13. Footnote omitted.

[112] The language is that of [19].

[113] The language is that of [24], emphasis added. What Mr. Justice Stevens is guilty of here is a category-mistake, to use an expression introduced by Gilbert Ryle. See his *The Concept of Mind* (Hutchinson House, London, New York, Melbourne, Sydney, Cape Town, 1949), at 16 ff.

[114] The language is that of [21].

[115] The language is that of [22].

[116] 437 U.S., at 598; 198 U.S.P.Q. (BNA), at 201. (Dissent.)

[117] See [16].

[118] See [26].

[119] In their respective systems, of course. In a non-Euclidean two-dimensional geometry the formula "$C = 2\pi r$" will not hold generally, although this fact may not become apparent, within the threshold of discrimination of their measuring in-

gorithm. The *Flook* formula, however, is not a self-sufficient scientific achievement, but only a component of a certain method for controlling a catalytic conversion process. It represents, not the discovery of an abstract truth, but a judgment how an industrial activity may be carried out. Mathematical theorems indeed should not be patentable, but that does not entail that the *Flook* formula ought not to be.

We might point out here that the Court's arguments about post-solution activity in connection with the Pythagorean theorem and the formula "$C = 2\pi r$" are also misconceived. Applying these theorems to problems of surveying or measurement is an incidental use of an antecedently established truth, and that, of course, cannot "transform an unpatentable principle into a patentable process".[120] But to argue similarly with regard to the *Flook* formula — in order to establish that, in spite of post-solution activity, it is unpatentable — is, of course, to beg the question whether that formula is an "unpatentable principle" in the first place. It is hardly a fair statement of what is being proposed in *Flook*.[121]

Just as the Court's mathematical examples are irrelevant, so are those taken from empirical science, like the law of gravity,[122] phenomena of nature,[123] such as that of magnetism,[124] and anything else that may be considered the mathematical expression of a scientific truth,[125] a law of nature,[126] or a scientific principle.[127] Unlike, say, the

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struments, to persons making measurements within a sufficiently small region of such a space. However, it would seem to require an altogether excessive suspension of disbelief to impute such notions to the Supreme Court, and injecting them into the discussion would in any case merely serve to transform the formula "$C = 2\pi r$" from one of pure mathematics into one of empirical science, which, as we shall see next, still does not make it like that in *Flook*.

120 The language is that of [16].

121 Strictly speaking, of course, to keep the Court's argument about the use of the Pythagorean theorem analogous to the *Flook* claim would require claiming, not the theorem, but only its application in surveying. (Perhaps that is what the Court means by the phrase "partially patentable". See [16].) Even if we grant, however, that the application should not be patentable — and, in view of [18], [19], [20], and [21], it is not at all clear that this must be granted — it would still not follow that use of the *Flook* formula in updating alarm limits should not be patentable, since, as we have argued, the formula has been proposed for no other purpose.

122 See footnote 62, *supra*.

123 See [6], [20], [23], [25].

124 437 U.S., at 598; 198 U.S.P.Q. (BNA), at 201. (Dissent.)

125 See [19].

126 See [18], [20], [23].

127 See [22], [24], [25].

gas law — to take the most clearly empirical of the examples discussed, even if it was ours rather than the Court's — the *Flook* formula states no relationship between independently measurable quantities; B_1 is *set,* rather than shown to be, equal to the number yielded by the right side of the equation.

Thus one may grant that the results of mathematics, the laws of science, the phenomena and principles of nature, and even "better ways of computing a number" all are outside the realm of statutory subject matter and still not be compelled to reach the result in *Flook.* The Court's digression into scientific matters has been a wild-goose chase. At the end of it, the *Flook* formula may still fall into the category of "'discoveries' that the statute was enacted to protect".[128]

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[128] The language is that of [23]. Now that we are at the end of our analysis, we are, perhaps, in a position to shed some light on the point in *Benson* that the *Flook* Court found "not entirely clear" ([17]) — "why a process claim is any more or less patentable because the specific end use contemplated is the only one for which the algorithm has any practical application" (*ibid.*), and in doing so relate the three strands, of pre-emption, post-solution activity, and the patentability of science, that run through the *Flook* opinion. Indeed, there is no reason to believe that the finding of pre-emption ([4]) in *Benson* was analytically necessary for the result in that case. Benson used a machine to do pure mathematics only, and that was enough, under the case law, to make his process nonstatutory, whether or not it would ever have been used other than in connection with a computer. Note that the notion of pre-emption in *Benson* is a lateral one: it has to do with the possibility of the existence of alternate modes of *accomplishing* the calculation. The *Benson* Court did not have before it the question of the patentability of possible uses of the *Benson* process (once it had been executed by a computer), say in the control of switching circuits. But let us suppose for a moment that Benson had claimed such an application (and only that). In a sense, that would have made his case more like *Flook,* because then Benson, too, would have looked toward controlling a physical process by use of the result of his calculations. Still, an ineradicable difference would remain: the *Benson* calculations are made in accordance with a theorem. Benson did not invent the relationship between the BCD representation and the pure binary representation of a number, and it would have been known, even before he came upon the scene, what the required result would have to be for a given instance of calculation. Flook's disclaimer of pre-emption, however, may be said to be vertical. It applies, not to alternate modes of *accomplishing* the computation — indeed, he seems not even to have claimed any one specific mode of doing that — but, rather, to possible alternate ways of *using* the result computed. He was not trying to patent a computerized calculation of weighted averages *per se,* which, as the direct analogue of what Benson claimed, would clearly have been nonstatutory. He claimed solely the use of his calculations in the updating of alarm limits in the catalytic chemical conversion of hydrocarbons. It is in this sense that post-solution activity is of the essence in *Flook,* and there is no scientific theorem that links the notion of a weighted average to that of the updating of an alarm limit. For all we know, had Flook not proposed using a weighted average in this context, no relationship would ever have existed between the two. Thus there are situations

Now it may very well be that the *Flook* patent should have been denied. It is, for example, conceivable that the formula would have failed on grounds of obviousness, under 35 U.S.C. §103.[129] It is also possible, though less likely, that the claim would have failed under 35 U.S.C. §102, which explicates the condition of novelty; less likely, because the *Flook* opinion seems to concede novelty.[130] The Court, of course, did not have to reach these questions, under its own ground rules.[131] Finally, it is possible that the formula should have failed of patentability for not being statutory subject matter after all; if so, however, that would have had to be for reasons not stated in the opinion of the Court.

It would, therefore, be going beyond the evidence to say that the case was wrongly decided. It may well have been, and indeed most likely was, but we do not at present know this with any certainty. What we can say with certainty is that, if the case was correctly decided, it was so decided for the wrong reasons. Perhaps the holding of *Flook* — even if correctly understood — represents the Court's sense of the law, but it surely is not a consequence of the reasons advanced in the opinion. Indeed, we are faced with the ironic fact that the one adequate argument for denying the patent was made by the examiner in the

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in which, if "the specific end use contemplated is the only one for which the algorithm has any practical application" ([17]), this might in fact militate for, rather than against, patentability — cutting the other way from that contemplated in *Benson* itself.

[129] 35 U.S.C. §103 makes it clear, of course, that obviousness must be judged by persons skilled in the art, and not by writers of cantankerous articles for law reviews. The present author knows next to nothing about the catalytic conversion of hydrocarbons, and he is therefore in no position to judge whether the use of a weighted average of an old alarm base and the present value of the process variable in the updating of alarm limits in the process would be obvious under §103.

[130] And not just *arguendo*, as in [15]. See [26], as well as the Patent and Trademark Office Board of Appeals opinion on the matter, reported in 437 U.S., at 587; 198 U.S.P.Q. (BNA), at 196, and, lastly, the phrase "the solution of respondent's novel formula" in the Appendix to the Court's opinion, 437 U.S., at 598; 198 U.S.P.Q. (BNA), at 200.

[131] "The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious." 437 U.S., at 593; 198 U.S.P.Q. (BNA), at 198-199. This seems to be a one-way street, however, preventing the parlaying of novel and non-obvious processes into statutory subject matter, for, in *Dann v. Johnston, supra* (footnote 1), a finding of obviousness was explicitly relied on by the Court to enable it to avoid reaching the problem of statutoriness. 425 U.S., at 220; 189 U.S.P.Q. (BNA), at 258.

original rejection,[132] promptly to disappear from the case.[133]

This is perhaps the proper place to note that, from the point of view of the quality of analysis, the dissent does no better than the majority opinion. The dissenters[134] see the issue as

> whether a claimed process loses its status of subject-matter patentability simply because *one step* in the process would not be patentable subject matter if considered in isolation.[135]

This shows, of course, that they essentially subscribe to the mistaken view of the majority; they diverge in result because — once they, like the majority, accept Flook's argument that the patent would pre-empt, not all uses of the formula, but only those that occur in the particular application to which the claim relates[136] — they regard *Benson* as wholly inapplicable on the question of statutoriness. In general, the dissent fully endorses the opinion of the Court of Customs and Patent Appeals.[137]

The net result, then, is that we see a unanimous[138] Court making a fundamental analytical error. The error is one of equivocation, of failing to distinguish among several possible meanings of the term "mathematical formula", and of falling into the trap of applying principles that properly[139] control *Benson,* given the type of formula that was (putatively) at issue there,[140] to *Flook,* which concerns a formula of an entirely different type, one to which the underlying rationale of these principles does not apply. The equivocation affects

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132 See [9].

133 It would, of course, have been of the greatest interest to learn whether the Supreme Court would endorse that argument. Its potential reach, however, seems staggering, affecting, as it would, much of the technology of automated process control in general, and of servomechanisms in particular, and it is therefore probably wide of the mark as a statement of the law.

134 The dissent was written by Mr. Justice Stewart, with whom the Chief Justice and Mr. Justice Rehnquist joined. 437 U.S., at 598; 198 U.S.P.Q. (BNA), at 201.

135 437 U.S., at 599; 198 U.S.P.Q. (BNA), at 201. Emphasis original. A footnote (giving the text of 35 U.S.C. §100(b) (see footnote 2, *supra*)), has been omitted.

136 See text accompanying footnote 51, *supra.*

137 437 U.S., at 600; 198 U.S.P.Q. (BNA), at 202. We shall draw the veil of mercy over the question who has the better of the argument on those points on which the dissent differs from the majority opinion.

138 The decision was 6:3.

139 For *Benson* was surely correctly decided (see footnote 128, *supra).* (The *analysis* in *Benson,* however, has not escaped criticism. See Judge Rich's concurrence in *In re Christensen, supra* (footnote 37), 478 F.2d, at 1395-1396; 178 U.S.P.Q. (BNA), at 38-39.)

140 See the sentence quoted in footnote 74, *supra.*

the Court's entire opinion, beginning with its introductory paragraph,[141] which clearly homologizes the *Flook* formula to the one supposedly in *Benson*. The equivocation is then carried over, with an equal lack of discrimination, into the various arguments depending upon the term "algorithm",[142] and its effect is enhanced by systematically ambiguous use of expressions such as "improved method of calculation".[143] That is a formula for intellectual disaster.

Now we do not, of course, expect judges — or even Justices — to be experts in subject matter, other than, perhaps, the law. Nor is it the duty of the Justices to spot error, unless it be plain error in the technical sense. Our theory of litigation is, after all, that it is up to the parties to frame the issues and to bring to the attention of the tribunal the materials necessary for and relevant to a decision. But that reflection simply raises the further question why, along the entire road that this case traveled, there was not one lawyer[144] or judge — or even law clerk! — able to discern the real significance of the fact of post-solution activity, which figured in the discussion from the examiner to the Supreme Court, or with a sufficient grasp of the structure of science to make the necessary distinctions, fairly clamoring to be made, between kinds of mathematical formulas.[145]

This suggests that, quite likely, the case would not have gone so differently if — as has been proposed[146] — we had something like a Patent Court. Such a court might be conducive to greater uniformity of patent decisions, and it would presumably relieve the dockets of the District and Circuit Courts somewhat. In theory, at least, the Patent

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[141] See [14].

[142] See [7], [8], [17], [18], [21], [24], [25], [27], [29], as well as the sentence quoted in footnote 102, *supra*.

[143] The language is that of [27]. See also [26] and [28].

[144] The case was apparently argued by different law firms before the Court of Customs and Patent Appeals and the Supreme Court. Compare 559 F.2d, at 21; 195 U.S.P.Q. (BNA), at 9, with 437 U.S., at 584; 198 U.S.P.Q. (BNA), at 195.

[145] One wonders, also, what happened to the expertise shown by the Patent and Trademark Office in its analysis of the situation underlying *Benson* (see footnote 93, *supra*). Did the persons handling the *Flook* case really think that it resembled *Benson* in any significant respect?

[146] E.g., by Judge Henry J. Friendly, in his 1972 Carpentier Lectures at Columbia University, published as *Federal Jurisdiction: A General View* (Columbia University Press, New York, N.Y., 1973). See Part VIII, "Patents and Taxes", at 153-171. Quotations from this book are used by the kind permission of Columbia University Press.

Court would be staffed largely from the patent bar,[147] and that should, of course, raise its level of scientific comprehension above that of the average court.[148] But the Court of Customs and Patent Appeals is not in this sense an average court, and while — although it, too, used the term "algorithm"[149] — it was not trapped into equivocation, its analysis, which trafficked heavily in the fact of post-solution activity, still did not penetrate to the heart of the matter, so that it was unable to fashion an opinion clear and incisive enough to forestall the disastrous misunderstandings of the Supreme Court.

It is interesting to speculate, also, how Flook's application would have fared if, instead of claiming a process, he had built and claimed apparatus whose workings would accomplish precisely what his process claim contemplates. It is not at all difficult to dream up such a contraption. The calculations that the *Flook* formula calls for are, after all, rudimentary and do not really require the services of a modern high-speed digital computer, however convenient one might be as a tool for getting them done. They could equally well be executed by an analog computer — one that represents numerical quantities in terms of (and performs calculations by manipulating) some physical unit, such as the volume of a liquid, a voltage, or the rotational position of a polished steel shaft. In practice, of course — since the physical unit must be measured at the end of the procedure — an analog computation yields a somewhat cruder result than a digital one, but the results could certainly be made functionally equivalent within the degree of precision required by the *Flook* process.

Would such a device be statutory subject matter?[150] We cannot, of

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147 "The patent bar, from whom most of the members of the court should be drawn . . .". Friendly, *op. cit.* footnote 146, *supra,* at 159.

148 "I am unable to perceive why we should not insist on the same level of scientific understanding on the patent bench that clients demand of the patent bar." Friendly, *op cit.* footnote 146, *supra,* at 157.

149 It also at one point terms the *Flook* formula a "mathematical control equation" [559 F.2d, at 22; 195 U.S.P.Q. (BNA), at 10], which seems a reasonable solution to the problem of describing its form of expression as well as its purpose.

150 Of course, if it were known that the device merely simulated a computation of the value given by the formula — on resubmission of the Flook application as an apparatus claim, say — the application might be held to run afoul of some language in *Application of Richman, supra* (footnote 67), viz.:

> That a claim includes a mathematical expression is not determinative. The decisive factor is whether a claimed method is essentially a mathematical calculation. If it is, deletion from the claims of the mathematical formula involved and substitution of "words which mean the same thing" would not transform the claimed method into statutory subject matter.

course, conclusively establish what the response of the Patent and Trademark Office and the courts would be. What does seem clear is that none of the arguments advanced against the patentability of the *Flook* formula — dependent as they are upon notions such as those of mathematical formula, algorithm, and scientific principle — would apply against the apparatus. Moreover, not even the abandoned argument of the examiner in the *Flook* case,[151] which does militate against the patentability of the formula, would apply. It is therefore not unreasonable to suppose that the apparatus might have a better chance than the formula of surviving scrutiny under 35 U.S.C. §101, despite the fact that the two perform essentially the same operation.

Now would not a categorization that makes the apparatus patentable, and the formula not, really be one that "exalts form over substance"[152]?

This case calls into question, in the most troubling way, the adequacy of the assumption that lawyers, as generalists, do not need training in specialties (except, possibly, legal ones) in a time when technical problems of all kinds — not merely scientific ones, but, certainly, economic ones as well — are the focus of intense litigation. Surely many of the technical issues are bound to exceed the

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563 F.2d, at 1030; 195 U.S.P.Q. (BNA), at 344. However, there are two reasons why this should not be applicable. One is that — as we have argued extensively — we are not, in *Flook,* dealing with a method that "is essentially a mathematical calculation". There can be no doubt that the *Richman* court interpreted this notion correctly and applied it properly; Richman claimed a method for calculating an average boresight correction angle for an airborne radar and a method for calculating the average vertical velocity component of the aircraft carrying the radar [563 F.2d, at 1027; 195 U.S.P.Q. (BNA), at 341], mathematical calculations in the strict sense. (Hence [28] — however inapposite in *Flook,* where the claim was surely not "directed essentially to a method of calculating" — was an entirely appropriate statement in *Richman.*) Secondly, the language "words which mean the same thing" must, in the context of *Richman,* be taken quite literally; it is in the court's response to appellant's contention that he was being penalized for drafting his claim in the form of a concise formula, whereas the inventor "whose attorney simply prolongs the expression with words which mean the same thing" [563 F.2d, at 1030; 195 U.S.P.Q. (BNA), at 344] might not be so penalized. The hypothetical attorney was obviously thought to have paraphrased, and not to have built an analog device.

Actually, of course, we should ask, not what would happen if the *Flook* claim were resubmitted in the guise of an apparatus claim, but what would have happend had it originally been submitted as such. In that case it might not have been at all evident that the device was a "mere" analog computer.

[151] See [9].

[152] The language is that of [16].

subject-matter grasp of the judges. One can only praise Judge Friendly for his candor when he writes

> I did not find the subject for what for long was my only patent opinion — women's girdles — to be unduly technical. But the courts must also deal today with a great number of patents in the higher reaches of electronics, chemistry, biochemistry, pharmacology, optics, harmonics and nuclear physics, which are quite beyond the ability of the usual judge to understand without the expenditure of an inordinate amount of educational effort by counsel and of attempted self-education by the judge, and in many instances even with it.[153]

Increasingly, in the years to come, we shall require lawyer-scientists, lawyer-engineers, lawyer-economists, lawyer-statisticians, lawyer-informaticians, and the like, for complex patent, antitrust, environmental, and other litigation. There would seem to be room for considerable doubt whether our law schools are paying sufficient attention to this need, either in recruiting members of these professions, or in sending signals to prospective students that prior training in them is useful and would be welcomed.[154] At the very least, the law schools would do well to instill into their students some sense of when it might be helpful to consult a specialist, and not perpetuate the pernicious notion that, once someone is trained as a lawyer, he is equipped to handle all problems and would, therefore, be wasting his time were he to study some substantive specialty.

In *Flook,* however, the failure was not in any esoteric reaches of the philosophy of science, but, rather, in those domains that — or so, in a scientific and technological age, one would have thought — had by now become assimilated as a part of the general culture. That this was not in fact so is not a good sign for the state of that culture.

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[153] *Op. cit.* footnote 146, *supra,* at 156-157. A footnote (footnote 17, at 156) on the word "girdles" gives the citation of the case as *International Latex Corp. v. Warner Bros. Co.,* 276 F.2d 557 (2d Cir.), *cert. denied,* 364 U.S. 816 (1960).

[154] The converse progression, from the law into one of the other callings, has, of course, also been known to occur, but, in most of the cases with which the present author is familiar — not a scientifically selected sample! — the motivation was not so much to combine several professions as to give up the practice of law.

LEGAL CONSEQUENCES IN NEW HAMPSHIRE FROM ASBESTOS CONTAMINATION OF DRINKING WATER BY ASBESTOS CEMENT PIPE

SCOTT F. EATON*

I. INTRODUCTION

Nature of the Problem

According to studies by the Environmental Protection Agency (EPA), asbestos cement (A/C) pipe used in many community water systems in the United States may under certain conditions shed asbestos fibers into water supplies.[1] As a result, the consumers of the water transported by such systems may be ingesting asbestos fibers. This article considers the legal treatment of the risk in New Hampshire, where A/C pipe is used in many public water systems.[2] The problem is by no means limited to New Hampshire, for there are approximately 200,000 miles of A/C pipe carrying water in the United States.[3] However, many of the legal aspects of the problem in New Hampshire are shared with other states.

The danger of asbestos contamination of drinking water carried by A/C pipe is in fact part of a larger problem. Water supplies can be contaminated with asbestos fibers from such other sources as asbestos

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[1] J.R. Millette, P.J. Clark & M.F. Pansing, *Exposure to Asbestos from Drinking Water in the United States,* Section 8, p. 8-9 (May, 1979) (Health Effects Research Laboratory, E.P.A. Office of Research and Development) (Draft Report).

[2] Memo from Stephen W. Leavenworth, Chief, Water Supply Division, N.H. Water Supply & Pollution Control Commission, to E. Tupper Kinder, N.H. Asst. Atty. Gen. (January 26, 1979) (memo on WSPCC posture toward asbestos contamination of water in N.H. from A/C pipe).

[3] Millette, *supra* note 1, at 7.

waste discharges from iron ore processing near Lake Superior, erosion of asbestos waste piles in Kentucky, natural erosion of asbestos bearing rock formations in California, and the asbestos tile roofs of cisterns used to collect rain for tap water.[4] One EPA review of 1500 water samples evaluated for asbestos showed that of the 365 United States cities whose drinking water was analyzed, 20.5% had concentrations of asbestos fibers over 1 million fibers per liter (MFL).[5] A report on this review has commented that "while this group of 365 cities cannot be considered a representative sample . . ., it suggests that asbestos is a contaminant in a significant number of U.S. water supplies."[6]

Samples of water collected in A/C pipe systems show various levels of contamination. A sample from the system in Bishopville, South Carolina, contained over 500 MFL of chrysotile,[7] the major type of asbestos used in A/C pipe.[8] Drinking water in other A/C pipe systems in Florida, Kentucky, Pennsylvania, and South Carolina contained "significant" amounts of chrysotile asbestos, that is, over 10 MFL.[9]

However, "not all A/C pipe leaches [asbestos] fibers into the water."[9a] Leaching action may be affected by several variables, including the existence of a lining in the pipe, the corrosivity of the water, pipe tapping for water line connections that puts asbestos debris into the water, and even hydrogen sulfide (H_2S) in well source water that may corrode the pipe.[10]

The quality of the water is a very important determinant in fiber release, and the corrosive effects can be indicated by means of an equation producing an Aggressiveness Index (A.I.).[11] Lower values of

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[4] L.J. McCabe & J.R. Millette, *Health Effects and Prevalence of Asbestos Fibers in Drinking Water,* 4 (Proceedings of the American Water Works Assoc. Annual Conference, June 24-29, 1979).

[5] Millette, *supra* note 1, at 1.

[6] McCabe, *supra* note 4, at 4.

[7] Millette, *supra* note 1, at 7.

[8] McCabe, *supra* note 4, at 2.

[9] Millette, *supra* note 1, at 2-4, 7.

[9a] Millette, *supra* note 1, at 7.

[10] Leavenworth, *supra* note 2, and Millette, *supra* note 1, at 7-9.

[11] Millette, *supra* note 1, at 7.

The Aggressiveness Index (A.I.) is given in the American Water Works Assoc. (AWWA) Standard C402-77 for A/C transmission and pressure pipe. The aggressiveness of the water transported through the pipe, within the temperature range of 40-80°F, is determined by the formula:

the index indicate greater corrosivity than higher values. (Note that for any given pH value, a lower value for $\log_{10}$ (A × H) corresponds to an increase in corrosivity. Since A and H refer to total alkalinity and calcium hardness in mg/1, respectively, i.e., dissolved CO_3 = (carbonate) and Ca++ (calcium ion), it seems reasonable to postulate that it is the solubilities of these species in water that lead to the deterioration of the pipe. Thus for a given pH, reasonably soft water would be expected to be more "corrosive" due to the enhanced solubilities of the $CaCO_3$ (calcium carbonate) in the pipe cement.) Where the A.I. value is less than 10, the water is "very aggressive to all types of pipe," whether A/C, cast iron, or another type, whereas the water with an A.I. value more than 12 is "essentially non-aggressive."[12] In one study water samples were taken and analyzed for more than one year from five A/C pipe systems. "Significant numbers" of fibers were found in the two systems with A.I. values below 10, but "few fibers" were present in the three sytems with A.I. values larger than 12.[13] A sample of representative water systems in the United States has indicated that 52% contained water that was "at least moderately aggressive", i.e., the A.I. values were between 10 and 12, and 16.5% had water that was "very aggressive", i.e., the A.I. values were less than 10.[14] An EPA review of this data stated that water supplies with very aggressive water "may have significant corrosion problems with any type of pipe used .... If A/C pipe is used, there exists the potential for

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A.I. = pH + $\log_{10}$ (A × H)
where pH = index of acidity or alkalinity of the water in standard pH units [i.e. 7 is neutral, the lower the number less than 7, the more acidic. The higher the number, the more alkaline].
A. = total alkalinity in mg/1 as $CaCO_3$
H = calcium hardness in mg/1 as $CaCO_3$
... The recommendations of AWWA Standard C402-77 are:
(a) where A.I. > 12.0 use either Type I (not autoclaved) or Type II (autoclaved) pipe.
(b) where A.I. > 10, use Type II.
(c) where A.I. < 10, consult the manufacturer.
Id. at 7-8. (footnote omitted)

A report was noted by the EPA in Millette, *supra* note 1, at 9 "that the majority of A/C pipe sold in the U.S. in the last 35 years has been Type II (autoclaved and therefore more resistant to corrosion [than Type I])."

[12] *Id.* at 7-8.

[13] *Id.* at 8.

[14] *Id.*

consumers to be exposed to significant concentrations of asbestos in their drinking water."[15]

Given the variables affecting asbestos leaching action and the available results of fiber analyses, the EPA review cited above concluded that the majority of persons receiving water from A/C pipe systems "are not exposed to significant long-term concentrations" of fibers.[16] However, "many residents" using A/C pipe may be exposed to "intermittent concentrations" of up to 500 MFL as the result of pipe tapping; a device to flush the debris out of the pipe instead of allowing it to enter is only a recent innovation.[16a] In areas of aggressive water "the consumer may be exposed to asbestos fiber concentrations of from less than 1 million to over 100 million fibers per liter depending on length of pipe and flow rate."[17]

Health Risk

It is stated that there is "no doubt" that the inhalation of airborne asbestos fibers "significantly increases the risk of lung cancer and pleural mesothelioma."[18] There is evidence to indicate the ingestion of asbestos fibers is also a health hazard, but the evidence is not as conclusive as for airborne asbestos. It is known that "generally fibers from [A/C] pipe are longer than those from natural erosion," and that "longer fibers are considered more hazardous."[19] In EPA's view, "higher than expected incidence rates of peritoneal mesothelioma and of gastric, kidney, and colon cancer among workers occupationally exposed to airborne asbestos suggest that ingested asbestos may be a hazard" because many inhaled particles are ultimately swallowed at a rate estimated to be equivalent to 45 MFL contamination of water.[20] The Occupational Safety and Health Administration (OSHA) has recommended a lower occupational limit for airborne asbestos equivalent to 4 to 15 MFL concentration in water.[21] Because the latency period for occupationally-induced cancer from asbestos is 20 to

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[15] *Id.*

[16] *Id.* at 9.

[16a] *Id.*

[17] *Id.*

[18] McCabe, *supra* note 4, at 1.

[19] *Id.* at 11.

[20] *Id.* at 1-2.

[21] *Id.* at 9, 11. "The general population exposures are usually kept well below the occupational exposure by a factor of 10 to 100." *Id.* at 11.

30 years,[22] the relationship between asbestos ingestion and disease is difficult to establish.

Several studies have been done or are under way, including a federally-sponsored animal feeding study,[23] on the health risk of ingested asbestos. EPA also has an ongoing study relating cancer rates with water-borne asbestos in Duluth, Minnesota and other communities affected by amphibole asbestos fibers from mine tailings in Lake Superior. Earlier studies were not conclusive.[24] A report on an EPA grant analyzing cancer incidence and chrysotile asbestos fiber concentrations in drinking water in five California counties indicated that little of the cancer was associated with asbestos exposure. However, there was a "statistically significant association."[25] A similar preliminary study in the Puget Sound region was inconclusive, but a more precise study is underway. Another is being conducted in Pensacola, Florida.[26]

The EPA has established water quality criteria for 65 toxic polutants, including asbestos, pursuant to the requirement of Section 304(a)[27] of the Clean Water Act (CWA).[27a] The water quality criteria for those toxic pollutants that are carcinogens or suspected carcinogens, like asbestos, are given as concentrations in water corresponding to incremental risks of cancer.[27b] However, since there is no known safe concentration of a carcinogen, "the recommended concentration of asbestos in water for maximum protection of human health is zero."[27c] Primarily based on occupational studies of airborne asbestos that is swallowed, the concentration and risk levels for asbestos, assuming a lifetime exposure from drinking water, are 300,000 fibers/liter for a "probability of one additional case of cancer

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[22] *Id.* at 8.

[23] *Id.* at 2.

[24] *Id.* at 8.

[25] *Id.* at 9.

[26] *Id.*

[27] 33 U.S.C.A. §1314(a) (1978).

[27a] 33 U.S.C.A. §§1251 et. seq. (1978).

[27b] 44 Fed. Reg. 56,628, 56,634 (1979). Such criteria are not regulations, although they may be used to develop enforceable standards under the CWA. 44 Fed. Reg. 15,926 (1979). The CWA does not regulate drinking water tap standards, however, and the criteria are not to be viewed as such standards. 44 Fed. Reg. 15,926, 15,927 (1979). The CWA itself is thus not available to address the contamination of drinking water from A/C pipe. The list of toxic pollutants is to be codified in 40 C.F.R. 401.15.

[27c] 44 Fed. Reg. 56,628, 56,634 (1979).

for every 100,000 people exposed," 30,000 fibers/liter for a probability of one in one million, and 3,000 fibers/liter for a probability of one in 10 million.[27d] Multiplying or dividing these figures by multiples of 10 can produce concentrations related to other levels of risk.[27e]

The Response of the Federal Government

The EPA and the Consumer Product Safety Commission (CPSC) are beginning to consider generally the problem of asbestos in the environment. The EPA has begun an investigation of asbestos-containing products and has requested public comment[28] on proposed regulatory approaches under the Toxic Substances Control Act (TSCA), which gives the Agency authority to regulate the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture found to pose an unreasonable risk to health and the environment.[29] Pursuant to its authority over consumer products, which apparently include A/C pipe, the CPSC is following the same procedure of requesting public comment on its proposed regulatory approach.[30] However, the EPA is focusing initially on asbestos-containing paper and friction products, stating that if A/C pipe were studied now, the promulgation of regulations for the former two categories would be delayed.[31] The EPA believes that the background information which the Agency has begun to gather will be relevant to the A/C pipe problem in any case.[32] It is considering a ban on nonessential uses of asbestos and an essential use exemption to the ban.[33] The CPSC is committed to avoiding conflict with EPA authority in regulating asbestos.[34] The request of the CPSC for public comment seems in any event to be directed more toward household products containing asbestos.[35]

[27d] 44 Fed. Reg. 56,628, 56,634, 56,635 (1979).

[27e] *Id.*

[28] 44 Fed. Reg. 60,061 (1979).Public comment period extended, 44 Fed. Reg. 73,127 (1979).

[29] 15 U.S.C.A. §§2601 et. seq. (Supp. 1979).

[30] 44 Fed. Reg. 60,057 (1979). Public comment period extended, 44 Fed. Reg. 73,121 (1979). In the original request for public comment, A/C pipe was included in a list of consumer products containing asbestos. 44 Fed. Reg. 60,057, 60,061 (1979).

[31] 44 Fed. Reg. 60,155, 60,156 (1979).

[32] 44 Fed. Reg. 60,155, 60,157 (1979).

[33] 44 Fed. Reg. 73,127 (1979).

[34] 44 Fed. Reg. 60,056 (1979).

[35] *See* 44 Fed. Reg. 60,057 (1979).

The EPA has the authority under Section 1412[36] of the Safe Drinking Water Act (SDWA)[37] to promulgate, as required to protect the public health, revised national primary drinking water regulations that establish maximum contaminant levels or require appropriate treatment techniques to control drinking water contaminants. The EPA has proposed an amendment to the National Interim Primary Drinking Water Regulations (NIPDWR) to direct community water supply systems to implement corrosion control programs, but the controls are not specified.[38] The Agency has not established a maximum contaminant level for asbestos in drinking water. However, it has proposed to establish the A.I. index or other indices as a maximum contaminant level and is considering the establishment of revised national primary drinking water regulations to control asbestos.[39] As indicated in a memorandum of understanding with the Food and Drug Administration (FDA), the EPA intends to study health risks posed by direct and indirect additives to drinking water, including those from pipe.[40] The NIPDWR contain turbidity standards[41] that relate indirectly to asbestos contamination by requiring filtration systems. However, the systems reduce only natural-occurring asbestos in drinking water.[42]

The Problem in New Hampshire and the State's Response

The total amount of A/C pipe in New Hampshire is not known. Because no records of its use are kept at the state level, questioning the persons responsible for each public water system would be necessary to obtain the answer.[43] Some estimate of the use is possible, however. The state has approximately 120 large municipal water

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[36] 42 U.S.C.A. §300g-1 (Supp. 1978).

[37] 42 U.S.C.A. §§300f et seq. (Supp. 1978).

[38] 44 Fed. Reg. 42,246, 42,258 (1979) (to be codified in 40 C.F.R. 141.30). However, the EPA has promulgated secondary maximum contaminant levels for corrosivity and pH value that are designed, as part of the National Secondary Drinking Water Regulations established pursuant to Section 1412 of the SDWA, to protect the "public welfare", i.e. the color, taste, and odor of drinking water. These levels are not enforceable by the EPA and are only guidelines for the states, which may establish higher or lower levels depending upon local conditions. The level for corrosivity is simply that which is "noncorrosive", and the level for pH value is 6.5 to 8.5. 44 Fed. Reg. 42,195, 42,198 (1979) (to be codified in 40 C.F.R. 143.3).

[39] 44 Fed. Reg. 60,155, 60,156 (1979).

[40] 44 Fed. Reg. 42,775, 42,777 (1979).

[41] 40 C.F.R. 141.13 (1979).

[42] 44 Fed. Reg. 60,155, 60,156 (1979).

[43] Leavenworth, *supra* note 2.

supplies.[44] In the last 20 years most of the new installations and repairs of water mains have used either cast iron pipe with Portland cement or bituminous linings or asbestos cement pipe with a bituminous lining.[45] The A/C pipe has been popular because of its low cost.[46]

The New Hampshire Water Supply and Pollution Control Commission (WSPCC), charged with the duty to protect the public health[47] and to require any treatment necessary to ensure the safety and fitness of public water supplies,[48] has required since 1958 that all new A/C pipe laid in the state be coated with an inner protective lining, originally a bituminous seal coat, in order to prevent corrosion caused by leaching action upon the lime constituents contained in the pipe.[49] However, the WSPCC does not know how much pipe in New Hampshire is lined or unlined.[50] The water in New Hampshire is soft and acid.[51] The pH value has been estimated at 6.0 to 6.5, but the actual A.I. index has not been calculated for the water in the state.[52] An acidic pH value is an indicator of aggressiveness.

The addition to the water supply of so-called "sweetening" agents like lime or sodium hydroxide can raise the pH level and lower the degree of acidity in the water, thus lessening the leaching action and corrosion.[53] The towns of Berlin, Concord, Dover, and Durham have taken this step. The primary purpose, however, may not be to reduce asbestos leaching from A/C pipe but instead to guard against the release of iron from cast iron pipe used in the towns' systems. Iron se-

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[44] Harris, *Asbestos in Drinking Water,* New Hampshire Times, January 24, 1979, at 22.

[45] Interview with Stephen W. Leavenworth, Chief, Water Supply Division, N.H. Water Supply & Pollution Control Commission, and the author, in Concord, N.H. (January 8, 1980).

[46] Leavenworth, *supra* note 2.

[47] N.H.R.S.A. §148-B:7 (Supp. 1979).

[48] N.H.R.S.A. §148:22 (Supp. 1979).

[49] Letter from W.A. Healey, Director, Sanitary Engineering, to Dr. Mary M. Atchison, Secretary, N.H. State Board of Health (May 22, 1958) (memo on rule pertaining to protective coating for water supply pipe). The requirement is to be codified as a regulation WS 30302. Leavenworth, *supra* note 45.

[50] Leavenworth, *supra* note 45.

[51] Healey, *supra* note 49 . "... most supplies in [New Hampshire] tend to be soft and acid, a combination of course resulting in a leaching action upon the lime constituents contained in the pipe lining." *Id.*

[52] Leavenworth, *supra* note 45.

[53] *Id.*

questration by the addition of phosphate compounds in the water and filtration to remove iron are also used in towns in the state.[54]

Pursuant to Section 1413(a)[55] of the SDWA, the WSPCC has had the primary enforcement responsibility since late August of 1978[56] to enforce the EPA regulations and standards of the SDWA. The state agency may also set up its own regulations and standards under Section 1414.[57] It has not done so for asbestos. Instead the Commission is waiting for the EPA to act, believing, on the one hand, that "there is too little data to demonstrate a level of asbestos particles in drinking water which should be established," and, on the other hand, that it does not have the budget or laboratory facilities to perform "proper and complete analysis for asbestos particles."[58] The EPA has provided no grants to states to study the asbestos contamination problem.[59] Finally, the WSPCC believes that any information they would obtain would be of "questionable value" and could be "misleading."[60]

II. COMMON LAW CAUSES OF ACTION

Potential common law causes of action against asbestos contamination are limited. Their usefulness is at best confined to suits against the individual officials responsible for local water supplies. At the state and federal levels statutory grounds for suit provide a sounder basis for legal action.

Suing in negligence would be likely to founder on two points. The first is inability to prove an injury caused by the leaching action upon A/C pipe, and the second is inability to prove a lack of reasonable care on the part of the officials in selecting and continuing to use the pipe. Proving an injury caused by asbestos fibers would be an insurmountable hurdle inasmuch as even the EPA has not determined the effects of ingestion of asbestos fibers beyond stating that there is evidence of a danger to health. (The significance of absence of such causal connection in suits against the state or federal government is separately dealt with below.) Similarly, showing lack of due care on the part of officials would likely prove impossible. Since the dangers from airborne asbestos, much less water-borne asbestos, were not commonly

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[54] *Id.*

[55] 42 U.S.C.A. §300g-2(a) (Supp. 1978).

[56] [1978] 9 *Envir. Rep.* (BNA) 844.

[57] 42 U.S.C.A. §300g-3 (Supp. 1978).

[58] Leavenworth, *supra* note 2. The laboratory facilities can identify only larger particles. *Id.*

[59] Leavenworth, *supra* note 45.

[60] Leavenworth, *supra* note 2.

known until recently, water supply officials could probably defend easily against an attack on their reasonable care in the selection and use of the pipe. The lack of conclusive data to show injury or even exposure to an abnormal or serious harm would defeat a suit for injury based on strict liability in tort.

An injunction to abate or stop a continuous, private nuisance is predicated on "an unreasonable interference with the use and enjoyment of another's property."[61] The contamination of public drinking water may interfere with that enjoyment. However, one must show a substantial harm in order to prevail in such a suit. The degree of injury must be objectively measured,[62] nearly an impossibility unless the plaintiff has already suffered a measurable health detriment. Given the long time between exposure to contaminants and the onset of asbestos-induced cancer, the injury is not likely to be evident now. The requirements that the interference be either "intentional and unreasonable" or "unintentional and otherwise actionable" under principles of negligence or "abnormally dangerous conditions or activities"[63] could not be satisfied for the same reasons they could not be satisfied in a negligence or strict liability action: the absence of conclusive data showing that ingested asbestos fibers cause disease and the absence of data on asbestos levels in New Hampshire water supplies.

A public nuisance has been defined as an "unreasonable interference with a right common to the general public," such as the health and safety of the community.[64] Normally the doctrine requires that an individual claimant prove harm of a kind different from that suffered by other members of the public protected by the right. An injunction brought against town water supply officials to abate the public nuisance could avoid this requirement.[65] A court could order "sweeteners" to be added to the water to raise the pH level and lessen the leaching problem. However, the difficulty of making the necessary causal connections, as discussed above, pertains here as well.

III. STATE STATUTORY REMEDIES

The New Hampshire Water Supply and Pollution Control Commission (WSPCC) has the authority to investigate the sanitary condi-

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[61] *Robie v. Lillis,* 112 N.H. 492, 495, 299 A.2d 155, 158 (1972).

[62] W. Rodgers, *Environmental Law* 107 (1977).

[63] *Id.* at 107, n.2 *Restatement (Second) of Torts* §822, at 22 (Tent. Draft No. 17, 1971).

[64] *Robbie v. Lillis, supra* note 61.

[65] Rodgers, *supra* note 62, at 105-106 referring to *Restatement (Second) of Torts* §§821C(1), C(2).

tions and methods pertaining to the distribution of any New Hampshire public water supplies for domestic use and to require any treatment necessary to ensure their fitness and safety.[66] The WSPCC also has the duty to adopt regulations to ensure compliance with drinking water standards and to protect the public health.[67]

Although New Hampshire has primary enforcement responsibility for the EPA's drinking water standards and regulations under §1413(a)[68] of the Safe Drinking Water Act (SDWA), the State is not required to act on water-borne asbestos without some standard or requirement to enforce. Section 1414(e)[69] of the Act allows the State to set up regulations other than those the EPA has promulgated, provided they are no less strict than the federal standards.

By its intra-agency memorandum of 1958 and subsequent requirement that all new A/C pipe laid in New Hampshire have an interior lining, the WSPCC has indicated it agrees there is a problem of pipe decay if not a potential health problem. Thus one avenue of public action is to request the Commission to promulgate a rule[70] that all community water systems in New Hampshire with A/C pipe use a "sweetener" to lower the degree of acidity of the water, citing the EPA's statement that the "release of fibers . . . can be controlled by conditioning the water."[71] If the Commission denies the request, a petition for rehearing can be made[72] on the ground that the denial

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[66] N.H.R.S.A. §148:22 (Supp. 1979).

[67] N.H.R.S.A. §148-B:7 (Supp. 1979).

[68] 42 U.S.C.A. §300g-2(a) (Supp. 1978). The federal regulations were adopted by New Hampshire pursuant to N.H.R.S.A. 148-B:5 (Supp. 1979), which mandates identification of contaminants and creation of maximum contaminant levels or treatment techniques as well as monitoring procedures.

[69] 42 U.S.C.A. §300g-3(e) (Supp. 1978).

[70] N.H.R.S.A. §541-A:6 (1974). "An interested person may petition an agency requesting the promulgation, amendment, or repeal of a rule . . . Within thirty days after submission of a petition, the agency shall either deny the petition in writing, stating its reasons for the denials, or shall initiate rule-making proceedings." *Id.*

[71] McCabe, *supra* note 4, at 12. See the EPA guidelines to states on corrosivity and pH value in drinking water, note 38.

[72] N.H.R.S.A. §541:3 (1974).

> Within twenty days after any order or decision has been made by the commission, any party to the action or proceeding before the commission or any person directly affected thereby, may apply for a rehearing in respect to any matter determined in the action or proceeding, or covered or included in the order, specifying in the motion for rehearing the ground therefor, and the commission may grant such rehearing if in its opinion good reason therefor is stated in said motion. *Id.*

was unreasonable. Further appeal can be taken from the Commission's decision to the state Supreme Court.[73] Although the state statutes on judicial review do not specifically address standing, a rehearing petitioner must be a party to the original action or "directly affected thereby,"[74] and any person whose rights may be "directly affected" by the appeal may join and become a party.[75] Presumably an allegation of injury, a traditional requirement of standing, would be necessary in an appeal before the Court. The requirements of proof state that the order of the Commission will be upheld unless "by a clear preponderance of the evidence ... such order is unjust or unreasonable."[76] The current data on asbestos in water makes it difficult to clear these evidentiary hurdles. The decision to open rule-making is discretionary, as it is a matter of judgment of the Commission. The decision to deny a petition for rule-making must be unreasonable, that is, an abuse of discretion, before the court will overrule the agency.[77]

The WSPCC could also be petitioned to institute a ruling banning the installation of A/C pipe entirely. However, by weighing the economic costs against the lack of conclusive evidence of the effects of asbestos in drinking water the Commission could deny the petition without risk of a judicial overruling for unreasonableness.

A third petition could be made that the WSPCC at least begin a monitoring program for asbestos. Although the Commission is currently waiting for EPA action and has stated that sampling information would be of questionable value, the state agency's duty does not allow it to remain passive in the face of a potentially serious problem. As stated in an EPA report, "elaborate electron microscope counts of fibers are not necessary to know that a problem exists."[78] A court

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[73] N.H.R.S.A. §148-B:11 (Supp. 1979) allows appeal specified in N.H.R.S.A. §541:6 (1974).

[74] N.H.R.S.A. §541:3 (1974), *supra* note 72.

[75] N.H.R.S.A. §541:8 (1974).

[76] N.H.R.S.A. 541:13 (1974).

> Upon the hearing the burden of proof shall be upon the party seeking to set aside any order or decision of the commission to show that the same is clearly unreasonable or unlawful, and all findings of the commission upon all questions of fact properly before it shall be deemed prima facie lawful and reasonable, and the order of decision appealed from shall not be set aside or vacated except for errors of law, unless the court is satisfied, by a clear preponderance of the evidence before it, that such order is unjust or unreasonable. *Id.*

[77] B. Schwartz, *Administrative Law* 609-610 (1976).

[78] McCabe, *supra* note 4, at 12.

reviewing the reasonableness of agency action should consider this factor.

IV. FEDERAL STATUTORY REMEDIES

The remaining bases on which to initiate action are at the federal level, particularly under the Toxic Substances Control Act (TSCA)[79] and the Safe Drinking Water Act (SDWA).[80]

Toxic Substances Control Act

The fact that the EPA has now begun a broad investigation of the asbestos problem and is requesting information and considering various regulatory approaches[81] under TSCA presents both opportunities and problems for the citizen seeking action to prevent contamination of drinking water from A/C pipe.

The EPA has admitted that "many sources of exposure to asbestos may present unreasonable health risks because of serious adverse health effects and the large numbers of people subject to exposure."[82] The EPA feels that under TSCA the Agency has authority "to weigh overall risks presented by the entire asbestos life cycle, from mining to final disposal," and intends to use this authority "to assess whether exposure to asbestos throughout its life cycle presents an unreasonable risk to human helath."[83] Under Section 6(a)[84] of the Act, the EPA may prohibit the "manufacturing, processing, or distribution in commerce" of a chemical substance that "presents or will present an unreasonable risk of injury to health or the environment." The Agency may prohibit certain uses, limit the amount of such substance that is manufactured, processed, or distributed, and require appropriate labels and record keeping.[85] Under Section 5(a)[86] the EPA can require manufacturers to submit pre-manufacturing notification for significant new uses of a chemical. The EPA anticipates that "most asbestos regulatory action" will be under Section 6(a) of TSCA, although Section 5(a) may be used where "appropriate."[87]

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[79] 15 U.S.C.A. §§2601 et seq. (Supp. 1979).

[80] 42 U.S.C.A. §§300f et seq. (Supp. 1978).

[81] 44 Fed. Reg. 60,061 (1979).

[82] 44 Fed. Reg. 60,061, 60,062 (1979).

[83] *Id.*

[84] 15 U.S.C.A. §2605 (a) (Supp. 1979).

[85] *Id.*

[86] 15 U.S.C.A. §2604 (a) (Supp. 1979).

[87] 44 Fed. Reg. 60,061, 60,063 (1979).

In June of 1979 a citizen petitioned the EPA as allowed under Section 21(a)[88] of the Act to request that the Agency initiate a proceeding for the issuance of a rule under Section 6(a) of TSCA "to prohibit further manufacture and distribution" of A/C pipe.[89] The EPA under Section 21(b)[90] must either grant or deny such petitions within 90 days and, if denial occurs, publish the reasons for the denial. The EPA granted the petition but only by stating that it plans to investigate A/C pipe as part of the Agency's broad asbestos regulatory program, and it noted that "granting a petition to initiate a proceeding to issue a rule does not mean" that the Agency "will promulgate or even propose a rule."[91]

The response of the EPA to the citizen's petition and its announcement of its approach to asbestos regulation indicate that the risks of A/C pipe have no higher standing with the Agency than the risks with any other asbestos product. Indeed, EPA believes that analyzing the A/C pipe problem now would delay its investigation's current focus on asbestos-containing paper and friction products.[92] EPA feels that the background information it has begun to gather on asbestos, such as on the health risk associated with ingested asbestos, will be relevant to the control of asbestos cement products.[93] However, this general approach does not attack the A/C pipe problem directly. For example, it does not address the pipe's propensity to shed asbestos fibers under aggressive water conditions and other circumstances. "Detailed scientific and socio-economic analyses related to A/C pipe" will not be completed until after the first rules on asbestos regulation (ones concerning asbestos-containing paper and friction products) have been proposed.[94]

Within the statutory discretion of the EPA the A/C pipe questions may remain unanswered for some time. The Agency can legitimately respond to any new petition requesting action on A/C pipe under Section 21 of TSCA that the Agency is pursuing the matter, as it has judged that a broad approach to asbestos regulation is better than one geared to specific asbestos products.[95] Yet EPA has in the past held

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[88] 15 U.S.C.A. §2620 (a) (Supp. 1979).

[89] 44 Fed. Reg. 60,155 (1979).

[90] 15 U.S.C.A. §2620 (b) (Supp. 1979).

[91] 44 Fed. Reg. 60,155 (1979).

[92] 44 Fed. Reg. 60,155, 60,156, 60,157 (1979).

[93] 44 Fed. Reg. 60,155, 60,157 (1979).

[94] *Id.*

[95] 44 Fed. Reg. 60,061, 60,062 (1979).

that some existing asbestos products, such as asbestos insulation in schools and other buildings, are amenable to specific evaluation and control, including, under Section 5(a) (5)[96] of TSCA, a proposal to remove the insulation if necessary to safeguard the health of building occupants.[97]

Under Section 21 (b) (4) (A)[98] of TSCA a citizen may commence a civil action in federal district court to compel the EPA to initiate a rule-making proceeding, such as one directed specifically to A/C pipe, for which the EPA has denied a petition filed pursuant to Section 21 (a). The judicial process is a de novo proceeding. According to Section 21 (b) (4) (B)[99] the petitioner will prevail in requiring the EPA to initiate a proceeding for the issuance of a rule under Section 6 (a) if he can show by a preponderance of the evidence that there is a reasonable basis for concluding that issuing such a rule is "necessary to protect health or the environment against an unreasonable risk of injury." But if the risk to health or environment is less than that with respect to which the EPA is taking action under TSCA and if the EPA's resources are "insufficient" to do what the petitioner requests, the court may permit the Agency to defer initiating the requested action.

The person who petitions the Agency to initiate a proceeding for the issuance of a rule specifically on A/C pipe will almost certainly fail, given the current state of information about A/C pipe contamination of drinking water and the fact of ongoing EPA investigations of asbestos. However, the existence under Section 21 of the Act of the right to petition and to contest the denial of the petition gives the citizen the means continually to spur the Agency to address A/C pipe issues and to defend its posture as the investigation of asbestos progresses and the volume of information available to the Agency increases. It must be remembered that under TSCA, as EPA has stated, "the risk presented by a chemical may be considered unreasonable if its potential adverse health and environmental effects outweigh the effects of contemplated regulatory action on the benefits of the substance."[100]

The citizen-suit provisions of Section 20[101] allow any person to commence a civil action against any person violating a provision of

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[96] 15 U.S.C.A. §2065 (a) (5) (Supp. 1979).

[97] 44 Fed. Reg. 54,676, 54,677 (1979).

[98] 15 U.S.C.A. §2620 (b) (4) (A) (Supp. 1979).

[99] 15 U.S.C.A. §2620 (b) (4) (B) (Supp. 1979).

[100] 44 Fed. Reg. 60,155 (1979).

[101] 15 U.S.C.A. §2619 (Supp. 1979).

the Act and against the Administrator of EPA to compel him to perform any act or duty under TSCA that is not discretionary. Rulemaking is discretionary as it is within the Administrator's judgment and is thus outside the bounds of a citizen suit under Section 20. However, the Administrator may be required to enforce existing rules and regulations.

The comment period on EPA's initiation of the regulatory process on asbestos was extended an additional 60 days beyond the original 60-day period while the EPA also solicited comment on a proposed ban on non-essential uses of asbestos.[102] Similar extensions are not unlikely in the months ahead as more rules on asbestos are proposed. In the extension announcement the EPA stated that in proposing a rule it would consider "all relevant information to the extent possible even if that information is submitted after the close of the comment period."[103] Comments on rule-making proposals are the easiest way for citizens to propose advice and supply information on the A/C pipe problem. If the EPA continues to accept relevant information on proposed rules after comment periods have expired, the opportunity for citizen input on the regulation of asbestos will be effectively continuous.

The SDWA and Judicial Environmental Standards of Risk

Except for the unlikely alternative of ordering the removal of existing A/C pipe, as contemplated by EPA for asbestos insulation in schools, TSCA does not provide ways to address the problem of continuing contamination of drinking water by A/C pipe already in the ground. The SDWA may fill this gap and thus give petitioners some relief outside of TSCA. However, the corrosion control rule proposed by EPA[104] as an amendment to the National Interim Primary Drinking Water Regulations under Section 1412[105] of the SDWA has not been promulgated, and, in any case, does not require designation of corrosive waters by the states and implementation of corrosion control measures (as yet unspecified) until 18 months after promulgation.[106]

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[102] 44 Fed. Reg. 73,127 (1979).

[103] *Id.*

[104] 44 Fed. Reg. 42,246, 42,258 (1979) (to be codified in 40 C.F.R. 141.30).

[105] 42 U.S.C.A. §300g-1 (Supp. 1978).

[106] 44 Fed. Reg. 42,258 (1979). By Section 1412 (b) (5) of the SDWA, 42 U.S.C.A. §300g-1 (b) (5), revised national primary drinking water regulations cannot take effect until 18 months after the date of promulgation.

The EPA originally promulgated maximum contaminant levels and treatment techniques for contaminants in drinking water under subdivisions (1) through (3) of Section 1412(b).[107] Under Section 1412(b)(4)[108] the EPA may also revise the regulations "whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons."

A great advantage of citizen action on the federal level is the relatively more relaxed standards of proof of risk or harm or injury that might be available to the citizen there than on the common law or state statutory levels. The difference is especially important because of the inconclusiveness to date of EPA studies of water-borne asbestos. It could be helpful in gaining relief under the SDWA, for example in petitioning for rule-making on A/C pipe contamination of drinking water.

In *Reserve Mining Co. v. Environmental Protection Agency*[109] the Eighth Circuit Court of Appeals considered the health effects of airborne and water-borne asbestos particles from iron ore mining near the shores of Lake Superior.[110] The case arose under the Federal Water Pollution Control Act (FWPCA).[111] The data on airborne asbestos introduced in the case indicated that a relatively short exposure could cause lung cancer. However, the evidence connecting human illness to asbestos in drinking water was uncertain.[112] The court balanced the economic benefits of the mining operation against the dangers it created. The mining company was given a "reasonable time" to abate the emissions, but since there was a more certain causal connection between inhalation of asbestos fibers and lung disease than between ingestion of asbestos fibers and human illness, the "reasonable time" was shorter for abatement of airborne asbestos emissions than for abatement of water-borne asbestos discharges.[113]

The court stated that, inasmuch as proof of harm with certainty would be impossible, the concepts of potential harm, whether assessed

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[107] 42 U.S.C.A. §300g-1 (b) (1) through (3) (Supp. 1978).

[108] 42 U.S.C.A. §300g-1 (b) (4) (Supp. 1978).

[109] 514 F.2d 492 (8th Cir. 1975).

[110] For one author's review of the question on scientific uncertainty in this extensively litigated case, see Prater, *Reserve Mining v. Environmental Protection Agency: Scientific Uncertainty and Environmental Threats to Human Health,* 1975 Utah L. Rev. 581.

[111] 33 U.S.C. §§1151 et seq. (1970), (current version generally known as the Clean Water Act at 33 U.S.C.A. §§1251 et. seq. (1978)).

[112] 514 F.2d 492, 515-20 (8th Cir. 1975).

[113] *Id.* at 536-538. *See* Prater, *supra* note 110, at 590.

as "probabilities and consequences" or "risk and harm," must apply in a determination of whether any relief should be granted.[114] The court concluded:

> In assessing probabilities in this case, it cannot be said that the probability of harm is more likely than not. Moreover, the level of probability does not readily convert into a prediction of consequences .... The best that can be said is that the existence of this asbestos contaminant in air and water gives rise to a reasonable medical concern for the public health. The public's exposure to asbestos fiber in air and water creates some health risk. Such a contaminant should be removed .... The existence of this risk to the public justifies an injunction decree requiring abatement of the health hazard on reasonable terms as a precautionary and preventive measure to protect the public health.[115]

Thus, applying the standard of "endangering the health and welfare of persons,"[116] required for action under the FWPCA at that time, the court found the asbestos to be potentially harmful and the potential harm to be covered by the "endangering" standard.[117]

Another case of great importance in analyzing risk and harm is *Ethyl Corp. v. Environmental Protection Agency*.[118] Petroleum and chemical companies appealed the EPA's order requiring annual reductions in the lead content of gasoline. The order was made pursuant to Section 211(c) (1) (A)[119] of the Clean Air Act (CAA) authorizing the EPA Administrator to regulate gasoline additives whose emission products "will endanger the public health or welfare." The court concluded that the "will endanger" standard was "precautionary in nature" and did not "require proof of actual harm" before regu-

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[114] *Id.* at 520.

[115] *Id.*

[116] 33 U.S.C. §1160 (g) (1) (1970) (current version at 33 U.S.C.A. §1364 (a) (1978)). The "endangering" standard has now been replaced. Since the 1972 amendments to the FWPCA, the EPA Administrator has had emergency powers to sue for an immediate injunction where pollution is "presenting an imminent and substantial endangerment to the health of persons." 33 U.S.C.A. §1346(a) (1978). The court commented in *Reserve Mining* that the term "endangering" indicates a "lesser risk of harm" than that posed by "imminent and substantial endangerment." 514 F.2d at 528. But it is still in the judgment of the trier of fact as to what degree of risk is "imminent and substantial." *See* Prater, *supra* note 110, n. 21, at 583.

[117] 514 F.2d 492, 528 (8th Cir. 1975).

[118] 541 F.2d 1 (D.C. Cir. 1976), *cert. denied,* 426 U.S. 941 (1976).

[119] 42 U.S.C. §1857f-6c(c) (1) (A) (1970). (Current version at 42 U.S.C.A. §7545 (c) (1) (A) (Supp. 1978)). The 1977 amendments to the CAA changed this provision so that the Administrator can now regulate gasoline additives "if in the judgment of the Administrator any emission products of such ... fuel additive causes, or contributes to air pollution which may reasonably be anticipated to endanger the public health or welfare." 42 U.S.C.A. §7545 (c) (1) (A) (Supp. 1978).

lation was "appropriate."[120] The Administrator was "authorized to assess risks of harm" and, where the risk was "found to be significant, to act to prevent the harm from happening."[121] Thus, "the regulatory action under this precautionary statute should precede" — and prevent — the perceived harm.[121a]

Citing with approval the analysis of the court in *Reserve Mining,* the court in *Ethyl Corp.* stated that *Reserve Mining* demonstrates that "the magnitude of risk sufficient to justify regulation is inversely proportional to the harm to be avoided."[122] The Administrator found a "significant" risk of harm to health by lead poisoning that was "more certain" than the risk of cancer death that justified regulation in *Reserve Mining.*[123] "Danger . . . is not set by a fixed probability of harm, but rather is composed of reciprocal elements of risk and harm, or probability and severity."[124]

Regarding the scientific evidence of the danger of lead poisoning, the court stated:

> As we have indicated above, we need not decide whether [the Administrator's] decision is supported by the preponderance of the evidence, nor, for that matter, whether it is supported by substantial evidence. To the contrary, we must sustain if it has a rational basis in the evidence. Keeping in mind the precautionary "will endanger" standard, we have no difficulty in terming his decision rational.
>
> . . . [W]e need not seek a single, dispositive study that fully supports the Administrator's determination. Science does not work that way; nor, for that matter, does adjudicatory fact finding. Rather, the Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative; the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion . . . We must decide whether the cumulative effect of all this evidence, and not the effect of any single bit of it, presents a rational basis for the low-lead regulations.[125]

Although this lower threshold of risk or harm for determining an adequate basis for regulation was applied to sustain agency action, it gives an encouraging indication to the citizen as to how a federal court will weigh evidence supporting regulations and other actions to protect public health. The current EPA studies on asbestos and those

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[120] 541 F.2d 1, 17 (D.C. Cir. 1976).

[121] *Id.* at 5.

[121a] *Id.*

[122] *Id.* at 19.

[123] *Id.* at 20.

[124] *Id.* at 18.

[125] *Id.* at 37-38.

underway should provide enough evidence for a citizen to request from the EPA that it open up rulemaking proceedings under the SDWA pursuant to 5 U.S.C.A. 553(e) (1977)[126] for the following actions:

1. Creation of an asbestos primary drinking water regulation, as defined in Section 1401 (1)[127] of the SDWA, specifying a maximum contaminant level for asbestos in drinking water. The original maximum contaminant levels set by the EPA Administrator under Section 1412 (b) (1) (B)[128] were established for "each contaminant which, in his judgment . . . may have any adverse effect on the health of persons" and at a level so that "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." This standard of evidence is broader even than that stated in *Ethyl Corp.*

2. If a maximum contaminant level could not be established, adoption of an EPA primary drinking water regulation specifying the treatment technique of adding "sweeteners" to acidic water conveyed by A/C pipe. Such a regulation could be justified in light of the knowledge of the leaching effect and the injunction allowed in *Reserve Mining* because of a "reasonable medical concern for public health."

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[126] Section 1412(d) of the SDWA, 42 U.S.C.A. §300g-1(d) (Supp. 1978), requires that regulations will be prescribed according to 5 U.S.C. §553. "Each agency will give an interested party the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C.A. §553(e) (1977).

[127] The term "primary drinking water regulation" means a regulation which —
(A) applies to public water systems;
(B) specifies contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons;
(C) specifies for each contaminant either — (i) a maximum contaminant level, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems, or (ii) if, in the judgment of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant, each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g-1 [Section 1412 of the Act]; and
(D) contains criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system, and requirements as to (i) the minimum quality of water which may be taken into the system and (ii) siting for new facilities for public water systems. 42 U.S.C.A. §300f(1) (Supp. 1978).

[128] 42 U.S.C.A. §300g-1 (b) (1) (B) (Supp. 1978).

3. Approval of the proposed corrision control regulation.[129]

4. Inclusion within federal grant money for public water supervision programs under Section 1443[130] of the SDWA amounts specifically for the testing of asbestos in the drinking water of all states with acidic, aggressive water in A/C pipe. In New Hampshire, for example, the WSPCC could do much more about contaminated water if it simply had the money to analyze it.

Civil actions by citizens are allowed under Section 1449 (a)[131] of the SDWA to enforce "requirements" of the Act. Without a standard or rule of some sort on water-borne asbestos, any suit against the EPA, states, or towns under this section is not possible for asbestos contamination of drinking water. Under this provision the Administrator of the EPA can be sued for an alleged failure to perform any act or duty under the SDWA which is not discretionary. Promulgation of standards or rules is discretionary, as it is a matter within the judgment of the Administrator. There is no provision for a civil action against the Administrator for such failure to open rulemaking on the A/C pipe problem as there is under Section 21 (b) (4)[132] of TSCA.

Other statutory or common law relief is not precluded by the Act, as stated in Section 1449 (e).[133] The more relaxed definition of harm developed in *Reserve Mining,* however, would likely prevail only in a case involving a suit under a federal statute, since that case involved construction of the EPA Administrator's authority under the FWPCA in a suit brought in a federal court. The private litigant is unlikely to be able to utilize that relaxed definition in a statutory suit in state court or a common law suit insofar as state or common law definitions prevail.

Under Section 1448[134] of the SDWA a citizen can petition in the United States Court of Appeals for the District of Columbia Circuit for judicial review of action of the Administrator in promulgating regulations under Section 1412. Under the judicial review provisions[135] of the federal Administrative Procedure Act applicable

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[129] 44 Fed. Reg. 42,246, 42,258 (1979) (to be codified in 40 C.F.R. 141.30).

[130] 42 U.S.C.A. §300j-2 (Supp. 1978).

[131] 42 U.S.C.A. §300j-8(a) (Supp. 1978).

[132] 15 U.S.C.A. §2620(b) (4) (Supp. 1979).

[133] 42 U.S.C.A. §300j-8 (e) (Supp. 1978).

[134] 42 U.S.C.A. §300j-7 (Supp. 1978).

[135] 5 U.S.C.A. §701 et. seq. (1977). "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof..." 5 U.S.C.A. §702 (1977).

to federal agencies one can appeal "agency action,"[136] including denial of a rule-making proceeding or the failure of the agency to act. To prevail, however, one must show that the action was arbitrary, capricious, or an abuse of discretion.[137] Any allegation of abuse of discretion in denying a petition for rule-making on the A/C pipe contamination of drinking water is likely to fail under the reasonableness standard.[138]

The bar to civil action against the Administrator under the SDWA for failure to perform a discretionary duty and the requirement of abuse of discretion to overturn judicially the Agency's inaction would also likely defeat any attempt by a citizen to appeal EPA's failure to utilize the SDWA emergency powers provision in Section 1431,[139] although the provision seems applicable to A/C pipe contamination of drinking water. Pursuant to Section 1431, if the EPA receives information that a contaminant present in or likely to enter a public water system may present an "imminent and substantial endangerment" to the health of persons and if state or local authorities have not acted, the EPA may step in to issue orders or commence a civil action even if the state has primary enforcement responsibility under the Act.

Particularly pertinent is the legislative intention behind the provision as expressed in the report of the House Interstate and Foreign Commerce Committee:

> The authority to take emergency action is intended to be applicable not only to potential hazards presented by contaminants which are subject to primary drinking water regulations, but also to those presented by unregulated contaminants.
>
> ... The Committee intends that this broad administrative authority not be used when the system of regulatory authorities provided elsewhere in the bill could be used adequately to protect the public health. Nor is the emergency authority to be used in cases where the risk of harm is remote in time, completely speculative in nature, or *de minimis* in degree... However,... the Committee intends that this language be construed... so as to give paramount importance to the objective of protection of the public health...
>
> Furthermore, while the risk of harm must be "imminent" for the Administrator to act, the harm itself need not be. Thus, for example, the Adminis-

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136 Defined in 5 U.S.C.A. §551 (13) (1977). "[A]gency action' includes the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."

137 5 U.S.C.A. §706 (1977). "... The reviewing court shall (1) compel agency action unlawfully withheld or unreasonable delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion..." *Id.*

138 B. Schwartz, *Administrative Law,* 608-609 (1976).

139 42 U.S.C.A. §300i (Supp. 1978).

> trator may invoke this section when there is an imminent likelihood of the introduction into drinking water of contaminants that may cause health damage after a period of latency.
>
> Among those situations in which the endangerment may be regarded as "substantial" are the following: (1) a substantial likelihood that contaminants capable of causing adverse health effects will be ingested by consumers if preventive action is not taken; (2) a substantial statistical probability that disease will result from the presence of contaminants in drinking water; or (3) the threat of substantial or serious harm (such as exposure to carcinogenic agents or other hazardous contaminants).[140]

Under this explication of emergency authority the EPA could step in to control asbestos contamination and to order "sweeteners" added to acidic water supplies, linings on all A/C pipe in use, or other corrosion control measures immediately without going through the necessarily slow rule-making process. The Committee statement clarifies that certainty of harm is not necessary, and, most importantly, that the contaminant involved need not be already regulated. With asbestos one has a potential hazard, a period of latency before damage actually occurs, and a threat of serious harm.

Other Federal Statutes

The Consumer Product Safety Commission (CPSC) has the responsibility under the Consumer Product Safety Act (CPSA)[141] to protect the public from "unreasonable risks of injury, illness, or death associated with consumer products and may take action against specific products presenting a substantial product hazard."[142] Under the Federal Hazardous Substances Act (FHSA)[143] the CPSC "may regulate hazards involved in the presence or use of toxic and other hazardous substances in the household."[143a] Pursuant to these laws the CPSC has commenced an investigation into the use of asbestos in consumer products.[144] Although A/C pipe has been included in a CPSC list of consumer products containing asbestos,[145] it is probable that the CPSC will not concern itself with this problem. It has already made an inter-agency agreement with the EPA to coordinate activity,[146]

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[140] H.R. Rep. No. 93-1185, 93d Cong., 2d Sess. 35-36, *reprinted in* [1974] *U.S. Code Congr. & Admin. News* 6487-6488.

[141] 15 U.S.C.A. §§2051 et. seq. (Supp. 1979).

[142] 44 Fed. Reg. 60,056 (1979).

[143] 15 U.S.C.A. §1261 (Supp. 1979).

[143a] 44 Fed. Reg. 60,056 (1979).

[144] 44 Fed. Reg. 60,057 (1979). Public comment period extended, 44 Fed. Reg. 73,121 (1979).

[145] 44 Fed. Reg. 60,057, 60,061 (1979).

[146] 44 Fed. Reg. 60,056 (1979).

and the EPA has already submerged the A/C pipe problem in its broad regulatory approach to asbestos under TSCA. Although the CPSC feels that its narrower approach "may enable it to reduce consumer exposure to asbestos-containing products pending more general proceedings" initiated under EPA's broader program,[147] the FHSA is not applicable because A/C pipe is not a household product, and the definition of "consumer products" in the CPSA does not seem to embrace A/C pipe,[148] notwithstanding the inclusion of it on a CPSC list of consumer products as noted above. Public comment can still be made on the CPSC's proposals in an attempt to persuade the CPSC to regulate A/C pipe specifically if the EPA will not.

The second potential conflict with EPA authority comes from the Food and Drug Administration (FDA). However, the EPA and the FDA have agreed that "the passage of the SDWA in 1974 implicitly repealed [the] FDA's authority under the Federal Food, Drug and Cosmetic Act (FFDCA)[149] over water used for drinking water purposes."[150] "The EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water," while the FDA retains jurisdiction over "bottled drinking water" and "water (and substances in water) used in food or food processing after it has entered the food processing establishment."[151]

V. CONCLUSION

The crucial factors in any legal action to abate the danger of asbestos in New Hampshire drinking water from A/C pipe are the lack of conclusive data connecting water-borne asbestos and human illness and the absence of information about asbestos levels in the state's

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147 *Id.*

148 For purposes of this chapter:

> (1) The term "consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include:
>
> (A) any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer . . . 15 U.S.C.A. §2052(a) (Supp. 1979).

149 21 U.S.C. §§301 et. seq.

150 44 Fed. Reg. 42,775, 42,776 (1979).

151 *Id.*

drinking water. The inconclusiveness is likely to cause an action to fail under the common law or state statutes. An action may fail at the pleading stage because of the complainant's inability even to allege personal injury. Requests for rule-making on the state level concerning corrosion control measures such as the addition of water "sweeteners" may certainly be made, but obtaining judicial reversal of the denial of any request involving great expenditures for studies or creating an asbestos drinking water standard is certain to founder on the reasonableness standard applied to the WSPCC's discretion.

Action against asbestos contamination is more likely on the federal level. The EPA's initiation of the regulatory process under TSCA to control asbestos presents citizens with rule-making and public comment opportunities embracing the A/C pipe problem. However, it is likely that the EPA will not give A/C pipe a greater priority of investigation than that accorded to other asbestos products in the broad EPA regulatory program. Since action has begun that will affect the A/C pipe problem at least indirectly, appeals through judicial review of agency inaction on A/C pipe and civil actions against the EPA Administrator for denial of specific rule-making on A/C pipe are likely to fail.

The SDWA's authorization of private civil suits is ineffective in dealing with the contamination problems of A/C pipe already in the ground given the absence of asbestos maximum contaminant levels or currently-required treatment techniques that directly address the leaching of asbestos fibers. Requests for rule-making hold out the best chances for citizen action under the SDWA, particularly concerning corrosion control methods such as the addition of "sweeteners" to the water to lower its acidity. The threshold or proof of risk or harm that a federal court would require in citizen actions for creation of a regulation or initiation of emergency powers could be lower than in the common law or state statutes. However, the standard of reasonableness governing EPA rule-making may still prevent agency inaction from being overruled in judicial review initiated by a private citizen.

The EPA needs comprehensive studies of the extent and degree of the asbestos leaching problem to be able to implement the Agency's proposed corrosion control program under the SDWA and future asbestos regulation under TSCA. Therefore, requests for federal funding for studies of asbestos contamination of drinking water are certainly consistent with the authority conferred on state agencies like New Hampshire's WSPCC for primary enforcement responsibility under the SDWA.

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PTC Research Report* BUT DOES ANYONE BOTHER TO READ THEM? A Study of the Role of Patent Disclosures and Research Literature in Stimulating Invention and Innovation

What provides the stimulus for significant new inventions and innovations of science-based products and processes? It is often assumed that publications play some role; two major sources are scholarly research papers and information disclosed in patents. The purpose of the PTC study reported here was to see whether or not these assumptions are valid. In particular, it focuses only on the significance of prior patents and research literature cited in the patent applications of a number of *basic* patents associated with major technological advances from 1950, as factors in stimulating the inventions covered by the patents.

Basic patents, for the purpose of the PTC study, were taken to be those which represented a major technological advance as determined by experts in the field. Each of the basic patents was examined for certain criteria and as shown in Table I in the Appendix hereof put into one of eleven technological categories: Chemicals and Plastics, Pharmaceuticals, Ceramics and Other Non-Metals. Communications Devices, Computers and Electronic Data Processors, Electronic Components, Metals and Alloys, Photographic and Optical Equipment, Scien-

*Report of a PTC Research study performed in conjunction with the Academy of Applied Science, the Law-Related Studies Program of the Massachusetts Institute of Technology, and National Science Foundation Contract NSF C939. The Research was done under the direction of Harry M. Saragovitz, Esq., PTC Associate Director and Manager, Washington, D.C. office, and Professor J.D. Nyhart of the Massachusetts Institute of Technology. The PTC acknowledges the editorial assistance of James Gleason, Esq. and Alfred Abel, FPLC '81.

tific Instruments, Non-Electrical Machinery, and Transportation Systems Devices. By organizing the data in this way, researchers could compare the innovation patterns of each technological category over time and to other technological areas.

VARIABLES AND METHODOLOGY

Several criteria were thought to be relevant for purposes of comparison. Naturally, the information disclosed in patents is the most obvious to consider. Each citation is to either a prior patent or publication. Research citations are also of two types: basic research or applied research. These categories permit analysis of the citations in patents.

To uncover other trends or patterns in innovation, other data was taken from the patents. These include: the date of the patent, to reveal patterns over time; host country of research, to show strengths or weaknesses in American research; the source of funds, to show which groups support research; and the institution sponsoring the research, to show the extent of public, private or government sector support.

Fully one half of the 179 basic patents forming the data base for the PTC study cited prior patents while 28% cited research literature, with approximately equal reliance on basic and applied research sources (Table 2). Through interviews with a number of inventors holding the basic patents, it was determined that over one half of the patent and literature citations were actual sources of stimulation, while the remainder were for defensive purposes or to educate the patent examiner. Other sources of stimulation were: conference discussions, private communication, and other, not cited, research results (Table 11).

A first step in the study was to find a number of basic patents which represented major technological advances. The major technological advances were selected from three different sources. First was the Gellman Research Associates, Inc. list of 500 significant technological innovations from six countries (United States, United Kingdom, Japan, France, West Germany, and Canada) introduced into the market during the twenty year period (1953-1972). This list was compiled as part of a study for the National Science Foundation.[1]

In the preparation of the list, Gellman Associates selected 1160 technological innovations by surveying trade publications for mention of new innovations. Each individual innovation was then ranked by

[1] Gellman Research Associates, Inc., Indicators on International Trends in Technological Innovation (April, 1976).

an international panel of experts in the fields of science, technology and management. The 500 highest ranked innovations became one of the source lists for the PTC study.

A second source was an unofficial list of significant inventions and innovations compiled by the National Inventors Council in the mid 1960's. This was partially updated by the Academy of Applied Science of Boston, Massachusetts and cites the more significant innovations of the immediate past decade as determined by unpublished studies of the Council and the Academy.

Additionally, a list of major technological advances was compiled by conducting ninety interviews with faculty at six universities, with investigators in industrial organizations, patent lawyers and government experts.[2] The results were combined with a literature search of technical publications, conference proceedings, society journals, yearbooks, and the like. References were of various forms such as editor's remarks, awards, and reviews of recent developments as recounted in conference proceedings.

To identify the most significant developments from the three lists, additional faculty interviews were conducted. Those interviewed were not shown the prior selections but were asked what they thought were the major technical advances in their particular fields of study. They were not limited to any particular number of advances. After the responses were recorded, those interviewed were shown the lists and asked to comment on the significance of the listed inventions and innovations. A final list of major technological advances was then prepared from the responses.

From Patent and Trademark Office (PTO) records, researchers identified the basic patent or patents that represented the individual major technological advances indentified in the prior step. (In many cases, there were no basic patents associated with the advance; e.g., jet freighters.) It was not difficult to find the basic patents once the basic technological advance and its inventor or industrial innovator were identified. The differences between a basic patent and a more limited or improvement patent could be determined from a study of the patent specification and/or claims and the chronology. Where it was difficult to determine which was the basic patent, patent examiners were most helpful.

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[2] The breakdown of this group is as follows: forty faculty from the Massachusetts Institute of Technology, Harvard University, University of Pittsburgh, Brown University, University of New Hampshire, and the California University of Technology; twenty researchers from industry; thirty patent lawyers and government experts.

In all, 179 basic patents associated with major technological advances were identified. These patents formed the data base for the PTC study. However, as mentioned earlier, the sample reflects only the major technological advances that were patentable. It is impossible to say that the present sample represents all of the major technological advances in a particular field.

After the basic patents were identified, the PTO file histories (file wrappers) of the prosecution of those patents were examined. A file wrapper contains the original application, all amendments, all PTO citations and communications from the examiner, all correspondence from the applicant and his attorney, the classes of patents and the publications searched by the examiner and, in general, all interchanges between the applicant and his attorney and the PTO.

From the file wrapper, the researchers identified the inventor, his attorney and any assignee; the filing and patent issue date; and the technical publications and other patents cited by the inventor or his counsel during the filing and prosecution of the application. From this information, it was possible to identify which publications and patents cited might have been stimulants to the invention and to assign the invention to one of the technological areas listed earlier in this report.

Once the important citations were identified, they were examined. For each of the referenced sources, researchers noted whether it was a patent or basic or applied literature; the date of publication; whether the research sponsor was a university, government, non-profit, corporate or private institution; the country where research was performed and the field of science of the referenced document.[3]

DATA VERIFICATION

From the record, it is difficult to assess whether or not the cited sources were useful in stimulating the new invention. There are several factors, however, that support an assumption that they were.

First, the PTO requires that the patent application set forth the major factors underlying the invention, including a recitation of the background of the invention; a description of the nature, problems and/or disadvantages in prior approaches to solving the problem underlying the invention; a narrative of how the invention differs from what was previously known and published; and the particular advantages of the new approach presented.[4]

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[3] Science classifications were based on National Science Foundation Report NSF72-315, *Resources for Scientific Activities at Universities and Colleges* (1971).

[4] 37 C.F.R. 1.171.

Second, to protect their basic patent rights, applicants must accurately and completely cite relevant prior art to be considered by the examiner. Failure to do so may negate any presumption of validity accruing to the patent when issued.[5]

Third, in conjunction with the second point, the courts have placed increasingly stringent requirements on patent applicants to disclose the closest prior art to the PTO in the application itself and in its subsequent prosecution before the patent examiner. Court decisions invalidating patents either for lack of candid disclosure by the inventor of prior literature or other public information, or for failure of the PTO to uncover pertinent prior publications in its search, have been increasing.[6] The trend has led to more copious citations of prior art publications and uses underlying and stimulating the invention.

For these reasons, the patent prosecution file history often contains references to what the inventor learned from previously published information prior to or during the making or completion of the invention. The only reason for the inventor to cite a publication when it was not a stimulant, is for defensive purposes or examiner education. The former purpose is to protect the presumption of validity and defend against invalidation for insufficient disclosure. Examiner education, of course, is to aid the examiner in evaluating the invention.

These reasons for disclosure are of slight use in determining which references did, in fact, stimulate the inventor. The researchers, therefore, formed a procedure to check the stimulation value of citations, since this type of sorting could not be done directly from the information in PTO file.

To test whether publications cited did stimulate invention, oral interviews were conducted with the inventors. The interviews were supplemented by questionnaires. In some cases, the attorneys who prosecuted the application in the PTO were contacted to check the relevance of the citations used with respect to stimulation of the inventions. Even long after the fact, the inventors agreed that the major portion of the citations in their patent applications did have an effect in stimulating or developing their invention.

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[5] These requirements now have been formalized by the Patent and Trademark Office. "Citations of Prior Art by Applicants," Pat. Off. Gaz. (September 3, 1974).

[6] See, for example, *Beckman Instruments, Inc. v. Chemtronics, Inc.*, 428 F.2d 555; 165 USPQ (BNA) 355 (5th Cir. 1970); *Gerner v. Moog Industries, Inc.*, 383 F.2d 56 (8th Cir. 1967). Of all published court opinions invalidating patents, those based on prior publications not referenced by the applicant or found by the Patent and Trademark Office have risen from 6% in the mid-1950's to over 20% in the late 1960's.

DATA RESULTS AND ANALYSIS

The data was compiled to provide indicators of the contribution of research and prior patents to significant patented advances. The purpose of the indicators was to allow analyses of:

1. Differences and similarities in the innovative patterns of the technological areas, as demonstrated by citation of different sources;
2. The role of patents versus scientific research in major technological advances;
3. Institutional factors influencing technological innovation;
4. The role of foreign science and technology in U.S. technology.

When the indicators are presented as time series, and are distinguished by technological categories, the small amount of data obtained from a search of the patent file does not lend itself to generalizations. The remaining indicators, however, which were formed independent of time series analysis do offer substantial generalizations (Tables 1-II).

The purpose of the tables is to permit analysis of the differences and similarities in the innovation patterns of the different technological areas. Such an analysis permits an evaluation of the role of patents as opposed to scientific research in major technological advances.

Ninety-two or 51% of the 179 basic patents cited research literature or prior patents (Table 2). Prior patents were cited more often than research literature. The research literature citations are distributed approximately equally between basic and applied literature with 28% citing one or both categories.

Not all patents cited research literature and prior patents. For the 92 that did, there was a total of 283 research citations of both types, as shown in Table 3. There are more citations to prior patents (171) than to research publications (112). Of the research citations, basic literature (61) was cited slightly more than applied literature (51). The conclusion drawn from these two tables is that inventors relied more heavily on prior patents than on research literature for stimulation, and evenly on the two types of research literature. In Tables 4 and 5, the data establishes a different trend. Table 4 shows, by time period, the percentage of basic patents which cite research literature and prior patents. There is an increase in total citations over the time periods, and a marked growth in research literature citations. However, in Table 5 the total number of reference citations compared to research literature per-basic-patent appears to be gradually declining. A com-

parison of these two tables indicates that reliance on research literature and prior patents is becoming more widespread (Table 4), with a corresponding decrease in the degree to which inventors rely on research literature (Table 5).

Table 6 shows the percentage of basic patents in each technology that cited research literature of prior patents. Some of the percentages are underlined to show that the values are greater than the corresponding group averages in Table 2, and indicate a higher incidence of citation. All of the technologies cited research literature or prior patents nearly equally, with the exception of the Scientific Instruments category. There, 82% of the basic patents contained citations as compared to 51% overall (Table 2). The technology categories of "Chemicals and Plastics," "Pharmaceuticals," "Communications Devices," "Photographic and Optical Equipment" and "Scientific Instruments" all had a relatively high proportion of basic patents citing research. Those areas that were proportionately high in prior patent citations were "Ceramics and Other Non-Metals," "Computer and Electric Data Processors," "Electric Components," "Scientific Instruments" and "Non-Electrical Machinery."

Table 7 distinguishes between the number of citations to research literature and the number to prior patents per-basic-patent. As in Table 6, the citations are grouped according to technology. Thus the number 2.4 for the technology "Chemicals and Plastics" under the heading of "Research Literature" indicates that for each basic patent in that technology citing research literature, there were 2.4 citations made to research literature. Again, the numbers that are greater than the group averages in Table 3 are underlined.

An analysis of Tables 6 and 7 provides insight into the innovation patterns of the technologies listed. Comparing the underlined figures in each table shows which technologies had a large percentage of basic patents citing a relatively large number of references. For example, in Table 6 the field of "Chemicals and Plastics" displayed an above average percentage of basic patent citations to research literature. Table 7 shows this field had more citations to research literature per-basic-patent than the overall average. From this, one can conclude that research literature cited in this area was heavily relied upon. Some technologies permit a similar conclusion with prior patents but not research literature, e.g., "Ceramics and Other Non-Metals." Likewise, the converse often holds true. For instance, the field of "Pharmaceuticals" displays an above-average number of citations of research literature per-basic-patent and a below-average amount of citations of prior patents per-basic-patent. Thus the conclusion in this

technological field is that there was heavy reliance upon the research literature citations in the basic patents with no more than average reliance upon the prior patent references. The innovation patterns may be interpreted for any technology listed by simply combining the two tables and finding the type of citation the particular technology relied upon for the significant advances in that field. Table 8 categorizes, by class of citation, the technologies having a relatively high percentage of basic patents citing a relatively high number of references.

Table 9 is an analysis of four basic sectors performing research: government; corporate and private; university; and other non-profit.

The table permits an overview of the citations that stimulated the inventor. This table demonstrates that corporate institutions and private individuals performed the research underlying the majority of prior patent and applied research literature citations. In turn, universities performed the research underlying approximately one-half of the basic research literature citations. Conclusions drawn from this table permit some analysis of the role that individuals and institutions play in stimulating inventions. Once it is known which institution is providing the relevant research, steps may be taken to insure that its contribution will be continued.

Worthy of mention is the role of foreign science and technology. This role is discovered by noting whether the United States or foreign countries hosted the research that provided the basis for the research literature or prior patent citations in the basic patent. The general observation to be made from Table 10 is that in most technologies 75%-90% of the citations represented research done in the United States. Those technologies that were particularly benefited by U.S. research were "Computers and Electronic Data Processors," "Electronic Components," "Photographic Optical Equipment," and "Transportation Systems and Devices." In contrast, nearly one-half of the citations in the field of "Communications Devices" were based upon research done outside the United States. This field, however, is clearly in the minority. Thus foreign research resulted in some contribution to the U.S. technology, but at the time of the study, contribution remained comparatively trivial.

As previously indicated, in order to supplement and verify the data presented in the tables, the information gathered from the PTO files was presented to the inventors and others to verify the assumption of the study that the citations in the basic patents represented references that actually stimulated or aided the inventors. The assumption is not always safe to make since, as previously mentioned, there are other

reasons for citing prior patents and technical publications. The presence of uncertainty necessitated correspondence and telephone interviews to determine reasons for the citations. The question asked of each inventor was whether or not the researchers would be correct in assuming that a particular citation stimulated or otherwise aided the inventor. The inventors were also asked to indicate the extent to which they were stimulated by information not referred to in their patent applications and why the information was not cited. Four possible reasons for not making a citation were noted:

1. Attorney had no knowledge of the citation;
2. Duplicate references;
3. Attorney feared the citation would be misconstrued to his client's detriment; and
4. Citation was irrelevant to the application.

Also noted were the possibilities of stimulation through conference discussion or private communications. The inventors were asked to make particular reference to the above possibilities, if relevant to their application. Those inventors who had no citations in their patent application were likewise requested to comment on the noted considerations.

INTERVIEW DATA

Letters were sent to 154 of the 176 basic patent holders. Each letter included an invitation to call the researchers to discuss any matter or clarify any questions. There were 15 phone calls received and 52 letter responses registered. The 52 letter responses represented 44 of the 176 basic patents. The phone conversations are not encompassed in any of the following tables, but they did serve to confirm the importance of prior patents and technical publications in stimulating, aiding and motivating the inventor. Data from the letter interviews confirmed that it was safe to assume that in the majority of instances the basic patents contained references that actually aided or stimulated the inventor. This data was divided into four parts (Table 11).

Part A shows that of the 44 responding patentees, 11 cited research publications and 12 cited prior patents. In 8 of the 11 basic patents that cited research publications there was a citation that stimulated the inventor. Also indicated is that in 7 of the basic patents citing prior patents there was at least 1 such citation that had stimulated the inventor.

Part B shows that there was a total of 25 research publication cita-

tions. From these totals 18 research publication citations were indicated by the inventors as having actually stimulated them. The other 7 citations were singled out as not having been a stimulant. Of the 30 prior patents cited, 17 were noted as being actual stimulants.

In Part C the responses of inventors were categorized to show the number who were in fact stimulated or enlightened by research publications or by prior patents *not* cited in their patent applications. There were 18 basic patents with citations and 26 without citations from this group of 44 inventors. Eight of the inventors named in the 26 patents without citations indicated they were in fact stimulated by research publications and prior patents. Inventors in only two of the 18 basic patents with citations indicated they were stimulated by prior patents.

Part D shows the extent to which inventors were stimulated by research they were made aware of by sources other than through research publications and prior patents. Inventors in 9 (20%) of the basic patents reported having been stimulated by conferences or private discussions.

The interview data permitted conclusions concerning the validity of the assumption that citations in the basic patents represent references that actually stimulated or aided the inventor. The clear majority of the inventors citing publications or prior patents were in fact actually stimulated by such citations. Thus, Part A suggests that citations in the basic patents generally represent references that were an actual stimulant. Part B reinforces this conclusion by breaking down the total number of citations made by the responding patentees. Because of the small amount of data, the actual proportion of invention-stimulating citations to citations that did not stimulate cannot be accurately measured. It seems reasonable to conclude that the majority of research publications cited in the basic patents stimulated the inventor. The same conclusion may be drawn regarding the prior patent citations in the basic patents.

In Part C, 31% of the basic patents have no citations indicated, but the inventors stated that they were stimulated by research publications and prior patents. Their reasons for not citing the other work are encompassed in the four possibilities noted above. The failure to cite actual stimulants is significant if the 31% figure holds fairly constant for the entire sample of 179 basic patents. Table 2 shows that 51% of the basic patents cited research publications. Thus it would appear possible that research publications are of greater influence than a study of the patent files alone would disclose.

As with research publications, it appears that conferences and private discussions are more of an influence upon invention than the

patent files indicate. Sufficient data is lacking to permit a firm conclusion, but the data presented shows that 20% of the basic inventions were stimulated by some type of discussion. At a minimum, it may be concluded that conferences or private discussions are worthy of recognition in considering the stimulation of invention.

STUDY CONCLUSIONS

Nine of the eleven tables permit analysis of the differences and similarities in the innovation patterns of the different technological areas. In Table 2 it is seen that approximately one-half of the basic patents analyzed cited some type of reference. Prior patents were cited as a reference more often than research literature. Table 3 is an overview of a total number of citations made by the basic patents. Here again there were more citations to prior patents than research literature. The conclusion from this data is that inventors relied more heavily on prior patents than research literature for stimulation.

While reliance upon research literature and prior patents appears to be increasing, as seen in Table 4, there may be a decrease in the degree to which inventors are relying upon research literature for stimulation since research citations have remained fairly constant while citations as a whole have increased. If the emerging trend to this effect continues, the significance of prior patents upon technological advances will greatly increase; however, the trend is still conjecture.

As seen in Table 6, each technology had about the same percentage of citations. From this table it may also be observed which technologies had relatively high reliance upon a certain type of reference (research literature or prior patents). Table 7 contains the number of citations per basic patent and when combined with Table 6 the innovation patterns of each technology may be discovered. It may be determined which references were relied upon by each technology. Once producers know which references are most productive, they may direct a majority of their inquiries to that particular stimulant. The technologies most likely to benefit from this are noted in Table 8, in which high reliance technologies are listed according to reference source.

An analysis of the basic sectors performing stimulating research is made in Table 9. Apart from the category of basic research literature, where most reliance was made upon university publications, the literature and prior patents of corporate institutions and private inventors served as the most numerous sources of useful material.

The impact of foreign publications is seen in Table 10. In most technological areas, foreign publications played a minor role at best. This table shows, however, that substantial influence by foreign liter-

ature and patent citations was found in the fields of Chemicals & Plastics and Communications Devices.

As noted above, the data presented in the tables was supplemented and verified by interviews. A significant portion of the responding basic patent holders indicated they were in fact stimulated by research publications or prior patents even though they made no such citations in their patent application. The significance of this would be greatly increased if it is true for the entire sample of 179 basic patents. At any rate, it is evident that some patentees do not cite every stimulant in their applications. This position is reinforced in Part D of Table 11 where it is seen that 20% of the responding patentees were stimulated by discussions not noted in their patent applications. Again it should be remembered that the interviews were merely a supplement to the study.

The data collected sheds some light on the differences and similarities in the innovation patterns in different technological areas and in different institutional settings, as well as the role of foreign science and technology toward stimulating invention in the United States. While data on these topics is limited some conclusions can be drawn.

1. The category of Transportations Systems and Devices seemed to be substantially below average in the number of all citations (Tables 6 and 7).
2. Four technological areas appeared to have an above average reliance on research literature: Chemicals and Plastics, Pharmaceuticals, Photographic and Optical Equipment, and Scientific Instruments (Table 8).
3. The two fields of Ceramics and Non-Electrical Machinery appear to have an above average reliance on prior patents (Table 8).
4. Universities were the source of most basic research citations, with corporate research providing most of the patent and applied research citations (Table 9).
5. Only the technology field of Communications Devices showed a substantially lower (63%) percentage of citations based on United States research than the other fields (75-95%) (Tables 10 and 11).

The PTC study provides some insight into the innovation patterns of certain technologies. Sufficient data was accumulated to provide substantial conclusions on the role of patent disclosures and research literature in stimulating invention. The conclusions, with their ensuing

implications, permit technology to establish patterns for guidance in stimulating significant new inventions and innovation.

APPENDIX
TABLE I

Summary of Technological Areas and Major Technological Advances.

TECHNOLOGICAL AREAS	NUMBER OF MAJOR ADVANCES	EXAMPLES
Chemicals and Plastics	26	Xerographic Electroplating Compounds N-Oxide of Double Standard RNA
Pharmaceuticals	12	Diabenese Oral Anti Diabetic Agent
Ceramics and Other Nonmetals	6	Manufacture of Flat Glass
Communications Devices	20	Color Television System Laser Device
Computer and Electronic Data Processors	17	Digital Information Storing Device Electronic Music Instrument
Electronic Components	25	Tunnel Diode Cathode Ray Storage Device
Metals and Alloys	16	High Chromium Steel Permanent Magnetic Materials
Photographic and Optical Equipment	8	Wavefront Reconstruction
Scientific Instruments	11	Ruby Laser Systems Low Energy Electron Sterilization
Non-Electrical Machinery	22	Fluid Spring Controlled Drag Parachute
Transportation Systems and Devices	16	Multiple Speed Transmission Missile Launching System
	179	

TABLE 2

Number and Percent of Basic Patents Citing Research Literature and Prior Patents

	NUMBER	PERCENT
Research Literature	51	28%
Basic Literature	34	19%
Applied Literature	34	19%
Prior Patents	70	39%
Total Basic Patents Citing Literature and Prior Patents	92	51%

TABLE 3

Number and Percent of Citations to Research Literature and Prior Patents

	Total	Number per Basic Patent	Percent
Research Literature	112	2.2	40%
Basic Research Literature	61	1.8	22%
Applied Research Literature	51	1.5	18%
Prior Patents	171	2.4	60%
	283		100%

TABLE 4

Percent of Basic Patents Citing Research Literature & Prior Patents, by Time Period

	1950-1953	1954-1957	1958-1961	1962-1965	1966-1969	1970-1973	1950-19
Research Literature	22%	21%	27%	33%	29%	50%	28%
Basic Research Literature	16%	18%	17%	23%	18%	21%	19%
Applied Research Literature	11%	14%	23%	19%	18%	43%	19%
Prior Patents	38%	43%	40%	31%	39%	57%	39%

TABLE 5

Number of Citations to Research Literature and Prior Patents per Basic Patent Citing Such Citation, By Time Period

	1950-1953	1954-1957	1958-1961	1962-1965	1966-1969	1970-1973	1950-1973
Research Literature	3.0	2.3	1.9	2.4	1.6	1.7	2.2
Basic Research Literature	2.3	1.2	1.2	2.3	1.6	1.3	1.8
Applied Research Literature	2.5	2.0	1.3	1.4	1.0	1.3	1.5
Prior Patents	1.9	3.3	2.5	2.4	2.8	1.8	2.4

TABLE 6

Percent of Basic Patents Citing Research Literature and Prior Patents, By Technology

Technology	Research Literature	Prior Patents	All Citations
1. Chemicals & Plastics	38%	31%	42%
2. Pharmaceuticals	50%	25%	50%
3. Ceramics & Other Non-Metals	17%	50%	50%
4. Communications Devices	35%	30%	55%
5. Computer and Electronic Data Processors	24%	47%	53%
6. Electronic Components	28%	44%	56%
7. Metals & Alloys	25%	38%	44%
8. Photographic & Optical Equipment	38%	38%	50%
9. Scientific Instruments	36%	45%	82%

10. Non-Electrical Machinery	14%	55%	55%
11. Transportation Systems & Devices	13%	31%	44%
Table 2 Averages	28%	39%	51%

TABLE 7

Number of Citations to Research Literature and Prior Patents per Basic Patent Citing Such Citations, by Technology

	Research Literature	Prior Patents	Total Making Citations
1. Chemicals & Plastics	2.4	4.4	5.4
2. Pharmaceuticals	3.5	2.0	4.5
3. Ceramics & Other Non-Metals	1.0	2.7	3.0
4. Communications Devices	2.0	2.8	2.8
5. Computer & Electronic Data Processors	1.0	1.8	2.0
6. Electronic Components	1.4	1.9	2.2
7. Metals & Alloys	1.5	1.2	1.9
8. Photographic & Optical Equipment	3.3	4.0	5.5
9. Scientific Instruments	3.0	1.8	2.6
10. Non-Electrical Machinery	2.7	3.0	3.7

11. Transportation Systems & Devices	1.0	1.2	1.1
Table 5 Averages	2.2	2.4	

TABLE 8

Technologies Having A Relatively High Percentage of Basic Patents Citing A Relatively High Number of References, By Class of Citation

Research Literature

Chemicals and Plastics
Pharmaceuticals
Photographic and Optical Equipment
Scientific Instruments

Prior Patents

Ceramics and Other Non-Metals
Non-Electrical Machinery

TABLE 9

Citations to Basic and Applied Research Literature and Prior Patents by Institution Performing Research

	Basic Research Literature	Applied Research Literature	Prior Patents	All Citations
Government	9	9	9	27
Corporate & Private	12	27	160	199
University	26	9	2	37
Other Non-Profit	7	1	0	8
Totals	51	46	171	268

Total does not match the 283 citations of the study since it was not possible to uncover the institution which did the research for some citations.

TABLE 10

Totals of United States and Foreign Literature and Patent Citations

	United States	Foreign	Percent of Citations Originating in U.S.
1. Chemicals & Plastics	44	15	75%
2. Pharmaceuticals	23	4	85%
3. Ceramics & Other Non-Metals	8	1	88%
4. Communications Devices	19	11	63%
5. Computers & Electronic Data Processors	18	0	100%
6. Electronic Components	29	2	94%
7. Metals & Alloys	10	3	77%
8. Photographic & Optical Equipment	21	1	95%
9. Scientific Instruments	16	4	80%
10. Non-Electrical Machinery	35	9	80%
11. Transportation Systems and Devices	8	0	100%

TABLE 11

Part A

Number and Percent of Basic Patents Indicated in Written Interviews As Having Cited Prior Patents or Research Publications that Stimulated the Inventor

	Basic Patents Citing Research Publications	Basic Patents Citing Prior Patents
Indicated as having a citation that stimulated the inventor	8 (73%)	7 (58%)
Indicated as having no citations that stimulated the inventor	3 (27%)	5 (42%)
	11 (100%)	12 (100%)

PART B

Number and Percent of Research Publication and Prior Patent Citations Indicated in Written Interviews as Having Stimulated Inventor

	Research Publication Citations	Prior Patent Citations
Indicated as having Stimulated Inventor	18 (72%)	18 (60%)
Indicated as not having stimulated inventor	7 (28%)	12 (40%)
	25 (100%)	30 (100%)

TABLE 11

Part C

Number and Percent of Basic Patents Where Inventors Indicated Being Stimulated by Additional Research Publications and Prior Patents

	Basic Patents With Citations	Basic Patents Without Citations
Noting Additional, Stimulating Publications	2 (11%)	8 (31%)
Noting Additional, Stimulating Prior Patents	1 (6%)	1 (4%)

Part D

Number and Percent of Basic Patents Where Inventors Indicated Having been Stimulated by Research Results Discovered in Conference Discussions and/or Private Discussions.

9 (20%)

THE TRADEMARK REGISTRATION TREATY
Its Implementing Legislation

PREPARED BY DAVID B. ALLEN*

INTRODUCTION

This writing discusses legislation drafted by the Patent and Trademark Office (PTO) in the Department of Commerce for the purpose of implementing the Trademark Registration Treaty (TRT).[1] Although the TRT legislation was submitted by the Department of Commerce to the Office of Management and Budget (OMB) as long ago as the Fall of 1975, it has not been introduced into the Congress and is still under consideration in the Administration. However, the complete draft, in essentially the same form as the one that was forwarded to OMB in 1975 has been published.[2]

The current interest in the TRT is based largely on its possible impact in facilitating foreign trade. Increasing U.S. exports is a major goal of the federal government. It is now a conviction of almost all economists that better export performance by the United States is essential if there is to be significant growth in our economy. The competitive edge enjoyed by many United States companies in international trade is due to superior marketing programs. The success of these programs in selling American products frequently depends upon international protection of the trademarks through which they are carried out. Perhaps the TRT is only a small part of this picture — but it is an important part, especially for small and medium sized firms for

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[1] The articles of the TRT and its regulations were published in 912 TMOG 205 (1973).

[2] Trademark Registration Treaty; Implementing Legislation, 973 TMOG 3 (1978).

which trademark protection is relatively more difficult and more costly.

The legislation proposed by the Department of Commerce has two purposes, set forth in general terms in the preamble of the bill:[3]

First, it implements the TRT, which was adopted in June, 1973 by a diplomatic conference in Vienna,[4] the essential purpose being to facilitate the protection of trademarks used or intended to be used in international trade. The TRT was signed by the United States and transmitted by the President to the Senate of the United States on September 3, 1975, with a message requesting the Senate to give its consent to ratification.[5]

Second, the TRT bill makes modifications in the domestic law to provide to United States nationals and residents the same benefits when filing national applications for trademark registration in the PTO as those which would be available to such applicants in the United States if they were filing under the Treaty.

The TRT will establish an international trademark filing arrangement under which persons and companies residing in one of the member States can more easily register their trademarks, service marks and collective and certification marks and maintain those property rights in all of the member States. The complexity and high cost of establishing and protecting trademarks in international markets through the diverse national laws and procedures is a serious problem for businessmen seeking to further their commercial objectives by the sale of trademarked products across national boundaries. If trademark protection in potential foreign markets is not secured promptly, the unprotected mark is liable to be appropriated by a "pirate" or may be coincidentally adopted by another.

International trademark filing arrangements alleviate these problems by establishing alternative international registration procedures through which the effects of national trademark registration in member countries can be secured, maintained and renewed on a central international register of marks more easily, more quickly and at

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[3] *Id.*

[4] The Report of the United States Delegation to the Vienna Diplomatic Conference on Industrial Property was published in 931 TMOG 64 (1975). A complete report of the conference is in the *Records of the Vienna Diplomatic Conference on the Trademark Registration Treaty,* World Intellectual Property Organization (WIPO), 1975 (WIPO Publication No. 317 (E)).

[5] Message to the Senate Transmitting the Trademark Registration Treaty, II Public Papers 1290 (September 3, 1975). This includes the President's Message and Report of the Secretary of State. The message was given before the 94th session of the Senate Executive. The Treaty was referred to the Committee on Foreign Relations.

lower cost than by the present country-by-country procedures.

DEVELOPMENT OF THE TRADEMARK REGISTRATION TREATY

The TRT was the culmination of continuous and painstaking efforts since 1965, by the United States, to participate in an acceptable international arrangement which would facilitate the protection of trademarks in international commerce.

The Madrid Agreement

Consideration was first given to the possibility of United States adherence to the Madrid Agreement for the International Registration of Marks.[6] The Madrid Agreement, in force since 1891, has long operated successfully and now has twenty-four member States.[7]

Essentially, a Madrid Agreement registration can be extended to the entire continent of Europe except for Poland, Greece, Bulgaria, Albania, and the four Scandinavian countries. There are also four member States in North Africa. The most recent member is the USSR which acceded in July 1976. By 1968, it became apparent that there was substantial U.S. private sector opposition to accession to the Madrid Agreement in its present form. Certain of its features, it was argued, would be contrary to the interests of the United States firms.

The Madrid Agreement provides for the registration of marks at an International Bureau, part of the World Intellectual Property Organization, located in Geneva, Switzerland. Registrations effected under the agreement are called international as every registration has an effect in several countries, and potentially in all member States of the Madrid Union. To be able to enjoy the advantages of this agreement, the applicant must be a national of or domiciled or have a real and effective industrial or commercial establishment in one of those countries. He must also first have his mark registered in the national office of that home country. He may then file, through that same national office, an application for international registration.

Once the international registration is effected, it is published by the International Bureau and communicated to the member States in

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[6] See Allen, A Report on the Madrid Agreement, 56 TMR 290 (1966).

[7] Measured in terms of trademark activity, the most important members are France, Germany (F.R.), Italy, Spain, Benelux (Central Trademark Registry for Belgium, Netherlands and Luxembourg), and Switzerland. For example, U.S. origin national applications in these countries are estimated to be approximately 12,000 in 1976. *Industrial Property,* Number 9, September 1977 (Annex) pp. 30-35. Statistics for Spain and Italy extrapolated from previous years.

which the applicant wishes to have protection. Each such State, within 12 months from the date on which the mark has been recorded in the international register, may declare that protection cannot be granted to the mark in its territory. The refusal must indicate the grounds for the decision. If a declaration of refusal is made, the procedure continues in the refusing national office or before the courts of the country concerned. If a declaration is not made within the one year period, the international registration then has the effect of a national registration.

International registration under the Madrid Agreement has a number of obvious advantages for owners of trademarks. In fact, the latest published statistics demonstrate that of all the trademarks applied for by firms located in Madrid Union member States, 95 percent are filed through the Madrid Agreement system and only 5 percent through national procedures.[8]

Some persons consider the home country registration feature of the Madrid Agreement to be a disadvantage. Not only is home registration a prerequisite to securing the international registration but the international registration also continues to depend on the home country registration for a period of five years. Thus, a successful attack on the home country registration which is started during the first five years results in total destruction of the international registration, including its national effects.[9] In practice, such destruction seldom occurs, probably because the home country rights are generally the most secure. But the effect of dependency is limiting, nevertheless.

Between 1968 and 1970, there was an effort to revise the Madrid

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[8] *Id.* For example, French residents filed only 120 national applications in Germany (F.R.) during 1976, compared to 1,597 extensions of Madrid registrations; during same year, residents of Germany (F.R.) filed only 374 national applications in France compared to 1,869 Madrid extensions. The significance of the Madrid Agreement in Europe is also demonstrated by its total impact on filings. For example, in 1976, there were 7,393 international registrations secured. However, the total number of extensions of international registrations to the 22 member offices (Benelux is a single office representing three member countries) during that year was 77,794. Although a small part of these (about three percent) were extensions of previous registrations, most (75,195) were extensions that were requested simultaneously with the international registrations to which they pertained. This Madrid Agreement activity represents forty-three percent of the total 1976 trademark filing activity (Madrid plus national) in the member countries. (*Note:* Italy, Spain and Tunisia were removed in making this comparison due to the unavailability of their 1976 national filing statistics.)

[9] See Allen, Report on Committee of Experts for the Revision of the Madrid Agreement, 60 TMR 163, 165 (1970).

Agreement in order to correct alleged deficiencies. These efforts were not entirely successful.

U.S. accession to the Madrid Agreement would have required only minimal changes in the law as the provisions of Section 44 could easily be accommodated to the Madrid international registration system.[10] However, since there was opposition to certain of the features of the Madrid Agreement, especially dependency, interested private groups continued to urge United States participation in the development of a more acceptable international trademark arrangement.[11]

Formation of the TRT

In September, 1970, a United States sponsored resolution to develop a new treaty was adopted unanimously by the competent administrative organs of the Paris Convention. After several drafts and examination by consultant groups and six Committees of experts, a final draft was considered at a diplomatic conference held in Vienna, Austria from May 17 to June 12, 1973. Fifty states and thirty-one international organizations were represented at the conference. On June 12, 1973, the TRT was signed by eight countries, including the United States, and it remained open for signature until December 31, 1973, by which date a total of fourteen countries had signed. The TRT entered into force among the U.S.S.R. and four African nations on August 7, 1980.[12]

The TRT establishes a multilateral trademark filing arrangement for securing, administering and maintaining national trademark registration effects in other countries. This simplified procedure involves the filing of a single international application, securing a single international registration and maintaining a record of such rights on a central international register. Under the TRT, international registration amounts to a central recording of what might be described as a "bundle of national rights" rather than being a separate property right. With some exceptions, the substantive aspects of these rights are regulated by each member State according to its national law.

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[10] For example, the other Madrid Union members were willing to accept the fact that the International Bureau might have to receive additional documents, i.e., the declaration of use "somewhere" and facsimilies to evidence such use, for forwarding to the PTO whenever territorial extension to the United States was requested. Note 6, *supra,* at p. 312.

[11] Note 9, *supra,* at 163.

[12] The four African countries are Gabon, Togo, Congo and Upper Volta. The USSR deposited an instrument of accession on February 7, 1980, the last of the five required for its entry into force after the six month delay prescribed by Article 41 (1).

The following paragraphs summarize the TRT procedure.

1. A national or resident of a member State may file directly with the International Bureau of the World Intellectual Property Organization (WIPO) an international application designating the States in which protection of the trademark is desired. Any number of States, including the applicant's home State, may be designated.
2. The international application may claim the priority (Paris Convention "right of priority") of an earlier first application to register the same trademark. Since the priority application under the Convention may be a filing under a treaty that is equivalent to the national application, one possible procedure under the TRT is to file first an international application designating a single country (probably one's home country) and follow that within 6 months with a request for recording later designations which claims the right of priority of the international application.
3. The application is subject to an international fee plus a fee for each signated State not higher than 100% of the total fees for national registration. The international fee which is prescribed by the Regulations is 400 Swiss francs.
4. After a brief examination as to formal requirements, the trademark is registered by the International Bureau. The details of the international registration are promptly published in English and French in an international gazette and communicated to each of the designated States.
5. Unless refused by a designated State, the international registration is accorded the same legal effect as if the same trademark were registered nationally in that State. The time limit for the initial notice of refusal, including all reasons or possible reasons for refusal, is fifteen months from the date of the international publication. The reasons for refusal cannot be different than those applicable to national applications.
6. If initially refused by any designated State, the owner is notified of the refusal and is guaranteed the same procedural rights of reexamination and/or remedies availa-

> ble in the case of refusals of national trademark applications. Further proceedings are not subject to any Treaty time limits, and are carried out directly between the owner and the concerned national office.

In an alternative filing procedure, the applicant files first a *national* application in his home country followed by an international TRT application. If the international application is filed within six months of the filing date of the national application, a right of priority may be claimed. The rest of the procedure is the same as outlined above.

The post registration effects are the same under either alternative. An international registration may be cancelled in any designated State according to the national law of that State. The effect of cancellation under TRT is always limited to the State in which the legal action for cancellation was brought, a change from the Madrid Agreement. An international registration may be renewed at ten year intervals by a single renewal application filed with the International Bureau. Also, States not originally designated may be added later by requesting the recording of later designations of the new States.

ADVANTAGES OF THE TRT

The long term objective of the TRT is to simplify by reducing the paper work. For instance, assignments, changes of name and limitations of the goods or services may be recorded by filing a single international request on a standard form with the same legal effect as if these changes were recorded in each of the national registers. For many users, the post-registration recording features of the TRT will be significant in terms of their benefits. For example, in the case of a change in the corporate name of a large company, the task of recording this change in all of the company's registrations world-wide is enormous. A significant advantage of the TRT is that the paperwork involved in such recording programs can be reduced to a single action on a standard form in a central office. This is easier, less costly, and less likely to result in errors. Errors may be costly and, in some countries, having the wrong owner could seriously prejudice an owner's position as a plaintiff when asserting registration rights in a foreign court. There is also a mechanism in the TRT whereby the post-registration benefits may be made applicable to existing national or Madrid Agreement registrations of the same mark by transforming these registration rights into international TRT registrations.

All of the benefits of the TRT will be available only to nationals or

residents of the member countries. As to these, the Treaty may be used to secure protection in a single country, a few countries, or in many, depending upon the extent of commercial interests. The regulations annexed to the Treaty provide rules concerning administrative requirements. Administrative instructions, including forms, are now under consideration by a TRT Interim Committee.[13]

EFFECTS OF THE TRT ON UNITED STATES TRADEMARK LAW

Participation in this international system for the United States will require that our national trademark law be amended in a number of respects. The most important change is one which is required by the third paragraph of Article 19 of the treaty. Under this provision, non-use of a trademark during an initial period of three years counted from its international registration date *cannot* result in refusal or cancellation by any designated State. However, any State may require that the owner declare his intention to use the trademark in that State and may further provide in its national law that no action for infringement may be started until the continuing use of the trademark in that State has started and that any remedy — for example, damages or profits — may relate only to that period after use has commenced.

Translated into the implementing legislation, the federal statute will permit the securing of a national registration in the United States based on an intention to use the trademark for which registration is applied.[14] During an initial period of three years counted from the filing date, non-use of the mark cannot be a basis for refusal of the application or cancellation of the registration.[15] It should be noted that the term "filing date" is used because the international registration date of an international registration is equivalent in our system to the filing date. Thus the date from which the period of permitted non-use begins is the filing date rather than the date of issue of the registration. The proposed legislation also provides, by amendment to Section 32 of the Trademark Act, that infringement actions will continue to be contingent upon the commencement of use[16] and, by

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[13] The fourth session of the Committee was held in Geneva, Switzerland from 26 February to 2 March, 1979, Industrial Property, Number 6, June, 1979, p. 154.

[14] Trademark Registration Treaty: Implementing Legislation, amended sec. 1 (a), 973 TMOG 7 (1978).

[15] *Id.* Amended sec. 1 (c) at 7.

[16] *Id.* Sec. 22 at 11.

amendment to Section 35, that remedies are limited to the period of actual use.[17]

The essence of these changes in United States trademark law is that they move from the strict use approach — today held only by the United States and very few other countries, for example the Republic of the Philippines and Panama — to a middle position, that is a use or intention to use system similar in principle to that of Great Britain and the many countries whose trademark laws were patterned after the British model. Proponents of the TRT believe that with the change, United States law will be more consistent with the legitimate needs of businessmen, especially where international trade is contemplated.

In fact, legislation permitting the filing of a trademark application based on an intention to use the mark was widely supported in the private sector beginning with the Dirksen bills which were developed and introduced at the request of a group of trademark lawyers from Chicago.[18] In the 91st and 92nd Congresses, identical House and Senate bills substantially the same as the earlier Dirksen bill were introduced at the request of the Administration and had broad public support.[19] This legislation was not reintroduced in the 93rd and 94th Congresses, however, since it was known at an early stage in the development of TRT that the use requirements of the United States law might be affected and the precise nature of these requirements would depend upon the outcome of the negotiations.

The support of intention to use legislation in the United States had its foundation in domestic concerns. Under present law, actual use of a mark is a prerequisite to the filing of an application for registration. Thus, every domestic applicant for federal registration, in addition to other requirements, is required to specify in his application the date of first use of the mark and the date of first use in commerce over which Congress has actual control.

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[17] *Id.* Sec. 24 at 11.

[18] *Dirksen:*
S. 4254, 85th Congress, 8 August, 1958.
S. 1063, 86th Congress, 16 February, 1959.
S. 150, 87th Congress, 5 January 1961.
S. 2786, 88th Congress, 29 April, 1964.
S. 2313, 89th Congress, 21 July, 1965.
S. 1858, 90th Congress, 24 May, 1967.
S. 1568, 91st Congress, 17 March, 1969.

[19] The last of these were:
McClellan, S. 2595, 92nd Congress Session (1971).
Kastenmeier, H.R. 10727, 92nd Congress Session (1971).

As applied to the adoption of new trademarks, the requirement to establish use of a mark prior to applying for its registration is believed by many to be unrealistic since the time interval between clearance and adoption of a trademark and its use on products in commercial quantities varies from several months to several years depending upon the products involved. Typically, before a consumer product is marketed commercially, considerable time and effort is expended in developmental stages. After having undertaken the effect and expense of creating and planning the promotion of a new mark the businessman may find that the mark is not registrable because of conflict with another mark or for some other reason. These problems led to the drafting and introduction of intent to use legislation.[20]

Such legislation is not new in the world. The United Kingdom has accepted applications based on use or proposed use since 1905 and the countries of the Commonwealth have long embraced similar laws. A recent illustration of the practicability of these laws in countries other than Great Britian is the recent work of the WIPO in developing a model law for English speaking African States. Although various innovations were tried, the Africans kept coming back to the fundamentals of the Trade Marks Act of 1905 and incorporated intention to use features in the final text.[21] In 1954, Canada, after careful study, adopted a system permitting applications for registration on the basis of proposed use. Canada recently completed a thorough review of its trademark system and the final report of that study confirms the acceptability of proposed use system in that country.[22]

Although similar in terms of their substantive effect, the intention to use provisions in the Dirksen bill and those introduced during subsequent sessions of Congress would not satisfy the requirements of TRT. There are these two basic differences.

First, under the Dirksen bill, the time period for filing the declaration of use was flexible, depending upon the length of time consumed by the examination process, that is, ninety days counted from the date of allowance of the application by the examiner. The period could be shortened if the application was opposed. Although entirely dependent upon the pendency experience of the Patent and Trademark Office, the period of permitted non-use for most of the applied for marks under

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[20] For an excellent discussion of these problems, see Dalsimer, Intention to Use — A Proposal, 53 TMR 934 (1963).

[21] *Model Law for English-Speaking African Countries on Trade Marks,* World Intellectual Property Organization (WIPO), 1979.

[22] *Working Paper on Trademark Law Revision,* prepared for the Department of Consumer and Corporate Affairs (WIPO) January, 1974, pp. 269, 270.

those bills would have been in the approximate range of one to two years to be counted from the filing date. Under the TRT, the time period during which use may be required cannot be less than three years counting from the filing date.

While the Treaty permits reservation of a mark for an initial three year period, a more extended reservation can be precluded by any member State, a possibility created by a sentence which was added to the third paragraph of Article 19 at the Vienna Conference. This limitation is included in the draft-implementing legislation. Thus, the three year period in the United States cannot be extended except for *extraordinary* reasons and the mere fact that the application is still pending at the date of expiration of the three years will not be accepted as a reason for an extension of time.[23] One might consider extraordinary circumstances to include, for example, the fact that an application to the Food and Drug Administration for approval to market a new drug is pending at the expiration of the three year time limit.

Second, under the Dirksen bill an application could be filed, and priority secured without actual use and based on an intention to use the mark, but the registration would not issue until a declaration demonstrating actual use had been filed and accepted. The concept was similar to that employed in the 1954 Canadian Trademark Act.[24]

Under the TRT, national registration effects may not be refused or cancelled on the ground of non-use for the initial three year period. However, any country may provide that the right to sue for infringement of the registered mark (even during the three years) is subject to the condition of use, i.e., there is no right to sue until after continuous use has commenced and any remedy in such action may relate only to the period after use has commenced.

This proviso of the Treaty has been carried forward into the implementing legislation. In fact, the legislation provides that filing and acceptance of the required declaration of use in the PTO is a prerequisite to filing suit for infringement based on the registration of the mark.[25] The registrant is not required to wait out the three year period before proceeding with these steps. Thus, under the implementing legislation, an application filed on the basis of an intention to use the mark may be followed *at any time* within the initial period of

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[23] Trademark Registration Treaty: Implementing Legislation, amended sec. 1 (c) 5, 973 TMOG 8 (1978).

[24] Trademarks Act, Section 39 (2).

[25] Canadian Trade Marks Act, sec. 39(2); Implementing Legislation, sec. 22, 973 TMOG 17 (1978).

four years with a declaration that use of the mark has commenced. If the declaration has not been filed by the end of the fourth year, then the registration is cancelled. But if there is an infringement before that deadline, the registrant can proceed with the declaration and then file the action for infringement. In such a situation, the PTO would accelerate the examination of the declaration.

The implementing legislation also includes some lesser changes which are required by the TRT. An example is the requirement that refusals of international registrations, together with all grounds for the refusal, be communicated within fifteen months of the date of publication of the international registration. This change has been handled in the implementing legislation by imposing a twelve month maximum, counted from the filing date of the application, for the communication of any *ex parte* ground of refusal and for publication of the mark in the Official Gazette.[26]

The details of how the publication for opposition in the Official Gazette would be handled are left to the regulations. There are two possibilities. One would be to publish all applications promptly after filing and receive oppositions based on that publication concurrently with, or prior to, the *ex parte* examination. The other, a less radical departure from our present procedure, would be to proceed on the timetable that is now followed in the United States. However, any case which has not been disposed of *ex parte* prior to the expiration of a given time period (say eleven months from the filing date) would be processed for publication even though the *ex parte* examination might be incomplete at that time. There might, for example, be a suspension of proceedings because the applicant has petitioned to cancel a registration which was cited against the applied for mark. In such cases, the oppositions to these applications would be received and docketed but further proceedings would be suspended pending completion of the *ex parte* stage. In the case of those applications which were based on international registrations, it should be noted that either procedure will enable the PTO to communicate the refusal to the International Bureau prior to the expiration of the fifteen month time limitation. There are other provisions that are related to this acceleration of examination system in the United States. For example, the legislation proposes that the six month response period of the PTO be reduced to three months.[27]

Of course, it has been understood all along that this aspect of the

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[26] *Id.* Secs. 9, 10, at 10.

[27] *Id.* Sec. 10, at 10.

TRT and the implementing legislation imposes burdens on the PTO. However, it is a matter of history that the proposed time limitations of the Treaty which result in these changes were supported by practically every private group in the United States. This support was based on the conviction that the international system requires reasonably prompt examination if it is to serve the interests of international trade.

CONCLUSION

The United States was an early supporter of the TRT. Its delegates signed the treaty in 1973 along with representatives of thirteen other countries. Following extensive study, including evaluation of public comments, the Departments of State and Commerce recommended to the President that the TRT be submitted to the Senate for advice and consent to ratification. The President did so on September 3, 1975 and in the transmitting letter stated that draft implementing legislation would be forwarded to the Congress in the near future.[28] The promised follow-up action is long overdue.

Moreover, unless positive steps toward ratification are soon taken by the United States, it appears that other countries may lose interest in the TRT and direct their attention to other agreements that will exclude participation by United States firms or be less advantageous to United States interests. Statements made at the February 1979 meeting of TRT Interim Committee in Geneva[29] by Sweden (speaking also for Denmark and Finland), the Federal Republic of Germany, Japan, France, U.S.S.R., Spain, Portugal, Austria, Romania and Hungary clearly indicate that their continued interest in the TRT is contingent on positive action by the United States.

More than seven years have passed since the diplomatic conference was held at which the TRT was negotiated. More than five years have passed since the treaty was forwarded to the Senate for advice and consent to its ratification. During this period of time, the problems faced by American firms in securing protection of their trademarks in foreign markets have not lessened — they have worsened. The increasing importance of trademarks is evidenced by the fact that trademark applications in the United States have been increasing at a rate of 6 per cent annually. At the same time, it has not become less expensive to secure rights under national trademark systems — it is more expensive. These are problems that the TRT is intended to solve. Accord-

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[28] Note 4, *supra*.

[29] Note 13, *supra*. The statements will be found in the final report of this meeting. WIPO document TRT/IAC/LV/4, dated March 2, 1979.

ingly, it is appropriate and important that the TRT and the proposed implementing legislation be considered by the Congress as soon as possible.

Eight of the countries listed above are among the twenty-four which already participate in the Madrid Agreement. Although the TRT is more modern and has more advantages for trademark owners than the Madrid Agreement, the position of these countries is understandably dependent on whether major countries outside the Madrid Union are taking positive steps toward ratification of the new arrangement. For these countries the position of the United States is crucial.

Since the United States is not a member of the Madrid Agreement, United States companies are not qualified to use the international system established by the Madrid Agreement to secure and maintain trademark rights. Accordingly, for United States trademark owners, obtaining protection is more difficult than it is for their competitors in countries which are members of the Madrid Union. The TRT will enable United States firms to use an international filing system if they wish to do so.

However, it cannot be said that the issue is not controversial. The Department of Justice is opposed to the TRT and the legislation which is necessary for its implementation. However, in an economic sense, deferring the consideration of the question of ratification by the Congress would not be in the best interests of the country. Deferral would not only forclose consideration of the merits of the TRT, it would also delay any consideration of possible alternatives should Congress decide that the TRT is not in the best interests of the United. States.

A TALE OF TWO APPLICANTS OR HOW DECLARATION AND INVENTORSHIP REQUIREMENTS RAISE THE DICKENS WITH PROMOTION OF PROGRESS

IRWIN M. AISENBERG*

The place was Italy. He was an inventor who did not want to be concerned with details involved in the execution and filing of applications for letters patent. She agreed to attend to the necessary formalities and to pay for expenses relating to filing and prosecution of appropriate applications in exchange for fifty percent of the profits obtained from future licensing or sale of such applications or patents.

In order to carry out her part of the agreement, she engaged an Italian patent agent, on whose advice she executed formal documents for filing applications for letters patent in a number of countries throughout the world, including the United States. She did not read, write or speak English, but was assured that the specification and claims of the application prepared for filing in the United States were directed to the same invention as the corresponding previously-filed Italian application and that she could properly execute the required Declaration. Upon doing so, she became the Applicant of the application filed in the United States.

When the application had reached a stage in its prosecution where routine issuance of a formal Notice of Allowance and subsequent issuance of a patent were virtually guaranteed, she (on advice of counsel) interrupted the smooth PTO[1] procedure in order to prevent the application from maturing into a patent which would not reflect the actual inventor and thus might be regarded as invalid *ab initio*. Instead of commending the Applicant and assisting her to obtain a valid patent (presumably a goal of the PTO), one impediment after another

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[1] United States Patent and Trademark Office.

was placed in her path. How such impediments could possibly serve the Constitutional purpose of promoting progress is difficult to perceive. Perhaps it is time to reexamine the entire approach to requirements for executing an application.

Although the facts at hand were certainly not on all fours with those of any known precedent, considerable light had been shed by the Court of Appeals, Fifth Circuit[2], by the Court of Appeals, District of Columbia Circuit[3] and by two articles[4, 5] relating to the latter, when the Commissioner of Patents and Trademarks rendered a Decision on Petition (in the United States application) on April 19, 1979, stating that the statutes do not permit a sole-to-sole conversion by the PTO and that the holding in *Stoddard* affirms this position. One might have logically reached a contrary conclusion from *Stoddard* and have actually interpreted from it that it was finally determined that the PTO was authorized to effect a sole-to-sole conversion and that the Commissioner of Patents and Trademarks had effectively accepted such determination without further challenge.[6]

A fundamental question is whether impediments to sole-to-sole conversion serve any useful purpose. Perhaps the entire emphasis on the import of the inventor in connection with formalities relating to the execution of applications for United States Letters Patent needs revamping or replacement. It is difficult to see how striking an unpublished application (with all claims allowed) can ever serve the patent system. When the true inventor comes to light during the prosecution of an application, one may wonder what difference it can possible make to the public (who will gain a disclosure in exchange for limited protection) whether such inventor was partially or wholly originally named or only identified shortly prior to patent issuance.

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[2] *Becton, Dickinson and Company v. Sherwood Medical Industries Inc.*, 187 U.S.P.Q. (BNA) 200 (1975); (henceforth referred to as *Becton, Dickinson.)*

[3] *A.F. Stoddard & Company, Ltd. v. Dann, Commissioner of Patents,* 195 U.S.P.Q. (BNA) 97 (1977); (henceforth referred to as *Stoddard*).

[4] Meikeljohn, "Misjoinder, Non-Joinder and Whatever — Stoddard v. Dann", 60 J.P.O.S. 487 (1978).

[5] Welch, "Stoddard v. Dann — Fundamental Principles from A to C", 61 J.P.O.S. 185 (1979).

[6] Assistant Commissioner Tegtmeyer concluded that "constitutional objectives sought by the patent laws would best be served" by permitting reissue of a patent to effect a sole-to-sole conversion in the case of *In re Shibata,* 203 U.S.P.Q. (BNA) 780 (1979), under the prevailing circumstances. In making this decision, consideration was accorded to *Bemis v. Chevron Research Company,* 500 F.2d 910, 203 U.S.P.Q. (BNA) 123 (1979), which was not regarded as controlling in view of the lack of "innocence" and the different parties in interest involved. In *Bemis* the parties were actually adverse parties.

The preceding points are presented only for consideration while a case history is reviewed. The cost to the PTO and to the ultimate party in interest will be readily apparent.

Five months after the *Becton, Dickinson* decision the Applicant was advised that all of her asserted claims were allowable. On learning that she might not actually be the true inventor by U.S. standards, her attorney petitioned for suspension of action, including suspension of issuance of the Official Notice of Allowance.

The petition (I) further pointed out that the apparent inventor refused to sign papers in connection with filing applications for Letters Patent in the United States (as well as in other countries) and that the actual Applicant had paid for the preparation and filing (throughout many countries of the world, including the United States) of applications for Letters Patent to obtain protection for the subject invention and had a significant proprietary interest in view of her investment. The Applicant believed she had a right to file and prosecute an application in the United States to protect her investment.

The following statutory considerations were noted:

> Any document to be filed in the Patent Office and which is required by any law, rule, or other regulation to be executed in a specified manner may be provisionally accepted by the Commissioner despite a defective execution, provided a properly executed document is submitted within such time as may be prescribed (35 U.S.C. 26).
>
> Applicantion for patent shall be made by the inventor, except as otherwise provided in this title, in writing to the Commissioner... (35 U.S.C. 111).
>
> ... When the application is made as provided by this title by a person other than the inventor, the oath may be so varied... (35 U.S.C. 115).
>
> Whenever an inventor refuses to execute an application for patent..., a person... who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage; and the Commissioner may grant a patent to such inventor upon such notice to him as the Commissioner deems sufficient, and upon compliance with such regulations as he prescribes (35 U.S.C. 118).

and it was urged that the involved remedial statutes should be liberally construed.

Another petition (II) was filed within several weeks which requested that the PTO recognize the actual inventor as the sole inventor and to substitute his name for that of the Applicant. This was accompanied by appropriate supporting documents, including two verified statements by the Applicant, one by the inventor, a Declaration and Power of Attorney by the inventor, and a certified copy and English translation

of the Italian priority document, upon which Convention rights were requested.

Within a month of the filing of Petition I, a copy of a written agreement was filed at the PTO to establish the Applicant's proprietary interest in the inventor's invention.

After an interval of less than two weeks additional pertinent facts were provided to the PTO in the form of verified statements by the Applicant and by the inventor. Slightly more than a month later (March 16, 1976) the Applicant was placed under an order to show cause why her application should not be stricken from the files in accordance with 37 C.F.R. § 1.56.

The position of the PTO was that:

> Section III of Title 35 requires that the application "shall be made by the inventor, except as otherwise provided in [Title 35]" and further provides that the application "must be signed by the applicant." Section 118 of Title 35 provides for filing by a person other than the inventor. However, the section places strict limitations on who may file and under what circumstances that person may file. The person must be one
>
> > "to whom the inventor has assigned or agreed in writing to assign the invention or who otherwise shows suficient proprietary interest in the matter justifying such action . . . ."
>
> Further, the person who meets the above criteria
>
> > "may make application for patent on behalf of and as agent for the inventor on proof of the pertinent facts and a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage . . . ."
>
> Unless the person can meet the requirements of 35 U.S.C. 118, he or she cannot make a valid application on behalf of a sole inventor who is not deceased or legally incapacitated as set forth in 35 U.S.C. 117. This is true because of the requirements of Section 111 set forth above and the additional requirements of 35 U.S.C. 115 that
>
> > "[t]he applicant shall make oath that he believes himself to be the original and first inventor . . . ."
>
> It is apparent from the above that strict statutory requirements have to be met in order to file a valid United States patent application. These requirements apply to both the person who files and the manner of filing. The statute is clear. Only certain persons can file and such persons must know what they are filing and what they are claiming (see 35 U.S.C. 112).
>
> The necessity that the person filing an application know what is disclosed and claimed therein is emphasized in 37 C.F.R. 1.56 which provides that
>
> > "[a]ny application signed or sworn to in blank, or without actual inspection by the applicant . . . may be stricken from the files."

The Order to Show Cause was predicated on Applicant's alleged execution of the application "in blank". In support of this conclusion the PTO explained:

> ... She has stated that "the form [declaration] was in English, which I did not understand and which he did not translate for me." It is believed obvious that if she had understood the form, or had it translated for her, she would not have signed it. Signing a declaration in a language one does not understand, and without having the declaration translated, is the same as signing a blank declaration. Likewise, signing an application in a language one does not understand, and without having the application translated, is the same as signing the application "in blank."
>
> While it is recognized that the applicant, Miss C, may not have intentionally and knowingly acted in an improper manner, the fact remains that the application was signed "in blank". She clearly did not understand that she was declaring herself to be "the original, first and sole inventor."

The PTO proceeded to enumerate what were regarded as deficiencies which precluded acceptance of the application under 35 U.S.C. 118 as having been filed by the Applicant on behalf of the inventor:

> ... First, there was no assignment or agreement in writing to assign the invention.
>
> Second, Miss C [the Applicant] did not have "sufficient proprietary interest" to file under 35 U.S.C. 118 on behalf of Mr. A [the inventor]. The "oral arrangement" to pay Miss C "fifty percent of the profits obtained from future licensing or sale of such applications or patents" falls short of the "sufficient proprietary interest" required by the statute. As observed recently by Judge McGuire in his "Memorandum Opinion, Judgment and Order" in *Staeger et al v. Commissioner of Patents and Trademarks,* Civil Action No. 75-0815 (D.C.D.C. January 13, 1976), "A 'proprietary' interest at the very least suggests some element of ownership or dominion, and since its passage in 1952 the Commissioner has consistently adhered to that interpretation of the statute and the interpretation so made has been left untouched by the Courts." See also *In re Striker,* 182 U.S.P.Q. 507 (Sol. 1973). Here the element of ownership or dominion is at best tenuous.
>
> The third basic deficiency in the argument for relief under 35 U.S.C. 118 resides in the failure to identify the true inventor. Clearly the present application, as filed on December 27, 1973, cannot be said to be made "on behalf of and as agent for the inventor...." Indeed, the inventor was not identified and the declaration unambiguously stated that Miss C [the Applicant] believed herself to be the inventor. Should the Office now ignore the declaration filed on December 27, 1973, and assume an unstated intent to file on behalf of Mr. A [the actual inventor]? Clearly the statute does not provide for such an action by the Office.

The possibility of regarding the application as having been provisionally accepted, subject to correction under 35 U.S.C. 26, was also considered:

> ... Section 26 provides no authority for granting the requested relief. If the Office were to construe Section 26 in the manner urged, the requirements of Section 118 would be rendered null and void. Clearly this was not contemplated when Section 26 was enacted since Section 118 was left intact. Further, Section 26, did not in any way remove the requirement of Section 111 that the application "shall be made by the inventor...."

Requests were made and granted to extend the Applicant's deadline

for reply to the Order to Show Cause until the resolution of issues in *Stoddard* (decided on August 26th 1977). The opinion in *Stoddard,* pointed out, *inter alia:*

> The Constitutional objectives sought by the patent laws would be best served by a reading of 35 U.S.C. §116 sufficiently expansive to justify the correction sought in the instant continuation application. The same correction, for the same reason, can with respect to U.S. Patent No. 3,691,069 be effected by means of the instant reissue application filed under the remedial reissue provision, 35 U.S.C. §251 (*supra,* note 7).
>
> Accordingly, we reverse the District Court's order and remand the case to the District Court, with directions to enter an order authorizing the Commissioner of Patents and Trademarks to issue patents on the involved applications upon compliance with all applicable requirements of law.

This was regarded as a virtually complete answer to the Order to Show Cause.

The response to the Order to Show Cause illustrated that the material facts of *Stoddard* paralleled those at hand. Had Mr. Walser understood the Declaration or had it been translated to him, he, also, may not have signed the Declaration and the chances are that he, too, was instructed by his agent to execute the Declaration so that the application might be filed in the United States.

With regard to "signing an application[7] in a language one does not understand, and without having the application translated", attention was directed to one of the Applicant's declarations which confirmed that she had previously been assured that the described and claimed invention was that of the inventor and conformed with that of the corresponding Italian application.

The Applicant clearly had a financial interest which was established by record evidence, whereas Mr. Walser (her counterpart in *Stoddard*) apparently had none. There was no assignment to Mr. Walser; he did not even allege that he was signing on behalf of the true inventor; he certainly did not name the true inventor; and he apparently even failed to indicate that he was executing the application papers as representative of the owner, SEREINE.

As far as can be ascertained from the facts of *Stoddard,* Mr. Walser did not have any proprietary interest whatsoever or any authority from the true inventor to sign the papers on his behalf. Even though

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[7] The Declaration [Form PTO-258T(10-77)] published by the PTO provides only that the Applicant "understand the content of the attached specification", not that he has read the specification or understands the language in which it is written. Although the Rules of Practice (37 C.F.R. §1.69) require an oath or declaration to be in a language understood by one who subscribes thereto, there is no such requirement with regard to the specification.

Mr. Walser may have been a director of SEREINE, there was no reason to believe that he executed the application in that capacity unless that was clearly specified in the Declaration. Otherwise, the involved application was merely signed by Mr. Walser as a private individual. There is absolutely no basis in the Court's opinion to lead to any contrary conclusion.

The alleged deficiency "in the failure to identify the true inventor" surely was as applicable to the facts before the Court in *Stoddard* as in the subject case. As in *Stoddard,* the true inventor did not wait until an adversary party found out the true facts; he promptly took action toward conversion when advised through counsel that such was proper and required.

In *Stoddard* the Court of Appeals, District of Columbia Circuit, remanded the case to the District Court "with directions to enter an order authorizing the Commissioner of Patents and Trademarks to issue patents on the involved applications upon compliance with all applicable requirements of law." Conversion from a sole applicant to a sole inventor (not originally referred to or identified) was required for both of these applications.

The Constitution lacks support for any holding that only the true inventor can *apply* for a patent. The Constitution speaks of *securing* to inventors the exclusive right to their discoveries, not that the inventor must *apply.* Thus, the Constitution is result-oriented and contemplates that the *grant* of the patent be to the inventor, either directly or through his assignee. In fact, the solicited conversion was the only way of achieving that end. The true inventor did not wait, as he might have done, until a patent was issued to him before bringing the facts to the attention of the PTO. He should not have been placed in a worse position than the assignee of the reissue application in *Stoddard.* To paraphrase Chief Judge Markey in *Stoddard,* the fact that the true inventor was not named at the time of filing the application in the United States raises no constitutional bar to the inventorship correction sought. To the contrary, the constitutional objective of granting a patent to the true inventor would be, and could only be served by permitting the requested correction.

The Court said further, at pages 103 and 104 in *Stoddard:*

> [O]ne of the constitutional objectives is to establish a patent system based on justice, wherein honesty and candor are encouraged, not penalized. Indeed, as with all human systems, the patent system cannot stand if long sullied by dishonesty; it, like all of mankind's endeavors, must be constantly nourished and given strength by daily and continuing infusion of candid fairness. The dependence of the PTO upon counsel for applicants, for information not normally available to the PTO, is often and rightly cited as

> requiring full and open disclosure by applicants. But justice, if it is to result from honesty and candor, must be a two-way street, on which both applicants and the government travel.
>
> The quid pro quo which supports the patent grant is the requirement of a full disclosure regarding the invention; indeed, the very purpose of the patent system is to encourage disclosures.***
>
> To permit the requested substitution of names on this record would harm no one. To deny the requested correction, on the other hand, would serve no useful purpose, would frustrate the constitutional objective, would exalt form over substance, and would punish the Stoddard's commendable candor, all to the injury of the patent system and of him to whom it must appeal, i.e., the inventor.

The United States has fully received its quid pro quo, the disclosure, and should not now deny the formal step requested.

In addition to making the preceding points, the Response to the Order to Show Cause incorporated by reference pages 18 to 21[8] of the original opinion of the Court of Appeals in *Stoddard,* which addressed the propriety of converting from one sole applicant to a different sole applicant.

More than ten months later (August 15th, 1978) the PTO presented two sets of interrogatories to be answered "before the Office can consider the questions of the conversion" from the Applicant to the inventor. One set was to be answered by the Applicant and/or the inventor; the other, by Counsel. The latter was entirely concerned with distinguishing the subject facts from those considered by the respective Courts in *Becton, Dickinson* and in *Stoddard.* Counsel provided detailed responses to questions directed to him, distinguished the cases directed to his attention and explained why the solicited relief was justified even without answers to the further questions addressed to the Applicant and/or the inventor; then separate verified responses by the Applicant and by the inventor were actually filed.

Almost two months later a decision was rendered by the PTO in which its position was made clear. Within two weeks after prosecution was reopened, all of the claims were rejected under 35 USC 102(f).

A review of what happened here demonstrates that presentation of the issue of a sole-to-sole conversion placed the Applicant under an Order to Show Cause why her application should not be stricken. The PTO, presumably charged with having full knowledge of the complete extent of its authority, presented Applicant with sets of questions when she followed available procedures to have a patent issue in the name of

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[8] Corresponds to the text (104 to 106) of headnotes 7 through 10 in the presentation of the opinion at 195 U.S.P.Q. (BNA) 97.

the actual inventor. If there were any question of the authority of the PTO to issue a patent to the true inventor in this case, it appears that the PTO had a duty to resolve that matter prior to subjecting the Applicant to further expense. Moreover, the issuance of interrogatories was tantamount to confirmation that the PTO had such authority and would proceed accordingly unless precluded by the provided answers.

After soliciting and obtaining answers (which required considerable time, effort and expense and which did not in any way support a lack of authority to convert an application from a sole applicant to a sole inventor), the decision that the PTO lacked the noted authority was unjustified. The PTO has a duty to applicants as well as to the public; its also has a duty to satisfy the Constitutional goal of promoting progress.[9]

The final stroke, however, was the remand to the Examiner with instructions to reject the claims as defining an invention which was not made by the Applicant. For the Applicant to pursue her rights further would require a response to the issued Office Action with the expectation of rejection, since the Examiner was not in a position to overrule the Decision of the Commissioner. A subsequent appeal to the PTO Board of Appeals would have been equally fruitless for a similar reason. The time and expense involved would continue to mount for no useful purpose.

From the conception of the invention a story unravelled as a series of advances and rebuffs which followed each other as day followed night:

The path was clear and success assured;

> roadblocks were encountered and progress encumbered.

He had made a significant break-through and she agreed to attend to details in connection with securing patent rights;

> she consulted, paid for and relied upon a patent agent in Italy.

A notice of allowability (POL-327) issued within two years of her United States filing date;

> she learned that the application should have been filed in the inventor's name and that immediate steps had to be taken to secure valid patent rights in this country.

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[9] The United State Constitution (Article I, Section 8) empowers Congress to 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.

She authorized and cooperated fully with initiating conversion procedures;

she was placed under an Order to Show Cause.

Encouraged by a decision of the Court of Appeals, District of Columbia Circuit, she provided necessary Declarations and verified statements and had the inventor do likewise;

she was faced with a questionnaire.

She had every reason to believe that the presentation of the questionnaire confirmed a determination that the PTO had authority to grant a sole-to-sole conversion (from a sole applicant to a sole inventor);

after arranging to have answers to all questions formally presented to the PTO, she was advised that the PTO lacked authority to make a sole-to-sole conversion.

There was a ray of hope — a renewed petition (III). In this petition each and every point was briefed. In addition the entire development and applicability of collateral estoppel[10] were argued. The issue of the authority of the Commissioner to "permit the conversion from one sole inventor . . . to another sole inventor . . ." was squarely before the Court of Appeals, District of Columbia Circuit, in *Stoddard,* to which the Commissioner was a party. There was every opportunity for the PTO to litigate that issue, which was finally resolved (with regard to the PTO) when the decision in *Stoddard* became final.

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[10] As stated in the Restatement of Judgments under the topic head "Persons not Parties or Privies", §93 (1942):

> General Rule. Except as stated in §§94-111, a person who is not a party of privy to a party to an action in which a valid judgment other than a judgment in rem is rendered (a) cannot diretly or collaterally attack the judgment, and (b) is not bound by or entitled to claim the benefits of an adjudication upon any matter decided in the action.

But by the time the Restatement was published, the mutuality rule had been under fire. Courts had discarded the requirement of mutuality and held that only the party against whom the plea of estoppel was asserted had to have been in privity with a party in the prior action. This statement, which appears in the opinion of the Supreme Court of the United States for *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation,* 169 U.S.P.Q. 513, is supported by a number of cases enumerated in footnote 9 of that case and incorporated herein by reference.

The California Supreme Court, in *Bernhard v. Bank of America Natl. Trust & Savings Assn.,* 19 Cal. 2d 807, 122 P.2d 892 (1942), unanimously rejected the doctrine of mutuality, stating that there was "no compelling reason *** for requiring that the party asserting the plea of res judicata must have been a party, or in privity with a party, to the earlier litigation." Id. at 812. Justice Traynor's opinion, handed

It is appropriate to charge the Commissioner's Office with complete knowledge of the law in regarding conversion of applications from one inventive entity to another. Under the circumstances, the Commissioner, having direct knowledge of the Court's holding in *Stoddard* and at least constructive (if not actual) knowledge of the holding of the Court of Appeals, Fifth Circuit, in *Becton, Dickinson* (decided July 28th, 1975), must accept full responsibility for knowing the extent of its authority with regard to conversions of the type involved at the time (August 15th, 1973) of issuing its Requirement for Information. No such requirement could be justified by a Commissioner who knew or should have known that "the PTO cannot permit the conversion from one sole inventor . . . to another sole inventor . . . ."

Both the Applicant and the inventor relied upon the Requirement for Information as a clear holding by the PTO that the Commissioner was indeed authorized to convert applications from a sole applicant to a sole inventor and only required supplemental information to determine whether such conversion was justified in this case.

Since the Commissioner has the responsibility of knowing his authority, based on prevailing case law, his decision to issue interrogatories constituted a holding that he possessed the authority to effect the requested conversion; it constituted a holding that he effectively had such authority, and such position should be respected.

The PTO has imposed a Duty to Disclose and has been vigilant in obtaining the full cooperation of applicants and those who work with applicants to obtain U.S. Letters Patent. Here Applicant had taken extraordinary measures to prevent the issuance of a patent to one who

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down the same year the restatement was published, listed criteria since employed by many courts in many contexts:

> In determining the validity of a plea of res judicata three questions are pertinent: Was the issue decided in the prior adjudication identical with the one presented in the action in question? Was there a final judgment on the merits? Was the party against whom the plea is asserted a party or in privity with a party to the prior adjudication? 19 Cal. 2d, at 813, 122 P.2d, at 895.

Following these guidelines, the issue of whether the PTO is authorized to convert an application for Letters Patent from a sole Applicant to a different sole inventor was clearly the precise issue decided by the Court of Appeals, District of Columbia Circuit, in the *Stoddard* case and is the same issue (resolved in a different manner) in the Commissioner's Decision of April 19th, 1979. The *Stoddard* case was a final judgment on the merits. The Commissioner of Patents was the party in the *Stoddard* adjudication against whom this plea is now asserted.

Although the force of the mutuality rule had been diminished by exceptions and *Bernhard* itself might easily have been brought within one of the established excep-

was not the actual inventor, and the PTO has effectively punished the Applicant for such cooperation.

All of Applicant's claims were allowed. Applicant then went out of her way to preclude the issuance of a patent to someone other than the true inventor. In so doing, she clearly did something more than the applicant in either *Becton, Dickinson* or the applicant in *Stoddard*; both of those applicants permitted the issuance of a patent to one who was not the true inventor.

It appears extremely inequitable to charge a foreigner, who neither speaks nor reads English, with knowledge of the patent laws of the United States when the Commissioner of Patents and Trademarks apparently did not even know his own authority years later, at the time of issuing the Requirement for Information. Applicant went to and relied upon the advice of an Italian Patent Agent; she did what she believed was proper to secure the patent rights she desired. Disregard-

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tions, "Justice Traynor chose instead to exterpate the mutuality requirement and put it to the torch." Currie, Civil Procedure: The Tempest Brews, 53 Cal. L. Rev. 25, 26 (1965).

> *Bernhard* had significant impact. Many state and federal courts rejected the mutuality requirement, especially where the prior judgment was invoked defensively in a second action against a plaintiff bringing suit on an issue he litigated and lost as plaintiff in a prior action. The trend has been apparent in federal question cases. The federal courts found *Bernhard* persuasive. As judge Hastie stated more than 20 years ago:
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> "This second effort to prove negligence is comprehended by the generally accepted precept that a party has had one fair and full opportunity to prove a claim and has failed in that effort, should not be permitted to go to trial on the merits of that claim a second time. Both orderliness and reasonable time-saving in judicial administration require that this be so unless some overriding consideration of fairness to a litigant dictates a different result in the circumstances of a particular case.
>
> "The countervailing consideration urged here is lack of mutuality of estoppel. In the present suit [the plaintiff] would not have been permitted to take advantage of an earlier affirmative finding a negligence had such a finding been made in [his first suit against a different defendant]. For that reason he argues that he should not be bound by a contrary finding in that case. But a finding of negligence in the [plaintiff's first suit] would not have been binding against the [defendant in a second suit] because [that defendant] had no opportunity to contest the issue there. The finding of no negligence on the other hand was made after full opportunity to [plaintiff] on his own election to prove the very matter which he now urges a second time. Thus, no unfairness results here from estoppel which is not mutual.

ing his duty to make a complete determination as to his authority to convert an application from a sole applicant to a sole inventor at the time (August 15th, 1978), the Commissioner issued his Requirement for Information, and effectively held that he had authority to so convert the subject application. The Applicant relied upon such holding and went to the expense of providing detailed responses to each relevant inquiry. After the detailed response to the Requirement for Information was provided, the PTO confirmed that it had all the information it needed in connection with this matter. This means that no amount of information would have led to a different conclusion than that enunciated in the Commissioner's Decision of April 19th, 1979.

Whether or not the renewed petition (III) actually struck a responsive chord, the subsequently-rendered decision held that the PTO had the requisite authority and that the facts at hand justified the solicited sole-to-sole conversion. Nothing altered the PTO's authority between

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> In reality the argument of [plaintiff] is merely that the application of res judicata in this case makes the law asymmetrical. But the achievement of substantial justice rather than symmetry is the measure of the fairness of the rules of res judicata. *Bruszewski v. United States,* 181 F.2d 419, 421 (CA3 1950), cert. denied, 340 U.S. 865 (1950)."
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> Many federal courts exercising both federal question and diversity jurisdiction are in accord unless in a diversity case bound to apply a conflicting state rule requiring mutuality.
>
> Of course, transformation of estoppel law was neither instantaneous nor universal. As late as 1961, eminent authority stated that "[m]ost state courts recognize and apply the doctrine of mutuality, subject to certain exceptions ***. And the same is true of federal courts, when free to apply their own doctrine." Moore & Currier, Mutuality and Conclusiveness of Judgments, 35 Tul. L. Rev. 301, 304 (1961) (footnotes omitted); see also IB Moore's Federal Practice, 0.412, pp. 1803-1804 (1965). However, in 1970 Professor Moore noted that "the trend in the federal courts is away from the rigid requirements of mutuality advocated herein." Id., 1970 Cum. Supp. p. 53. The same trend is evident in the state courts.
>
> Undeniably, the court-produced doctrine of mutuality of estoppel is undergoing fundamental change in the common-law tradition. In its pristine formulation, an increasing number of courts have rejected the principle as unsound. Nor is it irrelevant that the abrogation of mutuality has been accompanied by other developments — such as expansion of the definition of "claim" in bar and merger contexts and expansion of the preclusive effects afforded criminal judgments in civil litigation — which enhance the capabilities of the courts to deal with some issues swiftly but fairly.
>
> The cases and authorities discussed above connect erosion of the mutualty requirement to the goal of limiting relitigation of issues where that can be achieved

the times of the several decisions. All of the claims in an application filed in 1973 had been allowed in 1975 and were again allowed in 1979. The delay may well be an example of the proverbial denial of justice, but even that might have some value if it provokes examination of the procedures and practices which thwart the processing of such matters.

When the authority of the PTO is in question, that issue should be directly addressed — perhaps even by a hearing. There is no justification for challenging an applicant in other areas merely to provide the PTO additional time to reach a conclusion on a pressing issue without input from the applicant whose rights are involved.

On a different level the entire approach to requirements of Declarations and for executing valid applications for United States Letters Patent is respectfully challenged. A different approach may prove far more helpful in promoting the progress of useful arts.[11]

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without compromising fairness in particular cases. The courts have often discarded the rule by commenting on crowded dockets and long delays preceding trial. Authorities differ on whether the public interest in efficient judicial administration is a sufficient ground in and of itself for abandoning mutuality, but it is clear that more than crowded dockets is involved. The broader question is whether it is any longer tenable to afford a litigant more than one full and fair opportunity for judicial resolution of the same issue. The question in these terms includes as part of the calculus the effect on judicial administration, but it also encompasses the concern exemplified by Bentham's reference to the gaming table in his attack on the principle of mutuality of estoppel. Although neither judges, the parties, nor the adversary system perform perfectly in all cases, the requirement of determining whether the party against whom an estoppel is asserted had a full and fair opportunity to litigate is a most significant safeguard.

Some litigants — those who never appeared in a prior action — may not be collaterally estoppped without litigating the issue. They have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue which stands squarely against their position. See *Hansberry v. Lee,* 311 U.S. 32, 40 (1940); *Bernhard,* supra, 19 Cal. 2d, at 811, 122 P.2d, at 894.

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Most of the text of the foregoing footnote is taken from the cited *Blonder-Tongue* case which relies on the following authorities cited in footnote 19 of that case in support of this position: *United States v. United Air Lines,* 216 F.Supp. 709, 725-730, affirmed as to res judicata Subnom *United Air Lines, Inc. v. Wiener,*335 F.2d 379, 404-405 (CA9 1964), cert. dismissed 379 U.S. 951 (1964); *Zdanok v. Glidden Co.,* 327 F.2d 944, 954-956 (CA2 1964), cert. denied, 377 U.S. 934 (1964); Currie, Civil Procedure: The Tempest Brews, 53 Cal. L. Rev. 25, 28-37 (1965); Vestal, Preclusion/Res Judicata Variables: Parties, 50 Iowa L. Rev. 27, at 55, 59 (1964); cf. Semmel, Collateral Estoppel, Mutuality, and Joinder of Parties, 68 Col. L. Rev. 1457 (1968); Weinstein, Revision of Procedure, Some Problems in Class Actions, 9 Buff. L. Rev. 433, 448, 454 (1960); Note, 35 Geo. Wash. L. Rev. 1010 (1967).

[11] See footnote 9, *supra.*

COMMENTARY

Patents, Mathematics and Computer Software
Bauer-Mengelberg, Parker v. Flook:
A Formula To Cause Alarm
21 IDEA 75 (1980).

Noting that a patent claim utilizes tools of mathematics in its expression is as helpful as noting that a claim is partly expressed in Latin. Many mathematical theorems and mathematically expressed scientific principles describe relationships which are fundamental truths. However, many relationships which are quite easily expressed "mathematically" have none of the universality of the relationships expressed in theorems or principles. When examining a claim to determine if what is claimed deserves a patent monopoly, it is necessary to go beyond the form of *expression* and examine the character of the *relationship* expressed. *In Parker v. Flook: A Formula to Cause Alarm,* these important issues are discussed in some depth with regard to the Supreme Court's opinion in *Parker v. Flook.* The author goes far in cutting through the mystique surrounding mathematics which the Court was apparently unable to penetrate. In this vein I would like to suggest some additional analysis of *Flook.*

Proper use of an extracted quotation requires making sure that the words in the quotation which are susceptible to alternative meanings will have the same meaning in the abstraction as they had in full context; perhaps it is the Court's failure to apply this principle which leads it to the decision that the formula in *Flook* is like a scientific principle. In analyzing the claim in *Flook* the Court (1) extracts the formula, (2) examines it, (3) finds it to be like a scientific principle, (4) therefore rejects the formula as capable of playing any role in innovative aspects of the claim, (5) examines the remaining steps in the claim, (6) finds them to be well known, (7) therefore finds no innovation and consequently no basis for a patent. If the formula is to be extracted for a fair examination, its meaning must be extracted, not just its symbols. When no specific meaning is attached to any of the symbols in a mathematical formula, the formula may appear to be quite universal in nature. When viewed in this naked fashion, the formula can appear to represent abstract intellectual concepts. In *Flook* the court states a well established rule:

> Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.

198 USPQ at 197. The court then concludes:

> We think this case must be decided as if the principle or mathematical formula were well known.

198 USPQ at 199. The court could only draw this conclusion if by "mathematical formula" the court refers to the naked string of symbols devoid of any of the meaning which Flook attaches to them. The relationships which these symbols represent in Flook's claim are hardly "the basic tools of scientific and technological work." These symbols specify what *Flook claims are useful relationships* among parameters in a hydrocarbon refining process; alarm limits are being computed based on measurements of process variables. The Court has ignored the bulk of the meaning in Flook's claim. Thus viewed, the claim contains nothing innovative. It is as if one took an oil painting, dissolved away the paints, hung the clean canvas on the wall, and complained, "This painter offers nothing of artistic value." The reasoning apparently used by the Court to find that a formula cannot play a role in the innovative features of a patent claim is unfair.

Another unfortunate complication in the *Flook* case is the patent examiner's finding that the aspects of the claim embodied in the formula were novel. This finding was accepted by the Patent and Trademark Office Board of Appeals and therefore was not argued before the Court of Customs and Patent Appeals or the Supreme Court. As discussed above the Supreme Court concluded that there is no novelty in the formula part of the claim as a matter of law. I believe, however, that the examiner should have found as a conclusion of fact that the features of the claim embodied in the formula are obvious extensions of the prior art.

Flook proposes a solution to the following problem: in the hydrocarbon refining process the person controlling the process should be notified when the value of a monitored process variable changes suddenly; if notification is to be performed automatically by a machine, the machine must embody some definition of "sudden change." A sudden change is deemed to occur when the value of a process variable exceeds the current alarm limit for that variable. In Flook's claim the alarm limit is periodically updated:

$$\text{the nth alarm limit} = B_n + K$$

where

$$B_n = (1-F) * B_{n-1} + (PVL_n) * F.$$

A value for F is not specified in the claim other than that it be between 0 and 1 (which is the range necessary for the formula to represent a running average). F simply determines how heavily the current prediction (B_n) depends on previous measured values (PVL_{n-1} PVL_{n-2} PVL_{n-3}, . . .). Thus, in this claim, sudden change is defined to occur when the process variable becomes far from the most recent prediction of where it is expected to be: "far" (K) is constant, but not otherwise specified; the prediction of "where it is expected to be" (B_n) is changed periodically based on the most recent actual measurement of the process variable (PVL_n) and the previous prediction ($B_n - 1$).

This method of prediction — a form of running average — is well known. I have seen the method applied to a variety of engineering problems. The method is also described in a 1963 book* cited, surprisingly enough, both in the Brief for the Petitioner p. 3A, and in an amicus brief supporting the respondent, Brief Amicus Curiae for the Association of Data Processing Service Organizations at p. 7.

Flook's claims are aimed at any process variable in either "catalytic chemical conversion of hydrocarbons" or "petroleum distillate hydrocracking." Specific methods for determining values for K or F are not claimed. At this level of generality, Flook's extension of prior art to these two classes of processes might very well be considered obvious to one skilled in at least certain arts. Certain methods for determining K and F, when used with this alarm setting method, might be particularly useful in controlling a specific class of process variables having certain characteristics in common. Such a discovery might be unobvious, but Flook's claims were not so specific.

The analysis used by the Court in *Flook* could readily be applied to computer software in a very broad sense. The innovative features of many computer programs are readily expressed in mathematical form. If so expressed they would be rejected on the basis of *Flook*. Although the CCPA disagrees, the PTO has taken this position in its rejection of the two patent cases which the Supreme Court has recently agreed to hear. *In re Diehr and Lutton,* 203 USPQ 44 (CCPA 1979); *In re Bradley and Franklin,* 202 USPQ 480 (CCPA 1979); cert. granted in both cases 205 USPQ 488 (1980).

A decision not to grant patents for innovations embodied in software leads to unpleasant anomalies. For instance, a specialized electronic circuit could be devised for which patent protection would be available. Another device could be devised whose external characteristics were

*R. Brown, *Smoothing, Forecasting, and Prediction of Discrete Time Series* (1963), pp. 101-104.

precisely the same as the first device. The second device might not have any novel circuitry, but be composed only of well known general purpose computer circuits. The innovative features which enable the second device to perform precisely like the first device might be entirely embodied in software. The engineer who chose to implement the innovative idea using specialized circuits would be allowed a patent, while the engineer who chose to implement the innovative idea using a different technology, computer circuits and computer software, would be denied a patent. In my mind this certainly "exalts form over substance," *Flook* at 197.

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Franklin Pierce Law Center — 1983
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Color and Appearance — A Trademark Issue

Recently, several decisions[1] have appeared in the area of trademarks and unfair competition that I find particularly disturbing both as a pharmacist and as a consumer. They effectively grant trademark protection to the color and appearance of prescription drugs. All of these erroneous decisions are based on the same false premise: that such appearance is non-functional. On the contrary, the color and appearance of prescription drug products serve several very important functions related to identification which, as a matter of public policy, far outweigh the benefits that are alleged to accrue from the granting of trademark protection.[2]

The pharmacist plays an important role in the treatment of accidental and intentional poisonings by identifying drug products which can be found near victims of accidental poisoning or attempted suicide. The tremendous proliferation of new drug products in the last decade has made this job of identification more difficult. The task, however, would

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[1] *SK & F Co. v. Premo Pharmaceutical Labs. Inc.* 481 F.Supp. 1184, 206 U.S.P.Q. (BNA) 232 (DC NJ), *aff'd* — F.2d —, 483 BNA's PTCJ A-1 (3rd Cir. 1980) *A.H. Robins Co. v. Medicine Chest Corp.* 483 BNA's PTCJ A-5 (DC E.Mo. 1980) *Ives Laboratories Inc. v. Darby Drug Co., Inc.*, et al. 202 U.S.P.Q. (BNA) 584, (DC EDNY 1980, *reversed,* 601 F.2d 631 (2d Cir. 1980).

[2] *Ives Laboratories Inc. v. Darby Drug Co., Inc. et al.* 601 F.2d 631, 206 U.S.P.Q. (BNA) 238, 241 (2d Cir. 1980).

be made virtually impossible if each manufacturer of an equivalent generic drug product (i.e., one that had the same active ingredients as and was bioequivalent to the brand name drug) were prevented from using the same color and appearance as the brand name product.

Likewise, the color and appearance of prescription drugs are essential to the identification of controlled drugs by the police (and pharmacists working with the police) in the enforcement of state and federal controlled substances laws.

Another important identification function that uniform color and appearance for generics serves is in helping the pharmacist to detect errors in labeling and packaging by a manufacturer. Occasionally, drug manufacturers put the wrong label on bottles. The most dangerous mixup that I can recall was when a fairly respectable brand name manufacturer accidentally distributed bottles labeled as a relatively innocuous drug (not often prescribed) which is used as a diuretic. The bottles actually contained a very toxic antineoplastic (anti-cancer) drug. Other examples are propantheline bromide 15 mg. mislabeled as prednisolone 5 mg., 17APhA Weekly 192 (1978); aminophylline tablets mislabeled as amitriptyline hydrochloride tablets 18 APhA Weekly 56 (1979); bottle of Cogentin^{R} 2 mg. found in a carton labeled as Periactin^{R} 4 mg. tablets, 17 APhA 96 (1978). In such instances, the pharmacist's ability to readily detect the manufacturer's error before it can be compounded by dispensing the wrong drug to the patient depends entirely on identifiability. This identifiability would clearly be diluted by the greatly increased diversification of drug product appearances that would result from banning "look-alike" drugs.

Identification by appearance is important to consumers for at least two reasons. One of them relates to a common practice in which, despite warning from doctors and pharmacists, patients repackage their medications putting several different drugs in a pillbox or vial. Although this practice may be illegal and is certainly not sensible it is a fact that such practice is commonplace. Eliminating "look-alike" drugs would result in greater likelihood of patient confusion as to which medication was which and, consequently, increased risk of overdose or non-compliance.

The second reason is that a consumer's sensitivity to a change in the appearance of his or her medication provides a crucial check on the mistakes in dispensing by pharmacists or prescribing physicians. No matter how careful a doctor or pharmacist is, he/she is human and is bound to make some mistakes. Any practitioner who has been on the receiving end of a phone call from a patient to the effect that, "Aren't my pills supposed to be green? They're purple this time," has praised

the Lord and the patient for being cautious. If consumers become complacent about changes in the appearance of their medication this essential safeguard will be sacrificed.

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Juris Doctor candidate — 1981
Franklin Pierce Law Center

Why not Law/Science?

Do the vast majority of technically trained lawyers end up practicing patent law because:

1) People doing the hiring don't think they are fit for anything else; or

2) It is easier to get a start in that area and difficult to move into other areas; or

3) Patent attorneys make more money and/or have a more interesting practice than they would have doing something else; or . . .?

Over the years, I have had many occasions to reflect on these questions and for the most part have gotten vague and inconsistent answers. On the one hand, I appreciate the significance of patent law. On the other, I can't help feeling that too large a percentage of a precious resource is diverted to patent practice. I can't help wondering why I so rarely encounter a technically trained lawyer engaged in solving the other law/science problems that seem to pervade modern regulatory and private law.

Perhaps some of your readers can help me out.

Thomas G. Field
Professor and Director
Innovation Clinic
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Possible Abuse of "New Use"

BY IRWIN M. AISENBERG*

Those who devote much of their time and energy to the art of prosecuting applications for Letters Patent are faced with new approaches to and variations in the interpretation of prevailing law as well as continual tests of their scientific skills. Twenty-seven years after the Statute expressly provided patent protection for a new use of a known composition (35 U.S.C. 100), problems still arise in connection with claim format, claim interpretation and disclosure requirements when an invention can be regarded as involving a new use.

Chemical arts in general and pharmaceutical arts in particular provide fertile grounds for novel issues in connection with this specific phase of practice. In one case (United States Letters Patent 4, 189, 469) an invention was based upon the discovery that a specified significant adverse side effect was considerably reduced by admixture of a pharmaceutical with a sufficient amount of swelling agent, thus making possible safe oral administration of the pharmaceuticals in considerably higher dosages.

It was previously well known that certain pharmaceutically-active compounds had a rather high level of the subject side effect. Such compounds were recognized compounds with established therapeutic utility. Pharmaceutical products containing these compounds were frequently used in the form of injection solutions, solutions for infusion, or coated tablets resistant to gastric juices. In the latter pharmaceutical form the dosage had to be kept low to avoid the side effect, and this had formerly restricted usefulness in oral therapy.

The fact that swelling agents were commonly used in pharmaceutical-tablet formulations and even in compositions based upon pharmaceuticals having this side effect further encumbered the road to patentability.

Original claims were directed to oral-unit-dosage pharmaceutical compositions and to a method for preparing such compositions. In addi-

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tion to art-based grounds of rejection, which were initially applied and maintained throughout the entire prosecution, all claims were rejected under both the first paragraph and the second paragraph of 35 U.S.C. 112. The first Office Action stated:

> The claims are based upon an insufficient disclosure since Applicants fail to set forth a specific use for the composition.

and

> The claims are too broad and indefinite in failing to recite a purpose for the pharmaceutical compositions and/or the amounts of active ingredients therein.

Reference to an insufficient disclosure was undoubtedly based on the failure of the specification to state ultimate pharmacological utilities for a number of identified compounds having the side effect.

An interesting aspect of this entire approach would naturally result if particular contemplated compounds were stated to have different pharmacological activities and utilities. Foreseeably, such a circumstance might then lead to a restriction requirement to limit claims to those active ingredients having an elected utility even though the peculiar pharmacological utility was not a fundamental consideration with regard to the invention.

The issue of alleged undue breadth and indefiniteness "in failing to recite a purpose for the pharmaceutical compositions and/or the amounts of active ingredients therein" similarly reflects a failure to appreciate that the claims were directed to the *use* of swelling agent and not to compositions based on novel "active" ingredients. The *purpose* was substantially unrelated to the pharmacological utility of the "active" ingredients. The only role the amount of active ingredient actually played in the invention was being sufficient to induce the stated side effect, and this was clear from the very wording of asserted claims.

The Office Action which was made final provided this amplification:

> Claims 1-18, all the claims in the case, are rejected under 35 USC 112, first paragraph, as based upon an insufficient disclosure since Applicants failed to set forth a specific use for the compositions.
>
> Applicants' remarks and the disclosure have been carefully considered, but they do not obviate the rejection since nothing is found in the disclosure except "treatment of blood flow complaints". The expression is vague and indefinite and does not represent a specific condition or disease. Regarding the utility in U.S. Patent 3, 422, 107, it is noted that (1) different xanthines may have different utilities and (2) the instant disclosure should be complete upon filing.
>
> Claims 1-18, all the claims in the case, are rejected under 35 USC 112 as failing to particularly point out and distinctly claim the invention. The

> claims are too broad and indefinite in failing to recite a purpose for the pharmaceutical compositions.
>
> The remarks regarding the rejection have been carefully considered; however, they are not persuasive since some indication as to what the compositions are useful for should be present.

There was clearly some confusion with regard to the meaning of the statutory requirement for "a written description . . . of the manner and process of . . . using" the invention. The use of the invention was for the purpose of rendering safe the oral administration of pharmacologically-active ingredients which would not otherwise be safely administered orally. Another way of stating the invention was the use of swelling agent to reduce the untoward side effect to a level at which such ingredients were safe for oral administration. This is what the invention was all about. The particular pharmacological activity of a specific pharmaceutically-active ingredient having the side effect was not directly involved with a complete description of the invention. Such pharmaceutically-active ingredients and their physiological indications were well known to artisans, and no issue had been taken with an allegation to this effect.

Novelty of the defined active ingredients was not being claimed. The novelty concerned a combination of a pharmaceutically-active component having the involved side effect with a sufficient amount of swelling agent to render such pharmaceutically-active component safe for oral administration. How to use the invention was thus made ultimately clear from the claims. The fact that the stated active ingredients were rendered suitable for oral administration provided a further utility of compositions that would not otherwise be suitable for such administration. The reason for administering or the actual pharmacological effect brought about by any particular active ingredient employed was not the invention to which the claims were directed and was not that which Applicants regarded as their invention.

Reliance was not placed on the novelty of any particular pharmaceutically-active component having the side effect to a degree which rendered it unsafe for oral administration. As previously noted, such compounds were known to those skilled in the art. The inventors found that admixing a sufficient amount of swelling agent with such a pharmaceutically-active component resulted in a composition which was safe for oral administration. The resulting products thus had an unexpected and "unobvious" property which was not suggested by anything found in applied art.

The repeated utility of reducing the involved side effect was urged to be adequate and to satisfy the statutory requirements completely. Pre-

vailing authority confirmed that an application need not describe that which was already known; in this particular case it had been well established that pharmaceuticals having the subject side effect were known and their pharmacological activity and utility were also known.

With regard to the first paragraph of 35 U.S.C. 112, the Statute requires only that the specification contain a written description of the invention and of the manner and process of making and using it; the subject specification completely satisfied these requirements. No statutory requirement was found for describing the use of every component in a claimed composition, particularly components whose utility was already known in the prior art. The invention was in a specified use of a swelling agent for a defined purpose which was manifested in pharmaceutical oral unit-dosage forms.

With regard to the second paragraph of 35 U.S.C. 112 the broadest composition claim was specifically directed to an orally-administrable pharmaceutical composition in unit-dosage form which had two required ingredients: a pharmaceutically-active component which was unsafe for oral administration because of the stated side effect and a swelling agent in an amount sufficient to reduce such side effect to a safe level. From the provided definition anyone of ordinary skill in the art would clearly know whether a particular embodiment fell within or without the provided definition. Moreover, the purpose of the invention was clearly appreciated from the manner in which this claim was drafted. Phamaceutically-active ingredients were known which had the side effect to a degree which rendered them unsafe (*per se* or above specified levels) for oral administration irrespective of the particular pharmacological activity of such active ingredient. The invention (in its broadest aspect) counteracted such incompatibility with a sufficient amount of swelling agent. The express purpose of the invention was thus providing a safe oral unit-dosage form of a pharmaceutically-active ingredient (which was normally unsafe for oral administration) by counteracting the specified side effect with a sufficient amount of swelling agent. The purpose of the pharmaceutical compositions was readily apparent from the very wording of the composition claims. The process (method-of-use) claims pointed out the purpose of the invention with equal clarity.

No statutory authority was found for requiring the recitation of the purpose of use for compositions in claims directed to pharmaceutical compositions. Compositions are defined by their components and amounts thereof. Composition claims stand on their express limitations irrespective of the use to which such compositions are placed; merely adding a use limitation to a composition claim serves no pur-

pose whatsoever. In this particular instant, moreover, the claimed invention (in its broadest aspect) was not concerned with any particular use or activity of a pharmaceutically-active component. To include in such claims a clear limitation of pharmacological use would constitute misleading information concerning the invention and would be directly contrary to the statutory requirement (35 U.S.C. 112) to present "one or more claims particularly pointing out and distinctly claiming *the subject matter which the applicant regards as his invention.*" (Emphasis added.)

Although it is true that the PTO Board of Appeals disposed of all outstanding issues (including applied art) in short order (cf. Appendix), the underlying question is why this case had to go to the Board of Appeals for decision. At one time there was a Division Chief, who could be called upon to act as a judge and to filter out issues or entire applications that could be settled without encumbering the work load of the Board of Appeals. It appears that this is a case in which the Examiner may have benefited by some guidance on the application of 35 U.S.C. 112. The absence of such guidance resulted in considerable cost to both the principal party in interest and the PTO.

In cases wherein an invention lies in a "new use" of a particular component in an otherwise known type of composition, questions of the following types still arise:

a) Must the disclosure fully support (35 U.S.C. 112, first paragraph) available uses of encompassed compositions in a manner commensurate in scope with the scope of claimed compositions or is it sufficient for it to support the "new use" which is the crux of the invention?

b) How can the PTO or the public tell from a process claim (35 U.S.C. 100) whether it merely defines a method of compounding a type of composition or is actually directed to a "new use" of an involved component?

c) Is a process-of-compounding claim entitled to different treatment on the part of the PTO when it is actually directed to a new use of one of the components?

d) As a composition claim can also reflect a new use of one of its components, how can the PTO or the public tell whether it merely defines a composition or has some life-imparting and, possibly, otherwise hidden attribute; should it be evaluated in a different manner than other composition claims?

e) Is it proper for the PTO to reject (under 35 U.S.C. 112, second paragraph) a process-of-compounding or a composition claim that is actually directed to a new use of a specified component because it does not convey that particular meaning to the casual reader?

f) Have we reached an appropriate stage to accept claims in a format which explicitly defines a "new use" of designated component?

APPENDIX

Group 125 Paper No. 21

MAILED

Appeal No. 377-29 JUN 2 6 1979 vgb

HEARD:
May 31, 1979

PAT. & T.M. OFFICE
BOARD OF APPEALS

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF APPEALS

Ex parte Klaus Gleixner
Roland Muller
and
Franz Lehrach

- - -

Application for Patent filed May 6, 1976, Serial No. 683,795. Pharmaceutical Compositions.

Irwin M. Aisenberg et al. for appellants.

Appeal No. 377-29

Before Serota and Blech, Examiners-in-Chief, and Lovell, Acting Examiner-in-Chief.

Blech, Examiner-in-Chief.

This appeal involves claims 1-8, 13-18 and 23-26. Claim 16 thereof is representative of the claimed invention and reads as follows:

16. An orally-administrable pharmaceutical composition in unit-dosage form which comprises an amount of pharmaceutically-active component having a degree of gastrointestinal-tract incompatibility which renders it unsafe for oral administration in combination with a sufficient amount of swelling agent to reduce such incompatibility to a level at which the unit dosage is safe for oral administration.

The references relied upon by the Examiner are:

Christenson et al. (Christenson)	3,065,143	Nov. 20, 1962
Robinson	3,577,514	May 4, 1971
Christenson et al. (Christenson)	3,590,117	June 29, 1971
Broeg et al. (Broeg)	3,639,169	Feb. 1, 1972
Reiser et al. (Reiser)	3,864,469	Feb. 4, 1975

Ritschel, Die Tablette, Editio Cantor KG/Aulendorf i. Württ, 1966, pages 93, 191-193.

We will not sustain the rejection of claims 1-8, 13, 16-18 and 23-26 under 35 USC 112, first paragraph, as based upon an insufficient disclosure. It is palpably evident from the plethora of art submitted by appellants, as well as from the very art cited by the Examiner (note Reiser), that the utility of the xanthines disclosed in the instant specification as pharmaceutical is well established. Consequently, we fail

to appreciate the Examiner's position that the claims are based on an insufficient disclosure, particularly when appellants' invention does not reside in the use of any particular pharmaceutical, as long as it evidences gastro-intestinal-tract incompatibility unsafe for oral administration in large unit-dosage form.

Nor will we affirm the rejection of all of the appealed claims under 35 USC 103 as unpatentable over Reiser in view of the Christenson patents, Robinson, Broeg and Ritschel. As stated by appellants at page 22 of their brief, they are not claiming novelty in the defined active ingredients. These ingredients and their pharmacological activity and utility concededly are known. The novelty herein on which appellants predicate patentability is the combination of a sufficient amount of swelling agent with a gastro-intestinal-tract-incompatible pharmaceutically-active component to render such pharmaceutically-active component gastro-intestinal-tract compatible. This concept clearly is not taught by, nor would be obvious from, the art adduced by the Examiner.

Thus, it is quite apparent from the references that the use of swelling agents in pharmaceutical preparations is known. However, what is not known, nor suggested by or obvious from the art, is that if an orally-administrable pharmaceutical composition is prepared in unit-dosage form comprising an amount of pharmaceutically-active component having a degree of gastro-intestinal-tract incompatibility which renders it un-

safe for oral administration, that such composition may be rendered safe for oral administration by combining it with a sufficient amount of swelling agent adequate for this purpose. This manifestly is unexpected and not suggested by the art relied upon by the Examiner.

Accordingly, the decision of the Examiner is reversed.

REVERSED

Examiner-in-Chief)
)
Examiner-in-Chief) BOARD OF APPEALS
)
Examiner-in-Chief)
(Acting)

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AN OVERVIEW OF RECENT INTERFERENCE DECISIONS OF THE COURT OF CUSTOMS AND PATENT APPEALS**

PAUL T. MEIKLEJOHN*

I. *Introduction*

The Court of Customs and Patent Appeals ("CCPA") has treated a broad spectrum of both substantive and procedural interference issues over the last two years. These issues include conception of the invention,[1] the corroboration needed to establish an actual reduction to practice,[2] suppression or concealment in an *ex parte* context,[3] right to make,[4] interference in fact,[5] derivation,[6] and even writs of mandamus and prohibition.[7] This article will also consider one case[8] which concerns the applicability of 35 U.S.C. §102(g) in an *ex parte* context.

These cases will each be treated hereinbelow. Certain of these cases simply illustrate the application of well-known principles to particular factual settings. Other cases involve an extension of existing law. These latter cases will be discussed in somewhat greater detail.

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[1] *Gunter v. Stream*, 573 F.2d 77, 197 U.S.P.Q. (BNA) 482 (C.C.P.A. 1978).

[2] *Kahl v. Scoville*, 609 F.2d 991, 203 U.S.P.Q. (BNA) 652 (C.C.P.A. 1979); and *Randolph v. Shoberg*, 590 F.2d 923, 200 U.S.P.Q. 647 (C.C.P.A. 1979).

[3] *In re Suska*, 589 F.2d 527, 200 U.S.P.Q. (BNA) 497 (C.C.P.A. 1979).

[4] *Holmes v. Kelly*, 586 F.2d 234, 199 U.S.P.Q. (BNA) 778 (C.C.P.A. 1978).

[5] *Almasi v. Strauss*, 589 F.2d 523, 200 U.S.P.Q. (BNA) 511 (C.C.P.A. 1979).

[6] *Mead v. McKirnan*, 585 F.2d 504, 199 U.S.P.Q. (BNA) 513 (C.C.P.A. 1978).

[7] *Godtfredsen v. Banner*, 598 F.2d 589, 202 U.S.P.Q. (BNA) 7 (C.C.P.A. 1979); and *Dueltgen v. Parker*, 579 F.2d 638, 198 U.S.P.Q. (BNA) 616 (C.C.P.A. 1978).

[8] *In re Bulloch*, 604 F.2d 1362, 203 U.S.P.Q. (BNA) 171 (C.C.P.A. 1979).

II. *Conception of the Invention*

Conception of the invention was at issue in *Gunter v. Stream.*[9]

A. *Facts*

The subject matter of the counts was a method and apparatus for employing heat pipe fittings for cooling glass fibers as they are drawn through orifices of a glass fiber forming machine. Gunter took no testimony and was restricted to his filing date (September 19, 1974) as his date of conception and reduction to practice.

Stream submitted testimony and documentary evidence to support a date of conception and reduction to practice prior to Gunter's filing date. Stream's testimony was to the effect that he had a conversation on or before August 27, 1970 with his supervisor, Mr. Glaser, in which he told Glaser of his invention. Glaser reported on Stream's idea to Gustafson, a patent attorney for Owens-Corning Fiberglass Corporation ("OCF"). Gustafson reduced Glaser's report to writing on September 2, 1970. Stream's invention was reduced to practice by the construction of a prototype fin shield by Hughes Aircraft Company and successful testing of this prototype by OCF at its Huntingdon Plant on April 17 and 18, 1974.

B. *The Decision and Opinion of the Board of Patent Interferences*

The Board of Patent Interferences ("Board") found that the Hughes prototype embodied every essential element of the counts and that the tests of that prototype by OCF on April 17 and 18, 1974 constituted proof of an actual reduction to practice. The Board also concluded that Stream conceived the invention on August 27, 1970 when he understood it enough to explain it to Mr. Glaser. The Board defined conception as a disclosure of an invention which enables one skilled in the art to reduce the invention to a practical form without exercise of the inventive faculty.

C. *Decision and Opinion of the CCPA*

The CCPA affirmed the Board's decision with respect to the reduction to practice issue even though Gunter argued that this reduction to practice should not inure to the benefit of Stream since Stream did not take part in the reduction to practice. The CCPA concluded that Stream could prevail in the Interference if he proved an earlier date of

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[9] *See* note 1, *supra.*

conception by a preponderance of the evidence.[10] The issue then was whether Stream proved by a preponderance of the evidence that he conceived on or about August 27, 1970. The Court concluded that the Board correctly restated the definition for conception initially stated in *Merganthaler v. Scudder:*[11]

> The conception of the invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished, in order to perfect the act or instrument, belongs to the department of construction, not invention. It is therefore the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice, that constitutes an available conception, within the meaning of the patent law.

Applying this definition to the instant factual setting, the Court concluded that the Gustafson memo memorializing Stream's August 27, 1970 conversation with Glaser evidenced the fact that Stream had conceived each element of the invention of the counts by August 27, 1970.

III. *Corroborated Reduction to Practice*

In two recent cases, *Randolph v. Shoberg*[12] and *Kahl v. Scoville,*[13] the Court considered the corroboration needed to establish the required testing in proving an actual reduction to practice.

A. *Randolph v. Shoberg*

1. *Facts*

The counts in issue were directed to floating beam weigh scales. Count 1 reads as follows:

> Floating beam weigh scale apparatus comprising: a base, a load receiving member spaced from the base, first and second pivot members disposed between the base and load receiving members, load transmitting means interconnecting the pivots, the base, and the load receiving member to produce moments in the pivots of opposite sense and about spaced axes, a substantially rigid beam connected to and extending between the pivots and means carried by the beam for producing a signal related to the bending stress therein over the elastic bending range thereof.

Shoberg was senior party patentee and Randolph was required to

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[10] *Land v. Dreyer,* 155 F.2d 383, 69 U.S.P.Q. (BNA) 602 (C.C.P.A. 1946); *Townsend v. Smith,* 36 F.2d 292, 4 U.S.P.Q. (BNA) 269 (C.C.P.A. 1929).

[11] 11 App. D.C. 264, 276, 1897 C.D. 724, 731 (1897).

[12] *See* note 2, *supra.*

[13] *Id.*

make a showing under 37 C.F.R. 1.204(c)[14] for the purpose of provoking an interference. Affidavits of Randolph and Dickinson, his patent attorney, were submitted. These affidavits established that Randolph constructed a weigh scale fully satisfying the language of the counts prior to Shoberg's filing date. Furthermore, they showed that Randolph tested his weigh scale by pressing down on the scale's load-support platform causing end couples to be transmitted into a bendable bar in the scale for summing, and for activation of piezoresistive elements bonded to the bar. The test also demonstrated that a direct, proportional, electrical read-out resulted from such action. The test was witnessed by Dickinson and corroborated by him.

The invention as described in Randolph's supplemental declaration was the substitution of the elongated unitary bendable bar for the complicated links and springs commonly employed to sum the load carried by a scale. Piezoresistive devices mounted on the bendable bar transform the deformation of the bendable bar into electrical signals which represent the weight present on the scale.

The issue was whether the Randolph and Dickinson affidavits were sufficient to comply with 37 C.F.R. 1.204(c).

2. *The Board's Decision and Opinion*

The Board agreed that Randolph had constructed a weigh scale according to the counts prior to Shoberg's filing date but held that the evidence of testing was insufficient to establish an actual reduction to practice. It concluded that successful testing of a weigh scale can be demonstrated only by an accurate readout for diverse weights or forces over a given range.

3. *The CCPA's Decision and Opinion*

The CCPA reversed the Board. The Court rejected the Board's

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[14] 37 C.F.R. 1.204(c) provides, in pertinent part:

> (c) When the effective filing date of an applicant is more than 3 months subsequent to the effective filing date of the patentee, the applicant, before the interference will be declared, shall file two copies of affidavits or declarations by himself, if possible, and by one or more corroborating witnesses, supported by documentary evidence if available, each setting out a factual description of acts and circumstances performed or observed by the affiant, which collectively would prima facie entitle him to an award of priority with respect to the effective filing date of the patent. This showing must be accompanied by an explanation of the basis on which he believes that the facts set forth would overcome the effective filing date of the patent. Failure to satisfy the provisions of this section may result in summary judgment against the applicant under §1.228.

conclusion that the successful operation of a weigh scale could only be demonstrated by tests which yielded accurate readouts for diverse weights over a given range. Although accurate calibration may be required before commercialization, such precise operation was not, in the Court's opinion, required to fulfill the testing requirement of a reduction to practice.

As authority for this position, the Court cited *In re Dardick*[15] where it is stated:

> To prove a reduction to practice, all that must be shown is that the invention is suitable for its intended purpose (citations omitted). There is no requirement for a reduction to practice that the invention, when tested, be in a commercially satisfactory stage of development (citation omitted).[16]

The Court noted that the test performed by Randolph of pressing down on the weigh scale's load-support platform and observing the changes in the readout inherently produced the range of forces applied to the load-support platform. Whether the changes observed were actually directly proportional to the pressing down force should not have been considered critical by the Board with respect to the testing required for a reduction of practice, because all that needed to be demonstrated was a change in the readout which was related to the pressing down force.

The Court concluded that the device as stated in the declaration performed as it was intended to perform, that is, it produced output signals related to the bending stress on the beam as caused by the pressing down force applied by Randolph.

Chief Judge Markey, joined by Judge Rich, dissented. The minority believed that the majority incorrectly applied the legal standard for testing needed to prove a reduction to practice. The minority also seemed to differ with the majority's conclusion that the readout was related to the force applied to the scale at any given moment.

B. *Kahl v. Scoville*

1. *Facts*

The invention of the counts was an automatic door operator which uses a combination of a radiant energy emitter and an energy detector, spaced apart from each other, to sense the presence of a person or object and to thereby operate the door. Count 1 is illustrative and reads as follows:

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[15] 496 F.2d 1234, 181 U.S.P.Q. (BNA) 834 (C.C.P.A. 1974).

[16] *Id.* at 1238, 181 U.S.P.Q. (BNA) at 837.

> An automatic door operator comprising a reversible drive including a drive motor for powering a door through a door opening and door closing cycle and a traffic responsive control therefor, said traffic responsive control comprising radiant energy emitter means for emitting a divergent beam of radiant energy spanning the path of travel of traffic through the door and radiant energy detector means spaced from said emitter and having an axis of sensitivity disposed transversely of said beam of radiant energy to intersect said beam and define in the intersection thereof a discrete divergent three-dimensional control zone for sensing diffuse reflected radiant energy from traffic within said three-dimensional control zone to control the actuation of said reversible drive, said three-dimensional control zone being spaced above the floor along said path of travel of traffic through the door.

Scoville was senior party-patentee and Kahl was required to make a showing under 37 C.F.R. 1.204(c).[17] Kahl submitted affidavits of himself and corroboration affidavits of others. For purposes of understanding the CCPA's opinion, it is necessary and sufficient to focus on the Symon and Kahl affidavits in connection with the "discrete divergent, three-dimensional control zone" of the counts. The Kahl affidavit contains an adequate description of that zone. Symon's affidavit, a corroboration affidavit, specifically refers to Kahl's affidavit when Symon states that he tested "door sensors of the plastic lens cluster type described in the Kahl supplemental affidavit."

2. *The Board's Decision and Opinion*

The Board felt that the affidavits of record were deficient in failing to corroborate that the devices tested included a "discrete divergent three-dimensional control zone" as required by the counts. The Board recognized that such a control zone was illustrated by Exhibit J of the Kahl supplemental affidavit but the Symon affidavit, *inter alia,* which related to the testing of Kahl's device, failed to corroborate the existence of such a zone.

3. *The CCPA's Decision and Opinion*

The CCPA reversed the Board. With respect to corroboration the Court quoted from *Breuer v. DeMarinis:*[18]

> We have frequently stated that a "rule of reason" approach is required determining the type and amount of evidence necessary for corroboration (citation omitted). This approach recognizes the realities of technical operation in modern day research laboratories (citation omitted).[19]

With this rule of reason firmly in mind, the Court recognized that only one corroborating witness was needed to establish a sufficient 204(c) showing and so the Court focused on the Symon affidavit.

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[17] *See* note 14, *supra.*

[18] 558 F.2d 22, 194 U.S.P.Q. (BNA) 308 (C.C.P.A. 1977).

[19] *Id.* at 29, 194 U.S.P.Q. (BNA) at 314.

The Court concluded that the only fault the Board found in Symon's affidavit was that it did not establish that a "device was tested having a zone defined by the counts." But, the Court reasoned, the Symon affidavit incorporated by reference the Kahl supplemental affidavit and such incorporation by reference contained in a contemporaneous affidavit was permissible.[20] Thus, the Court concluded that Kahl had presented the requisite corroboration to establish a reduction to practice.

Scoville argued that the Board should not have excused Kahl's originally insufficient Rule 204(c) showing and should not have considered the additional affidavits submitted by Kahl. The CCPA correctly pointed out that the excusing of the originally insufficient Rule 204(c) showing is a matter within the discretion of the PTO and will not ordinarily be overturned unless there is a clear showing of abuse of that discretion.[21] Since Scoville did not allege any abuse of discretion, the CCPA did not follow Scoville's suggestion.

Scoville further argued that the documents attached to Kahl's supplemental affidavit were now shown to have been in existence at or prior to the filing date of Scoville's patent application. The Court characterized Scoville's argument as mere rebuttal to a Rule 204(c) showing which was not appropriate and could not be considered until after the interference had been declared.

Finally, Scoville argued that Kahl did not offer any proof of conception. The CCPA pointed out that it is permissible for Kahl to establish a prima facie case by proof of actual reduction to practice of the invention prior to Scoville's effective filing date and thus evidence of conception was not required.

IV. *The Effect of Suppression or Concealment in an Ex Parte Context*

In re Suska[22] involved a novel issue concerning the effect of a suppression or concealment in an *ex parte* context.[23]

A. *Facts*

Suska was involved in an interference where priority was awarded

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[20] The Court cited *In re Clarke*, 356 F.2d 987, 991, 148 U.S.P.Q. (BNA) 665, 669 (C.C.P.A. 1966) for this proposition.

[21] *See Cochran v. Kresock*, 530 F.2d 385, 396, 188 U.S.P.Q. (BNA) 553, 561 (C.C.P.A. 1976).

[22] 589 F.2d 527, 200 U.S.P.Q. (BNA) 497 (C.C.P.A. 1979).

[23] For a review of recent decisions concerning abandonment, suppression or concealment in an interference context *see* P. T. Meiklejohn, "Abandon, Suppress or Conceal in an Interference Context," 20 IDEA 137 (1979).

to his opponent (Martin) because Suska, the first to reduce the invention of the counts to practice, had suppressed or concealed the invention of the counts. The claims of the present application were rejected under 35 U.S.C. §103 as obvious in view of the lost counts in combination with two other prior art references.

The issue was whether the invention of the interference counts which were lost to an opponent because of Suska's suppression or concealment should be prior art under 35 U.S.C. §103 against Suska, notwithstanding the fact that Suska was the first to reduce the invention to practice.

B. *Suska's Contention*

Suska argued that under §102(g), an invention must be made in the United States by another before Suska's invention in order to be prior art against Suska. Since it was determined in the interference that Suska *de facto* reduced the invention of the counts to practice before Martin, the acts of Martin cannot be prior art against Suska.

Suska relied upon *Steierman v. Connelly*[24] where the Commissioner of Patents concluded that Steierman suppressed or concealed his invention but was accorded priority nevertheless because Connelly was less than candid with the PTO in failing to disclose his "best mode." The Commissioner stated:

> Under the statute an applicant's suppression or concealment not amounting to abandonment prevents him from establishing priority over a subsequent inventor, but does not destroy his right to a patent.[25]

C. *The PTO's Contention*

The Solicitor contended that Martin was the *de jure* first inventor of the invention of the counts and that Suska suppressed and concealed not only the invention of the counts but the obvious modifications which he presently claims. Thus, by his suppression and concealment Suska lost the right to rely on his actual date of invention not only for priority purposes but also for purposes of avoiding the invention of the counts as prior art under the §103 obviousness rejection.

D. *Decision and Opinion of the CCPA*

The CCPA, agreeing with the Solicitor, affirmed the Board of Appeals.

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[24] 197 U.S.P.Q. (BNA) 288 (Com. Pat. 1976).

[25] *Id.* at 289. The Commissioner cited *Young v. Dworkin,* 489 F.2d 1277, 180 U.S.P.Q. (BNA) 388 (C.C.P.A. 1974) for this proposition.

The Court reasoned that if an applicant were granted a patent on claims to obvious variations of the invention of the counts which he lost in an interference because of his suppression and concealment, the public policy underlying the suppression and concealment doctrine would be frustrated and the rights of the *de jure* first inventor would clearly not be commensurate with the scope of the benefits to the public resulting from his disclosure of the invention. Suska's reliance on *Steierman, supra,* was not well-founded in the Court's view since the considerations of public policy underlying the suppression and concealment doctrine were noticeably absent from that opinion.

The Court concluded that the invention of the counts lost by an appellant in an earlier interference is, because of his suppression and concealment, proper prior art against him under 35 U.S.C. §103 in an *ex parte* context.

V. *Right to Make*

Right to make was the dispositive issue in *Holmes v. Kelly.*[26]

A. *Facts and Proceedings Below*

Kelly was the junior party-patentee. Holmes copied the counts from Kelly's patent. The issue was whether these counts were supported by Holmes' application.

The counts were directed to a method of making an electrical resistor. Count 1 is illustrative and reads as follows:

> A method of forming an electrical resistance element including the steps of:
>
> forming a mixture of finely ground particles of glass, a solution of dissolved noble metal compound including at least one of the noble metals selected from the group consisting of iridium, rhodium and ruthenium, and particles of at least one filler material selected from the group consisting of $MgSiO_3$, Al_2O_3, $CaSiO_3$, $BaSiO_3$, $PbTiO_3$ and $PbZrO_3$;
>
> heating said mixture to drive off the volatile materials thereby producing a dry mixture of glass, filler material and finely divided particles of a noble metal alloy;
>
> grinding the dry mixture to a powder; mixing the dry powder with a volatile liquid to form a viscous mixture;
>
> applying a layer of the viscous mixture to a high temperature resistant, electrically non-conductive substrate;
>
> heating the substrate and layer to at least the melting temperature of the glass constituent but less than the melting temperature of the metal alloy to produce a continuous glassy phase having the metal alloy particles and filler material uniformly dispersed therethrough.

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[26] *See* note 4, *supra.*

Kelly moved to dissolve the interference on the ground that Holmes had no right to make the counts with respect to the last two steps of count 1 (and other counts reciting the same steps). That motion was granted and Holmes' claims were rejected in an *ex parte* context for lack of support under 35 U.S.C. §112. Holmes appealed and the Board of Appeals reversed the Examiner. The interference was then reinstated and Kelly filed a second motion to dissolve. That motion was granted by the Board of Patent Interferences.

> The board concluded that Holmes's application does not support the last two steps of the counts and awarded priority to Kelly. It observed that Holmes, the copier, has a "heavy burden to show clear and unambiguous support" for each limitation of the claims and found that all of Holmes's examples relate to self-supporting resistors — not film-type resistors (i.e., those with a film supported by a nonconducting base). It pointed out that, regardless of how "substrate" is defined, Holmes does not disclose applying a layer of viscous mixture to any substrate, since, in his example in which a powder is mixed with a volatile liquid to form a viscous mixture (step 4 of the counts), the viscous mixture is not applied as a "layer" to a substrate. The board noted that the test is not whether the Holmes disclosure might lead a skilled worker to the method of the counts, but whether there is an unequivocal disclosure.[27]

B. *Opinion and Decision of the CCPA*

The Court noted that the burden of proof on the right to make issue is on the party who copies the claims[28] and is a heavy burden regardless of whether that party is junior or senior.[29] Furthermore, doubts should be resolved against the copier.[30]

The effect of the decision of the Board of Appeals in the *ex parte* proceeding and the fact that Kelly was under an order to show cause was, at most, to shift the burden of going forward to Kelly. The burden of persuasion remained with Holmes to show clear and unambiguous support for each limitation of the counts.[31]

The Court concluded that Holmes did not meet this burden, stating:

> Holmes does not have support for the limitation — "applying a layer of the viscous mixture to a*** substrate." In the example where Holmes makes a viscous mixture, he presses the mixture together into a relatively rigid body with a form of its own. He then places the body in a tunnel kiln on a support (or substrate) for heating. Since the body already has a definite form, the support in the kiln merely serves to keep the body from falling due to the force of gravity. In the counts, the layer is applied to a substrate,

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[27] 586 F.2d at 236, 199 U.S.P.Q. (BNA) at 780.

[28] *Snitzer v. Etzel,* 531 F.2d 1062, 189 U.S.P.Q. (BNA) 415 (C.C.P.A. 1976).

[29] *Fontijn v. Okamoto,* 518 F.2d 610, 186 U.S.P.Q. (BNA) 97 (C.C.P.A. 1975).

[30] *Dreyfus v. Sternau,* 357 F.2d 411, 140 U.S.P.Q. (BNA) 63 (C.C.P.A. 1966).

[31] *Rainier v. Unger,* 333 F.2d 244, 142 U.S.P.Q. (BNA) 23 (C.C.P.A. 1964).

indicating that the layer has no form of its own separate from the substrate. We are persuaded that it would unreasonably stretch the meaning of the words of the count to equate Holmes's placing of the body on the kiln support with applying a layer to a substrate [citation omitted].

Nor does the statement in Holmes's specification, that with his mixture "the metal glass type resistor can be produced not only as a film supported by a non-conducting ceramic base, but as a self-supporting resistor," provide adequate support for the limitation. There is no description of how a film (clearly a "layer") supported by such a base is produced.[32]

VI. *Interference in Fact*

The materiality of count limitations and hence "interference in fact" was at issue in *Almasi v. Strauss*.[33]

A. *Facts*

Strauss copied claims from Almasi's patent. These claims were rejected under 35 U.S.C. §112 for lack of support for "magneto-resistive sensing means". In response to that rejection, Strauss omitted this and related limitations from the claims and an interference was declared on the basis of the following modified claim of the Almasi patent (omissions bracketed, additions underscored):

A magnetic bubble domain system in which said bubble domains can be nondestructively sensed, comprising:

a magnetic medium capable of suporting single wall [cylindrical] magnetic bubble domains;

[magneto-resistive] sensing means located adjacent said medium for detecting said bubble domains when the magnetic flux of said domains intercepts said sensing means, said magnetic flux being sufficient to change the [resistance] electrical properties of said sensing means, wherein said sensing means comprises a [magneto-resistive] sensing element whose [resistance] properties depend upon the magnetic flux thereacross, [said sensing elements having a length which is approximately equal to a bubble domain diameter,]

means for establishing current flow through said sensing element, and

means to detect said [resistance] change of said properties of said [sensing] element.

The Almasi patent discloses that:

In addition to the fact that other materials than permalloy can be used for the magneto-resistive sensing element, it is possible to use other properties than the magneto-resistance. For instance, the presence or absence of bubble domains may be sensed by magneto-optic effects***, magneto-strictive properties, magneto-caloric properties, and other effects. Whatever the particular properties used, it is possible to incorporate the sensing element in the propagation means which is used to move the domains in the magnetic sheet.

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[32] 586 F.2d at 237, 199 U.S.P.Q. (BNA) at 781-82.

[33] *See* note 5, *supra*.

Almasi moved to dissolve on the ground, *inter alia,* of no interference in fact.

B. *Opinion of the Board*

The Board found no "conclusive indication... that the magneto-resistive recitations necessarily constituted a material factor in the Examiner's allowability decision", interpreting the above-quoted paragraph as an indication that properties other than magneto-resistance were equally useful in sensing magnetic bubble domains. Thus, the Board concluded that the omitted limitations were immaterial.

C. *Opinion and Decision of the CCPA*

The CCPA reversed the Board, stating the test for determining the propriety of claims copied from a patent as follows:

> The materiality in proposed counts of portions omitted *from such claims* must be determined *solely* by an analysis of whether such portions defined material aspects *of the patentee's invention.*[34]

The significance of the "magneto-resistive" limitation should be determined by an examination of Almasi's patent. In reviewing that patent, the Court noted that Almasi disclosed that the magneto-resistor sensing system is fast, fully compatible with existing propagation circuitry, easy to fabricate, high in conversion efficiency, small and easily mobile in contrast to certain disadvantages of prior art sensing techniques. Accordingly, the Court concluded that Almasi's invention may not function as intended when "magneto-resistor" sensing is omitted and therefore that limitation defined a material aspect of the invention.

The CCPA viewed the disclosure in the Almasi patent that

> [w]hatever the particular properties used, it is possible to incorporate the sensing element in the propagation means which is used to move the domains in the magnetic sheet

as a second invention of Almasi of integration of a sensing element with propagation means. The Court found that just because various sensing means may be integrated with propagation means is not inconsistent with the finding that "magneto-resistive" is a material element as claimed in Almasi's invention.

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[34] *Brailsford v. Lavet,* 318 F.2d 942, 946, n. 9, 138 U.S.P.Q. (BNA) 28, 32, n.9 (C.C.P.A. 1963) (emphasis in original).

VII. *Derivation*

"Derivation" and "suppression and concealment" were at issue in *Mead v. McKirnan.*[35]

A. *Facts and Proceedings Below*

McKirnan was junior party-patentee and Mead copied his claims which were directed to child resistant overcaps for aerosol containers. Count 1 is illustrative and reads as follows:

> A childproof cover for a container such as an aerosol container having a roof, a circular collar located on said roof with said collar having an undersurface positioned above said roof, said cover being formed of a flexible plastic and including:
>
> a circular top, an outer skirt depending from said circular top, an inner skirt coaxial with said outer skirt and also depending from said top, a pair of lips projecting inwardly from the lower end of said inner skirt and positioned to engage the undersurface of said circular collar when said cover is positioned on said container said lips being spaced from and located opposite each other, a pair of slits formed in said inner skirt and extending from the lower edge thereof towards the circular top with said slits being located generally diametrically of each other and between said lips, and a pair of webs connecting said outer and inner skirts with said webs positioned relative to said slits so that forces inwardly applied to opposite sides of said outer skirt at the lower edge thereof adjacent said slits will cause distortion of said outer skirt and radially outward movement of said webs which in turn will cause distortion of said inner skirt and release of said lips from engagement with the undersurface of said circular collar.

McKirnan charged Mead with derivation of the complete invention from him. To establish derivation, McKirnan had to prove by a preponderance of the evidence that he had conceived and communicated the invention to Mead prior to Mead's filing date of September 30, 1971 on which he relied. The Board concluded that McKirnan met that burden and so he was awarded priority.

B. *Decision and Opinion of the CCPA*

The CCPA affirmed the Board, noting that one who charges derivation has the burden of showing prior complete conception of the claimed invention and sufficient communication of the subject matter to the party charged to enable one of ordinary skill in the art to construct and successfully operate the invention.[36]

Mead also alleged that the McKirnan application was filed long after

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[35] 585 F.2d 504, 199 U.S.P.Q. (BNA) 513 (C.C.P.A. 1978).

[36] *Hedgewick v. Akers,* 497 F.2d 905, 908, 182 U.S.P.Q. (BNA) 167, 169 (C.C.P.A. 1974); *Anderson v. Anderson,* 403 F.Supp. 834, 845, 188 U.S.P.Q. (BNA) 194, 204 (D.D.C. 1975), *aff'd,* 543 F.2d 1389 (D.C. Cir. 1976).

the fact, i.e., long after McKirnan's reduction to practice and that this constituted abandonment or suppression. The CCPA felt that the mere assertion of "long after the fact" filing was insufficient on its face to establish abandonment or suppression.[37]

VIII. *Writs of Mandamus and Prohibition*

In both *Godtfredsen v. Banner*[38] and *Dueltgen v. Parker*[39], petitioners requested the CCPA to issue writs of mandamus and prohibition directing the Commissioner of Patents and Trademarks to substitute a count in an interference[40] or to dissolve the interference[41].

A. *Dueltgen v. Parker*

Deultgen petitioned the Court to order the Acting Commissioner of Patents to dissolve the interference alleging that respondent Sullivan failed to disclose 1) the subject matter of the claims corresponding to the interference counts, or 2) any "patentable utility" for that subject matter. Alternatively, Dueltgen sought writs directing the Commissioner to promptly decide its pending motion to dissolve and that proceedings in the interference be stayed pending that decision.

With respect to the first allegation, i.e., the right to make issue, the CCPA held that that issue is ancillary to priority and is therefore subject to consideration by the Board of Patent Interferences and by the CCPA in a normal appellate process. Since effective relief would be available on appeal, writs of prohibition and mandamus would not be appropriate.

With respect to the allegation that Sullivan failed to disclose any patentable utility, the Court stated that although the allegation is couched in terms of "utility", it appears to rest on a failure of the Sullivan specification to support an "unexpected properties" argument which may be made against an obviousness allegation. This allegation would then raise an issue not ancillary to priority and thus would not be subject to consideration by the Board in its determination of priority or by the CCPA in a normal appellate process.

But, noted the Court:

> Redress from an examiner's denial of a motion raising a non-ancillary issue is by petition to the Commissioner. 37 C.F.R. 1.181, 1.231(d), 1.244.

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[37] The Court cited *Young v. Dworkin*, 489 F.2d 1277, 180 U.S.P.Q. (BNA) 383 (C.C.P.A. 1974) for this proposition.

[38] *See* note 7, *supra*.

[39] *Id.*

[40] *See Godtfredsen, supra,* note 7.

[41] *See Dueltgen, supra,* note 7.

> Here, a petition was filed and the Commissioner refused to disturb the examiner's denial. The standard of review of the Commissioner's decision in such cases, upon petition for writs of prohibition and mandamus, concerns only the exercise of the Commissioner's discretion.
>
> Petitioners have not here established that the Commissioner abused his discretion. Writs of prohibition and mandamus would therefore be inappropriate with respect to the motion based on allegation (2) and interpreted as raising an issue not ancillary to priority.[42]

B. *Godtfredsen v. Banner*

Godtfredsen petitioned the CCPA for writs of mandamus and prohibition requiring the Commissioner of Patents and Trademarks to substitute a count in an interference. The Petition was dismissed by the CCPA.

1. *Facts and Proceedings Below*

The count in the interference was directed to a mixture of ampicillin and an amidopenicillanic acid (hereinafter "mecillinam").

Count A, which petitioners desired to substitute, was directed to a composition comprising mecillinam and either 1) ampicillin, 2) benzylpenicillin, or 3) azidocillin.

Godtfredsen also moved to add counts B and C which recited the two mixtures additionally found in count A in the event the motion to add count A was denied.

The Examiner concluded that count A was unpatentable since it was directed to a mixture of independent and distinct inventions under 35 U.S.C. §121. Godtfredsen petitioned the Commissioner under 37 C.F.R. 1.181 requesting that the Commissioner invoke his supervisory authority and reverse the Examiner's decision denying the motion to substitute count A. The Commissioner, acting through the Chairman of the Board of Patent Interferences, granted the petition to the extent that it was remanded to the Primary Examiner with the instruction that he provide the basis for his conclusion in his decision on the motion.

The Examiner on remand stated further that a prior art reference anticipating one species would not anticipate or render obvious either of the other synergistic combinations. Godtfredsen again petitioned the Commissioner under 37 C.F.R. 1.181 alleging abuse of discretion by the Examiner and requesting that the Commissioner exercise his supervisory authority and instruct the Examiner to substitute count A as the sole count in the Interference.

Before the Commissioner acted on this later petition, a supplemental petition was entered based on the CCPA's decisions in *In re*

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[42] 579 F.2d at 640, 198 U.S.P.Q. (BNA) at 618.

Weber[43] and *In re Haas*[44] to the effect that 35 U.S.C. §121 does not provide a basis for an Examiner, acting under the authority of the Commissioner, to reject a particular claim on the basis that it contains an independent and distinct invention. Godtfredsen argued that *Weber* and *Haas* removed any legal basis the Examiner may have had in refusing to substitute count A.

The Commissioner denied the petition stating that

> while it may be that, in view of the Weber and Haas cases, a *claim* corresponding to proposed count A could not properly be rejected under 35 U.S.C. 121, it does not necessarily follow that the fact that proposed count A "was directed to more than one invention" as stated by the Examiner in Paper No. 39, is not a proper ground for refusing to substitute it as the *count* of the interference. [Emphasis in original][45]

The Commissioner cited as policy considerations underlying his conclusions, the following:

> Where, as here, the parties both disclose the same three species, that fact does not justify including those species in a single count as members of a Markush group if the Examiner has determined that the three species are patentably distinct inventions. If such a count were permitted, then the party who proved the earliest date of invention as to any one of the members of the group would be awarded priority as to the entire count, i.e., as to all three members. It is not considered that such a result would be consonant with the primary purpose of an interference or within the intent of 35 U.S.C. §135, since there would be no determination of priority as to *each* of the common inventions claimed by the parties. [Emphasis added][46]

Godtfredsen then petitioned the CCPA for a writ of mandamus ordering the Commissioner to allow the interference to proceed with count A as the sole count and for a writ of prohibition preventing the interference from proceeding as currently constituted on counts 1, 2 and 3.

2. *Opinion and Decision of the CCPA*

The Court denied Godtfredsen's petition on the ground that the Court's jurisdiction to consider the propriety of the Commissioner's decisions is only in the context of matters which are ancillary to priority.[47] Substitution of a count in an interference is not considered ancillary to priority.

Petitioner relied on *Dueltgen v. Parker*[48] as authority for the prop-

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[43] 580 F.2d 455, 198 U.S.P.Q. (BNA) 328 (C.C.P.A. 1978).

[44] 580 F.2d 461, 198 U.S.P.Q. (BNA) 334 (C.C.P.A. 1978).

[45] 598 F.2d at 592, 202 U.S.P.Q. (BNA) at 10.

[46] *Id.*

[47] *Nitz v. Ehrenreich*, 537 F.2d 539, 190 U.S.P.Q. (BNA) 413 (C.C.P.A. 1976).

[48] *See Dueltgen, supra*, note 7.

osition that the CCPA has jurisdiction to grant appropriate relief for a clear abuse of discretion by the Examiner, even with respect to non-ancillary matters. Petitioner noted that the Court in *Dueltgen* said:

> Redress from an examiner's denial of a motion raising a non-ancillary issue is by petition to the Commissioner. 37 C.F.R. 1.181, 1.231 (d), 1.244. Here, a petition was filed and the Commissioner refused to disturb the examiner's denial. The standard of review of the Commissioner's decision in such cases, upon petition for writs of prohibition and mandamus, concerns only the exercise of the Commissioner's discretion.
>
> Petitioners have not here established that the Commissioner abused his discretion. Writs of prohibition and mandamus would therefore be inappropriate with respect to the motion based on allegation (2) and interpreted as raising an issue not ancillary to priority.[49]

The Court construed this language in *Dueltgen* as not requiring that if the existence of an abuse of discretion is established then a writ of mandamus should be issued. The *Godtfredsen* Court read the quoted *Dueltgen* language as stating that *even if the Dueltgen Court had jurisdiction to consider the issue* (which it did not), no abuse of discretion was shown.

Clearly, the quoted language in *Dueltgen* is dicta with respect to the issue of whether the CCPA has the right to review non-ancillary issues vis-a-vis Commissioner's decisions. Just as clearly, however, that same language implies such authority.

Judge Miller concurred with the majority, agreeing with the conclusion as to the interpretation of *Dueltgen*. Judge Miller found it unnecessary to decide that substitution of a count in an interference is not ancillary to priority. Instead Judge Miller would premise his dismissal on Godtfredsen's failure to demonstrate that the CCPA has subject matter jurisdiction based on authority other than the All Writs Act itself, "in and of" which a writ could be issued.

Judge Miller believes that the substitution of a count in an interference is ancillary to priority. He notes that the Court has over the years expanded the types of issues regarded as ancillary. Such issues include phantom counts, modified claim counts, or Markush claim counts. Judge Miller correctly noted that selection of a particular count for the determination of priority could have a significant impact on the interference proceeding and could be decisive in the award of priority. This "significant impact" can be observed in *Godtfredsen*.

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[49] *See* note 42, *supra*.

IX. *Prior Invention In An Ex Parte Context*

In re Bulloch[50] involved a combination §102 (g)and §103 rejection similar to that involved in *In re Bass.*[51] The CCPA referred to its *Bass* opinion as standing for the proposition that the prior invention of another is prior art within the meaning of §103 by virtue of §102(g), "notwithstanding that such disclosure was not available to the public prior to the date of applicant's invention."

A. *Facts*

The rejected claims were directed to alcoholates of orthophosphate salts in stable color developer concentrates. Claims to the color developer concentrates of the orthophosphate salts were allowed but claims to the alcoholates of these salts were rejected under §102(g) and §103 over the prior work of Kroll as evidenced by the Kroll patent which describes the preparation of these alcoholates and their use as claimed by Bulloch.

Three declarations were submitted. Kroll et al the patentees of the reference patent, stated that they invented the alcoholates themselves but that the *use* of alcoholates was developed by Bulloch et al. The alcoholates were developed by Kroll et al a few months after, and as a consequence of, the disclosure to Kroll et al of the Bulloch et al invention.

Appellants filed the other two affidavits to the effect that the broad generic invention of concentrates of these orthophosphate salts as stable color developing agents was made prior to the discovery of the alcoholates themselves and that the *use* of the alcoholates in a water concentrate was developed by Bulloch et al and not by Kroll et al.

B. *Opinion of the Board*

The Board concluded:

> Consequently, with regard to the alcoholate salt, the evidence indicates that appellants were not the inventors and the Kroll et al patent *is* prior art under 35 USC 102(g)/103. Thus, to the extent that the examiner's remarks are directed to claims 6 and 7, limited to concentrates containing the alcoholate, we agree that, on this record, the claims to the aqueous solution of the alcoholate compound are rendered unpatentable by the teachings in the Kroll et al patent. As noted [in appellants' brief]*** at column 7, lines 36-47 of the cited [Kroll] patent, it is taught that the Kroll et al salts can be incorporated in working color developer baths as described in Weissberger patent 2,192,015. We consider that this clearly shows the obviousness, as meant in 35 USC 103, of said salts' corresponding incorporation in con-

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[50] *See* note 8, *supra.*

[51] 474 F.2d 1276, 177 U.S.P.Q. (BNA) 178 (C.C.P.A. 1973).

> centrates of the instant type. [emphasis in original][52]

In their petition for reconsideration, Bulloch argued:

> As inventors of the use of the concentrate genus, they should be entitled to their earlier invention date and they should be entitled to claim the use of any disclosed compound species falling within the genus, even if the species, *as compounds,* were the inventions of a different inventive entity than appellants.
>
> Appellants are not claiming the alcoholates as their invention. They are merely claiming the use of these alcoholates as a *concentrate,* the concentrate being their invention. [emphasis in original][53]

but the Board refused to change its decision.

C. *Opinion and Decision of the CCPA*

The CCPA reversed the decision of the Board. The Court recognized that the claims on appeal were not directed to the alcoholates *per se* but to concentrates containing alcoholates, which concentrates are used as stable color developers. The preamble language "stable color developer concentrate" was considered by the Court to be

> more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims.[54]

The dispositive issue, in the Court's view, was whether the claimed invention would have been obvious to one having ordinary skill in the art at the time appellants made their invention assuming, *arguendo,* that the prior invention by Kroll et al of the alcoholates themselves could be cited as prior art under §103 against the subsequent invention by appellants of concentrates of the alcoholates as stable color developers. The Court concluded that the only evidence relied upon by the Board to support its decision on that issue was appellants' own teachings that these salts could be used as stable color developers. Since "appellants own teachings" are not in the prior art, the Board's decision was reversed.

X. *Conclusions*

The Court has essentially applied well-known principles to different factual settings in the conception, right to make, and interference in fact areas, but has established new law to the effect that interference counts lost by a *de facto* first inventor who suppressed or concealed his

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[52] 604 F.2d at 1365, 203 U.S.P.Q. (BNA) at 173-74.

[53] *Id.* at 1365, 203 U.S.P.Q. (BNA) at 174.

[54] *Id.* The Court cited *Kropa v. Robie,* 187 F.2d 150, 88 U.S.P.Q. (BNA) 478 (C.C.P.A. 1951) for this proposition.

invention are prior art against him in an *ex parte* context. Furthermore, the Court has continued to apply a rather liberal "rule of reason" approach in deciding whether there exists sufficient corroborative evidence of a reduction to practice. The law concerning writs of mandamus and prohibition has been established and the seemingly clear statement by the Court in *Dueltgen* that it has jurisdiction to review decisions of the Commissioner concerning non-ancillary matters has been negated in *Godtfredsen*. Finally, the Court has continued to treat the prior invention of another as prior art under §103 by virtue of §102(g), following its *Bass* decision.

AN OVERVIEW OF COURT OF CUSTOMS AND PATENT APPEALS REVIEW OF INTERNATIONAL TRADE COMMISSION DECISIONS**

PAUL T. MEIKLEJOHN*

I. *Introduction*

The amendment of Section 337 of the Tariff Act of 1930 by the Trade Act of 1974[1] gave the Court of Customs and Patent Appeals ("CCPA")

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[1] 19 U.S.C. §1337. Section 337 provides in pertinent part:

(a) Unfair Methods of Competition Declared Unlawful.

Unfair methods of competition and unfair acts in the importation of articles into the United States or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, or to restrain or monopolize trade and commerce in the United States, are declared unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

* * * *

(d) Exclusion of Articles from Entry.

If the Commission determines, as a result of an investigation under this section, that there is violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. The Commission shall notify the Secretary of the Treasury of its action under this

authority[2] to review by appeal final determinations by the International Trade Commission ("ITC") under Section 337.

Since the unlicensed importation and/or sale of a product which is protected by a domestic patent is considered both an unfair method of competition and an unfair act under Section 337(a),[3] patent infringement and defenses thereto have become the subject of CCPA review.

Although the CCPA has disposed of several cases from the ITC on threshold issues,[4] it has reached the merits in only three cases as of this writing,[5] finding one patent not infringed,[6] a second invalid for obviousness,[7] and a third valid and infringed.[8] The CCPA's opinions and decisions in this area of the law are of interest not only to those

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subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers refuse such entry.

[2] Section 337(c) provides:

(c) Determinations; Review.

The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section. Each determination under subsection (d) or (e) shall be made on the record after notice and opportunity for a hearing in conformity with the provisions of subchapter II of chapter 5 of Title 5. All legal and equitable defenses may be presented in all cases. Any person adversely affected by a final determination of the Commission under subsection (d) or (e) of this section may appeal such determination to the United States Court of Customs and Patent Appeals. Such court shall have jurisdiction in review such determination in the same manner and subject to the same limitations and conditions as in the case of appeals from decisions of the United States Customs Court.

[3] *See, e.g., Reclosable Plastic Bags,* Inv. No. 337-TA-22, ITC Pub. 801 at 6 (1977); *Certain Exercising Devices,* Inv. No. 337-TA-24, ITC Pub. 813 at 5 (1977); *Certain Solder Removal Wicks,*Inv. No. 337-TA-26, ITC Pub. 823 at 1 (1977).

[4] *Import Motors, Ltd. v. ITC,* 530 F.2d 937, 188 U.S.P.Q. (BNA) 102 (C.C.P.A. 1975) (Order granting stay), 530 F.2d 940, 188 U.S.P.Q. (BNA) 490 (C.C.P.A. 1976) (Decision dismissing appeal and vacating stay), 530 F.2d 940, 188 U.S.P.Q. (BNA) 491 (C.C.P.A. 1976) (Opinion in support of decision); *Rohm & Haas Co., v. ITC,* 554 F.2d 462, 193 U.S.P.Q. (BNA) 693 (C.C.P.A. 1977); and *Refractarios Monterrey, S.A. v. Ferro Corp. & ITC,* 606 F.2d 966, 203 U.S.P.Q. (BNA) 568 (C.C.P.A. 1979).

[5] *Stevenson v. ITC,* 612 F.2d 546, 204 U.S.P.Q. (BNA) 276 (C.C.P.A. 1979); *Solder Removal Co. v. ITC,* 582 F.2d 628, 199 U.S.P.Q. (BNA) 129 (C.C.P.A. 1978); and *Coleco Industries, Inc. v. ITC,* 573 F.2d 1247, 197 U.S.P.Q. (BNA) 472 (C.C.P.A. 1978).

[6] *Coleco, supra* note 5.

[7] *Solder, supra* note 5.

[8] *Stevenson, supra* note 5.

concerned with ITC practice, but also to those engaged in patent infringement litigation in federal courts since the CCPA is that federal court with recognized expertise in patent matters and any CCPA pronouncements may be given considerable weight by a federal district or appellate court.

Stevenson[9] and *Solder*[10] are of interest in setting forth the standard of review of the ITC's decisions by the CCPA. Both are also of interest with respect to validity determinations. *Solder* contains an enlightening discussion of the presumption of validity. *Stevenson* treats the defense of unenforceability due to inequitable conduct. Both cases involve obviousness issues. In *Coleco,*[11] the controlling issue was the doctrine of file wrapper estoppel by admissions or file wrapper estoppel by attorney's arguments.

II. *Standard of Review*

This issue, of course, is relevant only to those who are interested in ITC practice. The issue is what standard the CCPA should use in reviewing decisions of the Commission under Section 337. In *Solder,* the Commission suggested that the standard should be the "substantial evidence" test of the Administrative Procedure Act.[12] The CCPA disagreed. The Court noted that the standard which the CCPA should apply is expressly set forth in Section 337(c) as

> in the same manner and subject to the same limitations and conditions as in the case of appeals from decisions of the United States Customs Court.[13]

When the "substantial evidence" test was advanced as a suggested standard of review of decisions of the Customs Court, the CCPA stated:

> We do not agree with [the] suggestion that we are bound to accept the Customs Court's findings of fact *whenever* there is substantial supporting evidence, and we will not do so when they are clearly contrary to the weight of the evidence [Emphasis by Court][14]

The Court correctly noted that the substantial evidence test is particularly inapplicable to judicial review of validity issues under Section 337 since prior art is citable against virtually every issued patent

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[9] *Id.*

[10] *See* note 5, *supra.*

[11] *Id.*

[12] 5 U.S.C. §706(2) (e)

[13] *See* note 2, *supra.*

[14] *Montgomery Ward & Co. v. United States,* 469 F.2d 1283, 1285 (1974).

and substantial evidence would exist in essentially every case. Effective judicial review of invalidity holdings would not be possible under such a test.

Although the Court in *Solder* stated what the standard of review was *not,* it failed to state what the standard actually *was*. That gap was filled by *Stevenson.*

In *Stevenson,* the Commission suggested that the standard of review was "whether the determination of the Commision is clearly contrary to the weight of the evidence before it."[15] The CCPA disagreed with that suggestion and noted that "obviousness is a legal conclusion based on factual evidence, [citing *Graham v. John Deere Co.*] and not a factual determination."[16] The standard set forth by the CCPA was "whether the Commission erred, as a matter of law, in holding that the claims were invalid under 35 U.S.C. §103."[17]

Thus, the CCPA will make

> an independent determination as to the legal conclusions and inferences which should be drawn from [the findings of fact].[18]

III. *Infringement*

The infringement issue was reached in both *Stevenson* and *Coleco*. In *Stevenson*, the Court agreed with the ITC's conclusion of literal infringement of the claims. In *Coleco,* however, the Court agreed with the Commission that there was no literal infringement but found infringement through the doctrine of equivalence. The Court nevertheless concluded that the patentee could not resort to the doctrine of equivalence because he was estopped to do so by certain arguments made to the Examiner during the prosecution of his application. In order to appreciate more fully the Court's comments concerning the doctrine of equivalence and file wrapper estoppel, it is first necessary to understand in some detail the facts of *Coleco.*

A. *Coleco – The Facts*

The claims were directed to certain above-ground swimming pools of the type having a flexible, water-retaining liner supported by a peripheral retaining wall assembled from sections fastened together. An important aspect of the claimed invention was the fact that the end

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[15] 612 F.2d at 549, 204 U.S.P.Q. (BNA) at 279.

[16] *In re Warner,* 379 F.2d 1011, 1016, n.6, 154 U.S.P.Q. (BNA) 173, 177 n.6 (C.C.P.A. 1977).

[17] See note 15, *supra.*

[18] See *United States v. Mississippi Valley Generating Co.,* 364 U.S. 520, 526 (1961).

portions of the horizontal support members have depending retaining elements thereon engaged with a seating surface portion to limit horizontal movement of the horizontal support members relative to the vertical support members and to each other.

Two issues were before the Commission: (1) patent infringement, and (2) predatory pricing. The Presiding Officer (known also as an Administrative Law Judge) concluded that the patent in issue was valid and infringed but that no predatory pricing existed. The full Commission concluded there was no predatory pricing but ruled that the patent was not infringed. The issue as the Commission viewed it was whether the claim limitation of "depending retaining elements thereon" included within its scope screws used to fasten together sections of the imported pools.

The Presiding Officer believed that it did. The Commission narrowly construed the quoted phrase finding that "thereon" required that the "elements" be in a fixed relationship with the horizontal support members even when the members were not in use but were completely disconnected. The Commission discussed but did not apply the doctrine of equivalence. It did not apply that doctrine because it felt that such application was preempted by the doctrine of file wrapper estoppel.

The issue before the CCPA was the infringement question alone. More specifically, the issue was the interpretation of the claim language "depending retaining elements thereon."

The CCPA believed that there were two underlying sub-questions: (1) whether the screws of the imported pools were equivalent to the "depending retaining elements thereon" of the patent in suit and, if so, (2) whether file wrapper estoppel should apply.

The CCPA answered yes to both questions and affirmed the Commission's finding of no infringement.

B. *Doctrine of Equivalence*

The CCPA concluded that the claims, when read in light of the specification, *literally* exclude screws as the words "depending" and "thereon" mean a permanent relationship between the horizontal support members and the tabs. Having concluded the absence of literal infringement, however, a majority of the CCPA would apply the doctrine of equivalence as a matter of course.[19] The well-known test for

[19] The Court majority cited several cases for the proposition that the doctrine of equivalence is invoked as a matter of course upon a finding of no literal infringement. One such case is *Acme Highway Product Corp. v. D.S. Brown Co.*, 473 F.2d 849, 850-51, 177 U.S.P.Q. (BNA) 130, 131 (6th Cir.), *cert. denied*, 414 U.S. 824, 179 U.S.P.Q. 321 (1973).

equivalency, as enunciated in *Graver*[20]

> is whether the allegedly infringing device performs substantially the same function in substantially the same way to obtain the same result.

The Court concluded that the screws of the imported pools do, in fact, employ substantially the same means as the depending retaining elements of the claims because the screws constitute elongated interlocking members. Furthermore, the screws accomplish substantially the same result as the depending retaining elements in that both restrict relative movement between the horizontal support members and the vertical support members by extending through apertures in the horizontal support members by resting on (although not permanently attached to) the horizontal support members and by extending through apertures in the seating surface of the vertical support members. Finally, the screws function in the same way as the depending retaining elements in that they cooperate with matching apertures in vertical and horizontal members.

C. *File Wrapper Estoppel By Admissions*

Having concluded that the three-prong equivalence test was met, the Court then inquired as to whether the doctrine of equivalence was limited by the application of the principle of file wrapper estoppel. The Court noted that the file wrapper did contain amendments to the claims but with respect to these amendments the Court concluded that

> we do not find that the amendment itself raises an estoppel with regard to applying the doctrine of equivalents to construe the claims.[21]

Thus, the Court was not relying upon a "classic" file wrapper estoppel but a broader doctrine of file wrapper estoppel by admissions. The Court found that the appellant, in his response to the Office Action, cited a *Gershman* patent. In discussing *Gershman,* the appellant stated that

> The specifically disclosed embodiment [of *Gershman*] is that of *upstanding tabs or projections on the horizontal rails* which seat within the side walls of the vertical post although an alternative arrangement is one in which the rails have slots receiving the side walls of the vertical posts. The present invention is directed to facilitating a more rigid assembly adapted to more massive vertical posts and rails than those specifically disclosed therein [Emphasis by Court].[22]

The CCPA concluded that *Gershman* was more pertinent to the estop-

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[20] *Graver Mfg. Co. v. Linde Co.,* 339 U.S. 605, 608, 85 U.S.P.Q. (BNA) 328, 330 (1950).

[21] 573 F.2d at 1256, 197 U.S.P.Q. (BNA) at 478.

[22] *Id.* at 1256, 197 U.S.P.Q. (BNA) at 479.

pel issue than the references cited by the Examiner.[23] The Court further found that the appellant distinguished its claimed invention so as to disclaim the tabs and screws disclosed in *Gershman* in order to secure allowance of his claims.

> Appellant distinguishes its invention from *Gershman* by describing tabs instead of screws for the locking function and by describing tabs which depend from the horizontal support members instead of from the vertical support members.[24]

The question raised by the CCPA was

> whether appellant is estopped by arguments made with regard to the Gershman copending application voluntarily cited by appellant and acknowledged as prior art.[25]

Rephrased somewhat, the legal issue was

> whether an estoppel arises in the prosecution history from arguments not directed specifically to examiner's cited references but directed to a reference cited by applicant.[26]

The CCPA recognized that there are decisions both pro and con on the issue of file wrapper estoppel by admissions but felt that not one of these cases was determinative of the case at hand.

> We are in the position of enunciating a rule braoder than the traditional "file wrapper" estoppel doctrine. A patentee having *argued* a narrow construction for his claims before the United States Patent and Trademark Office (PTO) should be precluded from arguing a broader construction for the purposes of infringement. We believe this to be a sound legal proposition which comports with the rationale underlying the traditional doctrine of "file wrapper" estoppel, that once a broader scope of interpretation for a claim is disclaimed by an applicant before the PTO, he is not entitled to reinstate the broader scope.[27]

The Court felt that it was unreasonable to restrict estoppel theory to so-called classic file wrapper estoppel whereby a claim is limited in response to a reference cited by the Examiner since the ultimate goal in submitting both arguments and amendments is the securing of the patent. The Court's holding is that arguments made by an applicant or his attorney may be just as effective in creating an estoppel as an amendment in response to the citation of prior art.

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[23] *Id.*

[24] *Id.*

[25] *Id.* at 1256-57, 197 U.S.P.Q. (BNA) at 479.

[26] *Id.* at 1257, 197 U.S.P.Q. (BNA) at 479.

[27] *Id.* at 1257, 197 U.S.P.Q. (BNA) at 480.

D. *The Concurring Opinion*

Judge Rich concurred in the result. He was joined by Chief Judge Markey. Judge Rich thought this case involved a relatively simple construction of claims which, in his opinion, required the same narrow interpretation as that given by the Commission. He felt that the case should simply be decided upon a construction of the claims, read in light of the specification, and, when so construed, he felt that they were literally limited to "depending retaining elements [tabs] 'on' the end portions of said horizontal support members [rails].'"[28]

Judge Rich concluded there was no basis for applying the doctrine of equivalence since a foundation had to be laid before invoking this doctrine. Such a foundation would include some proof of 1) pioneer status, or 2) appropriation of the "gist" of the claimed invention by the alleged infringer. Judge Rich felt that no such showing was made in the instant case.

Judge Rich also criticized the majority for unnecessarily invoking the doctrine of equivalence and analyzing the claimed invention vis-a-vis that doctrine when it was clear that its decision was based upon an estoppel theory. Judge Rich did not expressly disagree with the comments made by the majority with respect to the doctrine of file wrapper estoppel by admissions.

IV. *Validity*

A. *The Presumption of Validity*

Much has been written about the so-called presumption of validity.[29] In *Solder,* the Administrative Law Judge concluded that the presumption of validity did not exist when the most pertinent prior art was not considered by the Examiner when he allowed the patent. The CCPA stated that that conclusion was unsound and that the presumption continues alive and well until rebutted.

Rebuttal of the presumption may be more easily and more readily achieved by relying upon prior art which is more pertinent than that considered by the Examiner. But the mere fact that the prior art considered by the ITC is more pertinent than that cited by the Examiner does not automatically rebut the presumption.[30]

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[28] *Id.*

[29] 35 U.S.C. §282 states that "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity . . . shall rest on the party asserting it."

[30] The C.C.P.A. recognized that some court opinions indicate that no presumption exists when prior art, not considered by the PTO, is cited to the court. *See Solder,* 582 F.2d at 633, 199 U.S.P.Q. (BNA) at 133.

Section 282 provides that the party asserting invalidity bears the burden of establishing it, i.e., he bears the burden of 1) going forward, and 2) persuasion. The Court concluded that the burden of persuasion is and always remains upon the party asserting invalidity whether or not the most pertinent prior art was considered by the Examiner.

B. *Obviousness*

1. *Introduction*

The CCPA concluded that the patent in *Solder* was invalid for obviousness but that the patent in *Stevenson* met the test of nonobviousness. In arriving at its conclusion in each case, the Court considered the so-called "secondary considerations"[31] of nonobviousness. The Court in *Stevenson* rejected the theory that

> commercial success can only tip the scales in favor of patentability in close cases.[32]

According to the CCPA, the secondary conditions should be evaluated in every case in determining the validity of the obviousness conclusion. The secondary considerations serve as a "guard against slipping into hindsight".[33]

The obviousness issues in both *Solder* and *Stevenson* will be briefly reviewed.

2. *Solder*

In *Solder,* the issue of patent validity was reached for the first time under the new Trade Act. The complaint alleged a violation of Section 337 in that certain solder removal wicks were being imported and sold in this country and such importation and sale constituted an unfair act or unfair method of competition under the new Trade Act. The Administrative Law Judge found the patent in suit invalid as obvious in view of the prior art and that there was no effect or tendency to destroy or substantially injure an industry, efficiently and economically operated, in the United States.

The Commission majority concluded that there was no violation of Section 337 because the claimed invention was deemed to be obvious in view of the prior art. The sole issue before the CCPA was whether the claimed invention was obvious at the time the invention was made to

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[31] These "secondary considerations" or subtests include long-felt need in the industry which the claimed invention filled, wide commercial success of the claimed invention, and long and unsuccessful search by the industry to solve a problem which the claimed invention solves. *See Calmar, Inc. v. Cook Chemical Co.,* 383 U.S. 1 (1966).

[32] 612 F.2d at 553, 204 U.S.P.Q. (BNA) at 282.

[33] *Id.*

one having ordinary skill in the art of solder and fluxes which could be used in the electronics industry.

Two basic obviousness sub-issues were involved: (1) the significance of the discovery of the source of a problem, and (2) the significance of commercial success in rebutting a prima facie case of obviousness.[34] With respect to discovery of the source of the problem, the Court concluded that the situation in *Solder* was unlike that in *Eibel* since in *Solder* there was no evidence that the specific problem relied upon by appellants was long known. Furthermore, the Court felt that the evidence of the very existence of the problem was at best equivocal.

In considering the commercial success issue, the CCPA noted that there must be a causal relationship or "nexus" between the commercial success and the features of the claimed invention before that evidence may be considered relevant to the issue of obviousness.[35] If the commercial success is attributed to superior business acumen or effective advertising, the required nexus cannot be established.

The CCPA found that appellants failed to establish the required nexus between market dominance and the features of the claimed invention and concluded that the claims were invalid under 35 U.S.C. §103.

3. *Stevenson*

In *Stevenson,* the CCPA held for the first time under the new Trade Act that a patent was valid and infringed. The Court reversed the Administrative Law Judge's conclusion that the subject claims were invalid as obvious.

The patent in suit was directed to skateboards which are commonly known as "kicktail" skateboards. There was ample evidence that kicktail skateboards possess functional advantages ("an inclined foot-depressible lever coupled to the rearward end section of the platform") over prior art skateboards and these functional advantages were claimed. The Court concluded that the required nexus between commercial success and the merit of appellant's invention existed in *Stevenson* and thus the prima facie case of obviousness was successfully rebutted.

The Court found unpersuasive appellee's attempts to rebut the

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[34] *Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45 (1923).

[35] *See, e.g., In re Thompson,* 545 F.2d 1290, 1295, 192 U.S.P.Q. (BNA) 275, 277 (C.C.P.A. 1976); *In re Felton,* 484 F.2d 495, 501, 179 U.S.P.Q. (BNA) 295, 299 (C.C.P.A. 1973); and *In re Caveney,* 386 F.d 917, 923, 155 U.S.P.Q. (BNA) 681, 687 (C.C.P.A. 1967).

prima facie nexus between commercial success and the merit of the claimed invention with the opinion testimony of a single witness with a demonstrative financial interest in the outcome. That witness unsuccessfully attempted to establish that commercial success was due to cosmetic reasons.

C. *Enforceability*

Appellee in *Stevenson* asserted that the patent was unenforceable because Stevenson failed to disclose relevant prior art (i.e., the rocker board art) to the Examiner during prosecution of the patent in suit. The CCPA, relying on its holding in *Norton,*[36] concluded that Stevenson's conduct was not inequitable because Stevenson did not consider the rocker board art to be as relevant to the claimed invention as conventional flat skateboards. Absent any evidence of bad faith on the part of Stevenson, the Court was precluded from a finding of fraud or inequitable conduct in his failure to disclose the rocker board art to the Patent and Trademark Office.

V. *Conclusions*

The CCPA is now reviewing decisions on validity and infringement. Its decisions on these issues will impact not only those who practice before the ITC but also anyone who is involved in litigation in the federal courts.

[36] *Norton v. Curtis,* 433 F.2d 79, 167 U.S.P.Q. (BNA) 532 (C.C.P.A. 1970).