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IN RE OCHIAI, IN RE BROUWER AND THE BIOTECHNOLOGY PROCESS PATENT ACT OF 1995: THE END OF THE DURDEN LEGACY?

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I. Introduction

The United States' patent laws allow the patenting of processes, n1 but do not specifically define the term "process." The Supreme Court has explained, however, that a "process is a mode of treatment of certain materials to produce a given result. It is an act or a series of acts, performed upon the subject matter to be transformed or reduced to a different state or thing." n2 Like all patents, process patents are held to standards of utility, novelty and nonobviousness. n3

In determining patentability of a process as a whole, an examiner must consider separately the acts, steps, or procedures themselves, as well as the materials used or produced by those acts, steps, or procedures. n4 Questions concerning the patentability of processes arise, however, when: (1) the "mode of treatment" is obvious in light of the prior art and the "materials" being treated are novel and nonobvious, or (2) the acts, steps, or procedures are obvious in light of the prior art and the "state" or

[*406] "thing" produced is novel and non-obvious. There has been considerable debate n5 surrounding the nonobviousness of these "analogous processes." n6

In the past ten years, the debate has centered around the Court of Appeals for the Federal Circuit's (CAFC's) decision in In re Durden. n7 The court held that a chemical process, otherwise obvious, does not become nonobvious simply "because either or both the specific starting material employed and the product obtained, are novel and nonobvious." n8 Contrary to the CAFC's hope of "putting an end for now to this potentially endless debate on what the 'law' is," the Durden decision instead spurred greater controversy and intensified the debate. n9

The United States Patent and Trademark Office (PTO) broadly applied the holding in In re Durden, reducing the availability of process patents in many areas. n10 In particular, the biotechnology industry was adversely affected when Durden was cited repeatedly to deny patent grants to certain biotechnology processes. n11 This gave rise to grave concerns about and strong criticism of Durden in the biotechnology industry. n12 Since 1990, successive bills in Congress were introduced to overrule

[*407] Durden and to clarify the law on this issue. n13 As a result of this Congressional action, the Biotechnology Process Patent Act was signed into law n14 on November 1, 1995. The law amends 35 U.S.C.

103, and other related sections of the Patent Act, to make biotechnological processes that use or result in novel and nonobvious compositions of matter per se nonobvious under certain conditions. n15 Although this amendment solved the Durden dilemma in the biotechnology arena, the issue remains open outside the field of biotechnology.

In re Ochiai n16 was the first case after the enactment of the Biotechnology Process Patent Act in which the CAFC addressed questions regarding analogous processes in fields other than biotechnology. Presented with a fact pattern similar to that of Durden, the CAFC, contrary to Durden, held that the "analogous" chemical process at issue was nonobvious because of the novel and nonobvious starting and resulting compounds. n17 The court stressed the requirement of fact-intensive inquiries and rejected per se rules of obviousness. n18 In a companion case, In re Brouwer, n19 the CAFC applied the Ochiai rationales and held that the "analogous" process of making a patentable chemical resin was nonobvious because ofthe novel and nonobvious resulting product. Ochiai and Brouwer signal a major shift in the CAFC's approach in dealing with the issue of nonobviousness of analogous processes. The court's rulings in Ochiai and Brouwer, along with the Biotechnology Process Patent Act, greatly affect the law regarding the patentability of method claims, and likely will have significant economic impact.

Part II of this article reviews the case law pertaining to the nonobviousness of "analogous processes" prior to Durden, n20 and then examines the controversial In re Durden and Amgen v. Int'l Trade Comm'n n21 decisions and reviews how these decisions negatively impacted the biotech industry. n22 Part III summarizes the judicial and legislative responses to the criticism of Durden, with a focus on the legislative his-

[*408] tory of the Biotechnology Process Patent Act of 1995 and the debate surrounding the various predecessor bills of the Act. n23 Part IV discusses Ochiai and Brouwer and the reasoning and analysis that led to the rulings by the Board of Patent Appeals and Interferences (the Board) and the CAFC, respectively. n24

Part V examines the costs and benefits of a per se nonobviousness rule. Further, the author argues that although alternatives are available to the Biotechnology Process Patent Act that are more consistent with the constitutional purpose of patent protection, the Act does provide needed protection to the biotechnology industry. n25 Finally, Part VI concludes that the Biotechnology Process Patent Act of 1995 is justifiable as a temporary measure to protect the U.S. biotech industry against unfair foreign competition, and that, outside the biotech area, Ochiai and Brouwer are significant steps taken by the CAFC toward resolving the Durden dilemma.

II. The Path to Durden

A. From Larsen to Kanter - Rejection Based on Obviousness

In In re Larsen, the Court of Customs and Patent Appeals (CCPA) was faced with the issue of whether an otherwise obvious process is patentable simply because it results in a patentable chemical compound. n26 In Larsen, the appellant applied for a patent on novel organic compounds and the processes of making them. n27 Both the examiner and the Board rejected the process claims for obviousness. n28 The CCPA

[*409] agreed, holding that the invention resided solely in the compounds. n29 The rationale employed by the court was that once the compounds were conceived by the inventor, the processes of making them became obvious in light of the prior art. n30 Judge Rich, in his concurring opinion, thought that selecting the starting materials and reacting them in a conventional process was the obvious thing to do if the product was what one wanted to make. n31 In contrast, Judge Smith, in his dissenting opinion, viewed "the product and process claims as but different ways of claiming the disclosed invention." n32 He argued that the prior art at the time the invention was made did not include the applicant's new compounds made by the processes and thus both the majority opinion and Judge Rich erred in their application of 35 U.S.C.

103. n33

Three years later, the appellant in In re Neugebauer n34 presented the same argument to the CCPA that Judge Smith made in Larsen. Relying on Larsen, the CCPA similarly held that the process claims, directed to a single-step of coating an article in a known electrophotographic manner, were obvious even though the final product, the article prepared by coating, was novel and nonobvious. n35

Shortly after Neugebauer, the same panel of judges, relying heavily on the Neugebauer n36 decision, decided In re Albertson, n37 which involved a similar fact pattern to that in In re Durden n38 . In Albertson, the claims in the appellant's patent application were directed to: (1) novel and nonobvious starting organic compounds, (2) novel and nonobvious resulting organic compounds, and (3) processes for the preparation of the resulting compounds by reaction of the starting compounds with a known reducing agent. n39 The process was analogous to a conventional reaction disclosed in the prior art. n40 The compound claims were allowed by the

[*410] examiner, but the process claims were rejected for obviousness. n41 The Board affirmed the rejection. n42

While the appellant conceded that "on a purely process basis the processes claimed would be directly obvious from the references to a chemist of ordinary skill," the appellant argued that In re Larsen could be distinguished in that, the starting material, as well as the product, was novel and nonobvious. n43 The appellant asserted that the use of an nonobvious starting material makes a process nonobvious because the specific reactants are a part of the chemical process. n44 The court emphatically rejected this argument, stating "Were this true, every step, for example, dissolving or heating, when performed on a new compound would result in a patentable process." n45 Judge Smith, again dissenting, criticized the majority for ignoring the fact that the statutory definition of process in 35 U.S.C.

100(b) also includes the new use of a process. n46

In 1968, the CCPA decided In re Kanter, n47 which, in combination with Larsen, n48 Neugebauer, n49 and Albertson, n50 laid the foundation for the Durden court's ruling. The invention in Kanter involved a process for forming adherent, silicon-containing coatings on iron or steel articles. n51 The appellant discovered that when the article to be coated was a so-called "alpha-delta" alloy (not disclosed in prior art), the article coated by the old process was improved in that the coating did not separate easily from the core metal article. n52 The claim directed to the final product was allowed, n53 and the selection of the starting material was presumed by the

[*411] court to be nonobvious. n54 The majority of the court, however, relying on In re Neugebauer, n55 affirmed the refusal of the process claim. n56

The appellant attempted to distinguish Larsen and Neugebauer by asserting that the unique, unexpected results in the final product were achieved as a result of the process and that the inventive concept resided in the process itself. n57 The court rejected this reasoning, stating that the selection of the new starting material resulted in only a patentable product, but not a new or nonobvious process. n58 Judge Smith again filed a dissenting opinion reiterating his previous arguments, n59 i.e., that the Patent Office erred in regarding the appellant's patentable product to be in the prior art. n60 Judge Smith would have allowed claims for both the product and the process because "they are but alternative, statutorily-recognized expressions for defining the invention." n61

B. Kuehl and Mancy - "Method of Using"

In the decisions of In re Kuehl n62 and In re Mancy, n63 the CCPA reversed its previous position by holding that specific process claims involving known processes were nonobvious when patentable materials were involved.

In In re Kuehl the appellant discovered ZK-22, a novel member of a class of chemical compounds called crystalline aluminosilicate zeolite catalysts, the method of making ZK-22, and a method of using ZK-22 as a catalyst to crack hydrocarbons. n64 While claims directed to the novel zeolite and the method of making it were allowed by the PTO, the claims directed to the method of using it were rejected for obviousness under 35 U.S.C.

103. The examiner rejected the claims because the prior art disclosed the cracking of hydrocarbons under similar reaction conditions using known members of crystalline aluminosilicate zeolite catalysts with

[*412] properties similar to ZK-22. n65 The examiner further asserted that the claims should not be allowed without a showing of unexpected results. n66 The Board affirmed the examiner's decision. n67 In contrast to the prior cases, the CCPA disagreed with the PTO and held the process claims to be nonobvious. n68

Emphasizing the necessity of case-by-case factual inquiries in determining nonobviousness, the CCPA first rejected the appellant's proposition that a broad per se rule of non-obviousness be applied to all processes that involve patentable starting materials or patentable resultant products. That is, the CCPA refused to find that the mere fact that the claims directed to the composition of matter, ZK-22, were allowable entitled the inventor to claims directed to the method of using the patented catalyst. n69 The CCPA applied the three part test set forth in Graham v. John Deere Co., n70 and found that both the examiner and the Board erred in including the appellant's process in the prior art. n71 The court premised its finding on the conclusion that the claimed process as a whole included the use of ZK-22. n72 Thus, because "one having no knowledge thereof would not find it obvious to crack hydrocarbons using it as a catalyst," n73 the appellant's process of using ZK-22 to crack hydrocarbons was nonobvious and should be patentable. n74 The court found that the premise in the Larsen line of cases, that the starting or resulting materials in the claimed processes should be regarded as a part of the prior art, was inconsistent with the statutory standard of section 103. n75

In an effort to reconcile the clear conflict with its prior cases, the CCPA for the first time explicitly held that the process of making a nonobvious product and the process of using a nonobvious material should be treated differently when examining each type of process claim for obviousness. n76 In re Larsen and In re Albertson were distinguished by the

[*413] Kuehl court as being cases regarding processes of making rather than processes of using, and limited Albertson's holding to its facts. n77 Finally, the court justified its ruling by noting that the constitutional purpose of the Patent Act was to encourage inventors to disclose their inventions fully to the public, and that, by allowing both claims in the Kuehl case, inventors would be encouraged to disclose their inventions in more detail so that the public could better benefit from the inventions. n78 In addition, the court asserted that because the patent rights granted for the compound already permitted the patent owner to exclude others from making, using, or selling the composition, allowing the claims directed to the method of using the composition did not materially broaden the scope of patent protection. n79

The rationale of Kuehl was adopted in In re Mancy. n80 In Mancy, the prior art taught the production of the antibiotic daunorubicin by culturing strains of a microorganism called Streptomycin. n81 The appellants claimed a process for producing the same antibiotic using a newly discovered strain of Streptomyces. n82 The Board affirmed the examiner's obviousness rejection, asserting that the appellants did not show unexpected results in the use of their strain. n83 The CCPA reversed under In re Kuehl, holding the process was nonobvious because the new strain was not part of the prior art, and one without knowledge of the novel strain would not have found it obvious to use the strain in the process of making the antibiotic. n84 The court again made a distinction between using a novel starting material and making a novel product, and interpreted the holdings in In re Kanter and In re Neugebauer as being limited to methods of making, so that neither of which controlled in Mancy or Kuehl. n85 However, the

[*414] distinction the court made as to Kanter was somewhat unconvincing, as the starting material in Kanter was not disclosed in the prior art and the selection of the starting material was presumably nonobvious.

C. In re Durden

The CAFC first faced the analogous process issue in In re Durden. n86 The facts in Durden were similar to those in Albertson. The inventors claimed: (1) novel oxime compounds, (2) novel insecticidal carbamate compounds, and (3) a novel process for making the carbamate compounds using the novel oxime compounds as the starting materials. n87 A prior art reference disclosed similar processes for making carbamate compounds homologous to the claimed novel carbamate compounds using homologous oxime compounds. n88 The inventors admitted that absent the novel and nonobvious starting and resulting compounds, the claimed process would have been obvious. n89 The examiner allowed claims directed to the starting compounds and the resulting compounds, but the process claim was deemed to be obvious in light of the prior art. n90 The Board, en banc, affirmed the examiner's rejection in a 9-7 decision. n91 The majority relied mainly on In re Albertson, while the dissent argued that Albertson was no longer viable and that, instead, In re Kuehl should control the case. n92

The CAFC agreed with the majority of the Board and held Albertson "still stands as a precedent until overruled." n93 The court stated that Albertson had not been overruled sub silentio by cases such as Kuehl and Mancy, as suggested by the dissenting board members, and was still binding precedent. n94 It found Albertson and Kuehl distinguishable because the "cracking process [in Kuehl] was not predictable on the basis of mere

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possession of the catalyst, whereas the process claimed in Albertson . . . was predictable and obvious to those of ordinary skill in the art . . . ." n95 The court declined to state a general per se rule and reaffirmed the case-by-case approach adopted by the CCPA. According to the court, "the question of obviousness under section 103 arises in such an unpredictable variety of ways and in such different forms that [adopting a per se rule] would be an indiscreet thing to do." n96

D. Amgen and the Effect of Durden

Even though the Durden court expressed impatience with the analogous process issue and hoped to end the debate once for all, n97 the bar did not grant the court's wish. In fact, In re Durden publicized and intensified the debate, and has been widely criticized as being illogical and inconsistent with earlier cases. n98 Critics have asserted that, in following Albertson, the Durden court misconstrued the prior art to include the inventor's novel and nonobvious starting and resulting materials, as pointed out by the court in In re Kuehl. n99 The Durden decision has had a significant chilling effect on patent applicants due to its inconsistent application by examiners, which has resulted in delayed issuance of patents and significant cost to inventors. n100

Further, the Patent Office applied Durden mechanically to applications involving biotechnology despite the fact Durden was concerned with a chemical process. n101 This is particularly problematic because many biotechnological processes employ methodology that is standard in the art to make known natural products using patentable starting materials. n102

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Normally, if a process is patented, the patentee has the right to exclude others in the United States from using, selling, or offering to sell the end product of the process, and the right to exclude others from importing into the United States any product made by the process, even if the product itself is not patented. n103 The patentee may also sue the importer for infringement under 35 U.S.C.

271(g) or file a complaint in the International Trade Commission for an exclusion order under section 337 of the Tariff Act of 1930. n104 Without protection for process claims, manufacturers abroad may legally import products into the United States that are the result of the unauthorized use of patented compounds. Relying on Durden, examiners repeatedly denied patents to biotechnology processes that employed novel and nonobvious starting materials in standard biotechnology methods. n105 This often left inventors and their assignees vulnerable when facing unfair foreign competition, and has had a detrimental effect on the U.S. biotechnology industry.

Amgen v. United States Int'l Trade Comm'n n106 gave rise to increased debate about the Durden problem. Amgen, a leading biotechnology company in the United States, held a patent on the gene encoding human erythropoietin and the host cells that express recombinant erythropoietin (rEPO). n107 However, on the basis of In re Durden, the claims directed to the biotechnology process using the patented gene and host cells to produce rEPO were rejected by the Patent Office as obvious. n108 Chugai Pharmaceutical Co., a Japanese company, produced rEPO in Japan using Amgen's patented gene and host cells and began importing it into the United States. n109

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Amgen filed a complaint against Chugai in the International Trade Commission for a section 337 proceeding. n110 The presiding Administrative Law Judge found that Amgen's patent did not cover the process for making rEPO, and thus Chugai was not prohibited from importing rEPO under section 337 of the Tariff Act of 1930, as amended in 1988. n111 The Commission terminated the section 337 investigation, holding that it lacked subject matter jurisdiction. n112 Amgen appealed to the CAFC, contending that the article claims contained unique biological process claims. The court held that, absent patent protection for the process, section 337 does not prohibit importation of products made by that process even if the stating materials were patented. n113 Thus Amgen v. Int'l Trade Comm'n fully exposed the negative effects of the Durden problem and generated a great deal of controversy. Many argued for legislative overruling of Durden while others criticized the PTO for misapplying In re Durden and advocated a judicial approach to correction. n114 The consensus was that Durden needed clarification.

III. The Judicial and Legislative Responses

A. The Judicial Efforts in Limiting Durden - In re Pleuddemann and In re Dillon

Five years after it decided In re Durden, the CAFC had a chance to reassess the Durden problem in In re Pleuddemann. n115 There, the inventor applied for patents on a new group of organosilane coupling agents and the new articles of manufacture produced using the new coupling agents. Both compositions were considered novel and nonobvious and claims directed to them were allowed. n116 In addition, Pleuddemann claimed processes using the coupling agents to make the claimed products. Specifically, the application included claims directed to a process for bonding a polymerizable material to a mineral filler and a method for

[*418] priming a surface to improve bonding to certain organic resins. n117 The prior art disclosed analogous organosilane coupling agents and bonding and priming processes using them. n118 The examiner therefore rejected the process claims based on In re Durden, asserting that "it would have been obvious to one skilled in the art to use one silane compound in place of another in the process . . . and in the method." n119 The Board affirmed. n120

On appeal, the CAFC reversed on the ground that the process claims involved methods of using novel agents. n121 Speaking for the court, Judge Rich reasoned that because the utility and inherent characteristics of a compound dictate the use of the compound, a novel compound itself and its use are but different ways of looking at the same invention. Thus such an invention may be claimed both as a new article of manufacture and as a method or process of using the article. n122 Therefore, Judge Rich declared, "there is a real difference between a process of making and a process of using." n123

Using this rationale, the court distinguished both the case at issue and In re Kuehl from prior cases such as In re Durden, In re Kanter, and In re Neugebauer. n124 The court explained that the process claims in the latter cases were obvious because they involved methods of making novel products, while those in the former were nonobvious because the claims were directed toward methods of using novel materials. n125 In concluding that the product and the process are but alternative expressions of the same invention, it seems Judge Rich essentially adopted the late Judge Smith's view. n126

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However, the distinction made between method of using and method of making is not convincing, especially with regard to Durden, because the process in Durden also involved using novel starting materials. n127 The court ignored the contents of the process and classified Durden's process claim as a method of making based merely on the fact that the language in the claim was directed to a method of making. n128

After Pleuddemann, patent attorneys tended to draft around Durden rejections by converting a process of making claim into a process of using claim. n129 Although Pleuddemann offset to some extent the negative effect of Durden by making a conventional method of using a novel and nonobvious product patentable, n130 it did not resolve the Durden problem. Rather, it created further uncertainty.

The broad interpretation of In re Durden was further narrowed by the CAFC in In re Dillon. n131 In Dillon, the court rejected the categorical interpretation of Durden as a per se obvious rule. n132

The material used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of Durden. n133

Under Dillon, both the starting materials and resulting materials in an "analogous process" are relevant, but not dispositive, in determining the obviousness of the process. n134 However, in Dillon, the examiner, the Board and the applicant did not rely on or cite In re Durden. n135 Thus the

[*420] court's interpretation of Durden in the Dillon case has been regarded as dictum and its authority has been limited. n136

B. The Legislative Response and the Biotechnology Process Patent Act of 1995

In response to the CAFC's decision in Amgen v. Int'l Trade Comm'n and the continuing Durden legacy, many who viewed both cases as major obstacles to the development of the biotechnology industry sought the overruling of Durden by Congressional legislation, even before the CAFC handed down In re Pleuddemann and In re Dillon. On February 6, 1990, in the House of Representatives, Congressmen Boucher (D-Va.) and Moorehead (R-Ca.) introduced H.R. 3957, the Biotechnology Protection Act of 1990 (Boucher I). n137 On March 22, 1990, Senator DeConcini (D-Az.) introduced S. 2326 in the Senate, a companion bill that was identical to H.R. 3957. n138 Boucher I would have broadly overruled both Durden and Amgen, even outside the biotechnology area. n139 The bill would have amended 35 U.S.C.

103 to provide "a process of making a product shall not be considered obvious . . . if an essential material used in the process is novel . . . and otherwise nonobvious . . . ." n140 Thus, it would have made only the method of using, but not the method of making, patentable materials per se nonobvious.

The bill also would have expanded ITC jurisdiction and made importation of a product made using a material patented in the United States an act of patent infringement. n141 In addition, section 3 of the bill

[*421] would have mandated application of the bill both prospectively and retrospectively. n142

Boucher I generated great controversy among patent law practitioners and biotechnology companies. n143 The most vigorous opposition came from the Chemical Practice Committee of the American Intellectual Property Law Association (AIPLA). n144 The committee argued that Durden was not wrongly decided in light of its particular facts, but was misinterpreted and incorrectly applied by both practitioners and the PTO. n145 It asserted that legislative intervention was unnecessary and the per se rules proposed in the bill would erode the traditional sound patent law test for obviousness. n146 The Committee further argued that, even if there was a problem with Durden, judicial resolution through case-by-case review would suffice. n147 The Committee also feared that under H.R. 3957, protecting the products of a process using patented materials would expand protection into other countries, which would generate jurisdictional controversy and cause problems under GATT. n148 Further, the Administration believed that protection of unpatented products of patented materials was unnecessary. n149 Another part of the controversy arose from a retroactive application provision, which opponents asserted would lead to relitigation of lost claims and create uncertainty and disorder. n150

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In September 1990, Representative Boucher responded by introducing H.R. 5664, the Process Patent Amendments of 1990 (Boucher II), which was a revised version of Boucher I. n151 Boucher II abandoned the retroactive application provision and would have been applied only prospectively. n152 Boucher II also omitted H.R. 3957's product protection provisions and thus was intended to focus on Durden processes. n153 It would have made a process that uses or makes a novel machine, manufacture or composition of matter automatically novel and nonobvious when the process and the machine, manufacture or composition are in the same application. n154 However, such a process would not have been presumed invalid when the article claims were later found invalid. n155 In addition, it would have required that a single patent be issued on the application if the patentability of the process claims was dependent upon the machine, manufacture or composition of matter. n156 Thus, Boucher II would have significantly expanded the scope of protection to both method of making and method of using claims.

In March 1991, Representative Boucher and Senator DeConcini introduced H.R. 1417 and S. 654, respectively, which were identical to H.R. 5664. n157 Hearings on these bills were held on June 12, 1991 on S. 654 before the Subcommittee on Patents, Copyrights and Trademarks of the Senate Judiciary Committee, and on November 21, 1991 on H.R. 1417 before the House Subcommittee on Intellectual Property and Judicial Administration. At the respective subcommittee hearings, many proponents of the bills, including the Industrial Biotechnology Association (IBA) and Amgen, argued the necessity of the bills and expressed their strong support thereof. n158 The IBA argued that the bills were merely the codification of the holding in In re Mancy, n159 but the IBA objected to

[*423] the single patent requirement and argued that it would negatively affect patent applicants because applicants would have no control in ensuring that process claims and article claims would be issued in a single patent. n160 On this issue, the Administration also commented that common inventorship was not essential where there was common ownership of the product and process inventions. n161 The Administration asserted that the process patent must expire at the same time as the product patent that it relies on, unless the process patent alone could satisfy the conditions for patentability. n162 Subsequently, a new version of S. 654 that omitted the single patent requirement was introduced in the Senate.

Many groups voiced their opposition to the bills at the hearings. n163 The Intellectual Property Owners, Inc. ("IPO") contended that the bills would establish a per se rule that sidestepped the traditional novelty and nonobviousness examinations, leading to uncertainty over the validity and scope of the process patents issued. The IPO argued that judicial clarification and proper application of the law by the Patent Office would be sufficient in resolving the Durden problems. Similarly, the AIPLA objected to the drastic change to the patent statute proposed by the bills and maintained that a traditional approach of judicial case-by-case review should be utilized instead. It also expressed concern that other countries might be encouraged to adopt similarly expansive aberrational patent law doctrines. n164

Nevertheless, the amended S. 654 was approved by the Subcommittee on July 25, 1991, and by the full Senate Judiciary Committee on November 21, 1991. The Senate passed a compromised version of S. 654 on September 18, 1992, with an amendment offered by Senator Heflin. n165 The amendment essentially took S. 654 a half step back towards Boucher I. The amended S. 654 would have limited the bill exclusively to biotechnology. n166 However, like Boucher I, it would have expanded the ITC's jurisdiction, and made it an infringing act to import into the United States, or to sell or use within the United States, a product made by using

[*424] a patented biotechnological material. n167 However, it would have allowed a person who used, sold, imported or made substantial preparation to use, sell, or import any protected product before the effective date to continue do so after the effective date. n168

The amended S. 654 approved by the Senate was not taken up by the House in the 102d Congress in 1992. Instead, on Feb. 3, 1993, in the House, H.R. 760, a successor bill to H.R. 1417 was introduced by Representative Boucher (Boucher III). n169 A companion bill, S. 298, was also introduced in the Senate on the same day by Senator DeConcini. n170 The new bills were essentially the same as the amended S. 654 approved by the Senate, and would have applied exclusively to biotechnology. n171 S. 298 was passed by the Senate but was not taken up by the House.

On April 28, 1994, Representative Hughes (D-N.J.) introduced H.R. 4307. Unlike H.R. 760, H.R. 4307 omitted the title on the ITC jurisdiction and focused exclusively on patentability of Durden process claims. n172 In addition, the bill applied not only to biotechnology, but applied generically to all industries. n173 However, this broadened approach was narrowed by two significant changes. First, the bill omitted the "machine and manufacture" language and would have applied only to processes using or resulting in a "composition of matter." n174 Second, H.R. 4307 also changed the presumption of validity provision and specified that a process that is patented solely on the basis of using, or resulting in a novel and nonobvious composition of matter, would no longer be presumed nonobvious once the claims to the composition of matter were invalidated. n175

On May 5, 1994, the House Subcommittee on Intellectual Property and Judicial Administration heard testimony by representatives from

[*425] the PTO, biotechnology trade organizations, and several private companies. n176 Although the bill garnered support from the biotechnology industry and the PTO, it met strong opposition from IBM and Dow Chemical Company. Dow expressed the concern that H.R. 4307 would interrupt the U.S. patent system in many ways, n177 arguing that the proposed law would establish two types of process claims: those to be examined under the traditional patentability and those that, according to the per se rule of H.R. 4307, would not be examined. n178 Dow also argued that while there are only a limited number of claims for making a composition, there could be numerous ways of using a composition and, thus, H.R. 4307 would permit an infinite number of process claims due to the lack of a distinction between processes of making and processes of using. n179 Dow asserted that because there would be unusual restrictions on the use of the product imposed by the patents of otherwise obvious processes, the bill also would create confusion on the part of a purchaser of a patented product and interfere with the purchaser's use of the patented product. n180 Further, Dow asserted that the additional process claims created by this bill would clog the Patent Office. n181 Thus, Dow feared that the bill would dramatically increase litigation and disrupt the patent system. n182 IBM also voiced similar concerns and objected to H.R. 4307. n183 In addition, IBM opposed the bill on the ground that "its revolutionary provisions would facilitate the recapture by owners of patents having product claims of potentially vast areas of process technology formerly free and available to the public." n184

Despite the opposition from computer and chemical industries, the House passed H.R. 4307 on September 20, 1994. n185 The Senate, however, wanted to amend H.R. 4307 to limit the proposed law's application

[*426] to biotechnology only, and failed to reach an agreement with the House. n186

In 1995, new successor bills again were introduced in both the House (H.R. 587) n187 and the Senate (S. 1111). n188 The two identical bills were drafted on the basis of H.R. 4307 but proposed to further narrow the scope of application to biotechnological processes only. n189 In the hearings on H.R. 587, held on March 29, 1995, by the Subcommittee on Courts and Intellectual Property, the bill received generally broad support from the PTO and the biotech industry. n190 Consequently, H.R. 587 and S. 1111 successfully passed the House and the Senate, respectively. n191 S. 1111 was approved by the House on October 17, 1995 in lieu of H.R. 587. n192 More than ten years after In re Durden and five years after Con-

[*427] gressman Boucher introduced H.R. 3957 in the House, S. 1111 was signed into law by President Clinton, on November 1, 1995. n193

Section 1 of Public Law 104-41 makes a biotechnological process using or resulting in a novel and nonobvious composition of matter per se nonobvious. n194 For this section to be applicable, the process claims and the composition of matter claims must: (a) be owned by or assigned to the same person; (b) be contained in the same application or have the same filing date; and (c) be issued in the same patent or set to expire on the same date. The meaning of "biotechnological processes" is also specified. n195 Section 2 provides that a presumption of validity does not apply to a process patented under section 1 when the related composition of matter claim is held invalid. n196 Finally, section 3 of Public Law 104-41 provides that the law is to be applied prospectively. n197

IV. In re Ochiai and In re Brouwer

The companion cases of In re Ochiai n198 and In re Brouwer n199 were the first two cases decided after In re Pleuddemann where the CAFC dealt with the Durden problem. These cases also represented the first time the CAFC addressed the Durden problem in light of the enactment of the Biotechnological Process Patent Act.

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A. Ex Parte Ochiai - The Rejection By the Examiner and the Board

Ochiai's application was for a process of using an acyl side chain from a particular type of novel and nonobvious organic acid having a 2-aminothiazolyl group, and a type of known amine to make a novel and nonobvious cephem compound, a cephalosporin type antibiotic. n200 The process employed an acylation reaction between the carboxyl group of the organic acid and the amino group of the amine, which was a standard reaction taught by the prior art. n201 The examiner in the Patent Office rejected the claims for obviousness based on prior art references that disclosed preparing analogous types of cephem by analogous acylation reactions using the same amine and analogous types of organic acids. n202 The examiner explained that "[t]he only difference between what is being claimed and the prior art is the selection of a slightly different acylation agent (i.e., acid) to result in a slightly different final product." n203

Before the Board of Patent Appeals and Interference, Ochiai argued that the novelty and nonobviousness of the starting reactant, the final product, and the method of introducing the particular reactant groups should be dispositive in finding the process nonobvious. n204 Explicitly relying on In re Larsen, In re Albertson, and In re Durden, the Board rejected Ochiai's argument and affirmed the examiner's rejection. n205 In response to the inventor's urging for adoption of a broader approach as espoused in In re Dillon, n206 the Board ruled that the Dillon court's remarks were merely dicta directed to method of using claims. n207 Reviewing the CAFC's prior decisions, the Board concluded that In re Pleuddemann had resolved the Durden problem by distinguishing method of using claims from method of making claims. n208 Because Ochiai had admitted that the appealed claims were directed to a process of making, the Board asserted the Durden line of cases controlled and the process claimed was obvi-

[*429] ous. n209 Notably, however, even though the Board reached its ruling based on precedents, it was frustrated with what it perceived as inconsistent case law. The Board commented:

The chicken/egg conundrum discussed by appellants . . . presents a real world dilemma to a patent examiner trying to balance the "invention as a whole" concept with the rationale of the Larsen, Albertson and Durden line of cases. Faced with the use of a novel and nonobvious material to make a novel and nonobvious product, it is difficult to determine whether the invention is patentable as "use" of the new starting material or unpatentable as a "method of making" the final product. Moreover, it is difficult to divorce from the patentability consideration the novelty and nonobviousness of starting materials and final products when one is constantly advised to consider the invention as a whole when reaching the ultimate conclusion of patentability. n210

B. In re Ochiai - The CAFC's Reversal

On appeal to the CAFC, Ochiai argued that the examiner and the Board failed to apply the "second Graham factor" offered by the Supreme Court in Graham v. John Deere Co. n211 The court agreed, and held that "Ochiai's process invention as claimed is not prima facie obvious." n212 The court framed the issue as "whether the Board erred in upholding the examiner's rejection of claim 6 as obvious under 35 U.S.C. 103 . . . when neither the particular acid used nor the particular cephem produced is either taught or suggested by the art that predates the parent application." n213

Beginning its analysis, the court first stated that the statutory test of obviousness requires a comparison between the prior art and the subject matter of the claim as a whole, and is therefore highly fact-specific in nature. n214 The court reasoned that because Ochiai's process claims required use of a novel, nonobvious acid as one of the starting materials, the selection of the particular acid is part of the process. n215 The court held,

[*430] therefore, that since "one cannot choose from the unknown," and "[o]ne having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem," the process was nonobvious. n216 It reasoned that the similarity between the claimed starting material, the acid, and the acids used in the prior art did not make the process obvious. Rather, the court held that the prior art must have suggested or motivated either modification of the acids to obtain what was claimed, or the production of the novel and nonobvious cephem by the process claimed. n217

In the court's view, the examiner and the Board erred in three respects. n218 First, they employed hindsight comparison and presumed Ochiai's novel and nonobvious starting material to be part of the prior art. n219 Second, they incorrectly drew a per se rule from Durden and thus sidestepped "the fact-intensive inquiry mandated by section 103." n220 The court asserted that "there are not 'Durden obviousness rejections' or 'Albertson obviousness rejections,' but rather only section 103 obviousness rejections." n221 Finally, the Board and the examiner committed legal error in applying per se rules with respect to the method of using and method of making claims, which were substituted for the "particularized inquiry required by section 103." n222

In response to the complaints made by both Ochiai and the Solicitor that the precedents were inconsistent with each other and created unnecessary confusion, the court stated that every case "has been grounded on the same analytic principle: namely, that section 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another per se rule." n223 The court reconciled the alleged conflicts among cases by asserting that all the cases present "applications of a unitary legal regime to different claims and fields of art to yield particularized results," n224 and that reasonable persons may disagree about the outcome of a given obviousness determination based on analysis of specific complex factual situa-

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tions. n225 The court further attributed the cause of the perceived conflicts to the desire of examiners, members of the Board, and patent attorneys for per se rules in this area. n226 The court vigorously condemned per se rules of obviousness and demanded fact-specific inquiries free from any presumed controlling effect of precedent. n227

C. In re Brouwer

The companion case of Ochiai, In re Brouwer, n228 was decided two days after Ochiai by the same panel of judges. n229 The principal method claim at issue was directed toward a process of making a novel, nonobvious sulfoalkylated resin catalyst by reacting a crosslinked resin with an ester of an alkenesulfonic acid. n230 The process claims employed a Michael addition reaction, which was known generally as a standard technique in organic chemistry for reacting a material having an , -unsaturated carbonyl group with a material having an active methylene group, and was taught in the prior art references cited by the examiner. n231 However, the cited prior art references taught only generic Michael addition reactions and did not disclose the particular process claimed by Brouwer. n232 Thus, Brouwer was factually similar to In re Larsen. n233 The examiner rejected the claim for obviousness, and the Board affirmed. n234 Like the Larsen court, the Board reasoned that based on the standard generic Michael

[*432] addition reactions disclosed in the prior art, to make the novel and nonobvious sulfoalkylated resin catalyst, one skilled in the art would have founded it obvious to select the starting products and utilize a Michael addition reaction. n235

Appealing the Board's decision, Brouwer contended that the Board erred by treating his disclosure of the resulting patentable product as prior art. n236 The CAFC agreed. n237 The court stated:

[T]he mere possibility that one of the esters or the active methylene group-containing compounds disclosed in Distler could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious "unless the prior art suggested the desirability of such a modification" or replacement. Without first knowing Brouwer's claimed process steps or the composition resulting from those steps, there is simply no suggestion in the references cited by the examiner to practice the claimed process. It is therefore not prima facie obvious. n238

Thus, the court essentially adopted Judge Smith's point of view expressed in his dissenting opinion in In re Larsen. n239 Citing Ochiai, the court reiterated its objection to any per se obviousness rejection under Durden or "any other precedent." n240

V. ANALYSIS

A. Policy Considerations

The constitutional purpose of the American patent system is to promote the progress of useful arts. n241 Thus it is a social and economic rationale, rather than a natural-rights theory, that forms the basis of American patent law. Inventors are granted limited patent "monopolies" to induce them to disclose their inventions to benefit the public. n242 Thus, a high level of patentability is required by the Constitution and only in-

[*433] ventions that are new, useful and capable of furthering human knowledge justify the limited monopoly. n243 Therefore, good patent law strikes a proper balance between maximizing the benefits to society that flow from the disclosed invention and discouraging overreaching monopoly. n244 The nonobviousness test in 35 U.S.C. 103 is a part of the U.S. patent law scheme designed to ensure such a balance.

B. The Per se Rule of Nonobviousness

In interpreting the statutory meaning of 35 U.S.C. 103, the Supreme Court has taught the importance of a fact-specific analysis of the nonobviousness of an invention. n245 The scope and content of the prior art must be determined and differences between the prior art and the invention in question analyzed. n246 The level of ordinary skill in the pertinent art must also be assessed. n247 In addition, secondary considerations, if applicable, should also be examined to aid determination of obviousness. n248 Such secondary considerations include commercial success of the invention, evidence of long felt need for the invention, failure of others and any unexpected results generated by the invention. n249

Thus fact-intensive case-by-case analysis is mandated by the Supreme Court for determination of nonobviousness of an invention. n250 In considering the nonobviousness of an "analogous process," i.e., an otherwise obvious process involving a novel and nonobvious starting or resulting material, neither a per se obvious rule nor a per se nonobvious rule strikes a proper balance as required by Constitution and the Supreme Court.

Indiscreetly applying a per se patentability rule could abridge the traditionally enforced exhaustion doctrine and drastically expand a patent owner's market power. Once a patent is issued for a machine, manufacture, or composition of matter, the patent owner is conferred a statutory right to exclude others from making, using, selling, offering for sale, or

[*434] importing the invention into the United States. n251 However, under the judicially created exhaustion doctrine, once a patent owner or licensee sells a patented product (a sale of the res), the purchaser has an implied license to sell the object and to use the object in any conventional way, unless a limitation is imposed by contractual agreements. n252

This exhaustion doctrine was developed by the courts early in the history of patent law, and has been adopted internationally. n253 It manifests an equitable rationale that selling a patented article while precluding its use would be inequitable without a clear notice of the restriction. n254 The exhaustion doctrine also simplifies the sales of patented products and enables purchasers to efficiently benefit from the products. n255 If a method of using a patented product itself is nonobvious and is patented, a purchaser's use would be subject to the process patent owner's exclusive rights. n256

In contrast, under the exhaustion doctrine, a purchaser of the product has an implied license to use the product in any conventional and obvious way. n257 However, if a process patent is granted to such a conventional method of use under a per se rule, the purchaser would have to obtain a separate license to use the product, and the patent owner or his licensee would be able to exercise control over the purchaser's conventional and obvious use long after the initial sales transaction was completed. Furthermore, because the right to subsequent sale under the exhaustion doctrine is not affected, the purchaser may sell the patented product to a second purchaser, who obtains the object itself without the right to use it. The potential for such extension of market power is especially significant when the patented product is capable of many conventional uses. n258 Essentially, for any single different use that is conventional, the purchaser would have to have a separate license. n259 Thus a per se rule that deems an obvious process nonobvious simply because a novel and nonobvious product is involved could unjustifiably grant an excessively

[*435] broad exclusionary right to the product patent owner and substantially interfere with the public's efficient use of the product.

In contrast to the burden imposed on the public, very little benefit flows from such a per se nonobviousness rule. Such a rule does not materially encourage full disclosure of an invention, notwithstanding the court's assertion in In re Kuehl. n260 The reasoning of the court in Kuehl suffers a flaw; a process like that in Durden or Kuehl is analogous to an old process disclosed in the prior art, in that once the patentable starting or resulting material is disclosed, the process would be obvious and thus further disclosure is not necessary. Also, granting a patent on such a process in exchange for an unnecessary disclosure would not be in accordance with the policy underlying patent law.

A per se rule of nonobviousness, just like a per se rule of obviousness, may be administratively convenient for PTO examiners and the Board since fact-specific analysis is eliminated. n261 However, it may also burden examiners with a tremendous amount of conventional process claims directed to conventional methods.

As for a patent owners, having a patent on a novel and nonobvious product bestows the right to exclude others from making, using, and selling the product. n262 Even after selling or licensing the patented product, the patent owner could still exercise control over the use of the product through contractual agreements made at the time of sale or licensing. n263 Thus, there is little need for a process patent to protect a conventional method of using or making, at least in the United States.

C. The Biotechnology Process Patent Act of 1995

Even in the international context where existing law does not fend off unfair foreign competition, as in the case of Amgen v. Int'l Trade Comm'n, given the problems discussed above a per se nonobviousness rule may not be the best alternative to the Durden problem. n264

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However, because of the interest in protecting the emerging biotechnology industry, the Biotechnology Process Patent Act of 1995 may still be a rational legislative alternative for the present since patents are critical to the livelihood of the biotechnology industry. n265 Biotechnology companies spend heavily on intensive research and development and rely especially on patent portfolios to attract investment. n266 In addition, many biotech products are natural products and are not patentable in and of themselves. Thus, process patents are particularly important to the industry. n267

After continuous debate and successive revision of the original bill over the five-year period, n268 the final version that became the Public Law 104-41 is narrow in scope. n269 The law applies only to "biotechnological processes," n270 which are defined very narrowly. They include procedures for altering gene expressions or physiological characteristics in cells or organisms, cell fusion procedures for making cell lines that express specific proteins, and methods of using the products produced by the above two procedures. n271 In addition, the House Committee on Judiciary indicated that the scope of a protected process is narrow and would not include downstream or upstream processes that are not themselves patentable

[*437] under the Act or traditional conditions of patentability. n272 This effectively deters overbroad process claims and prevents unfair monopoly.

Another feature of the Biotechnology Process Patent Act is the absence of the presumption of nonobviousness provision contained in some of the predecessor bills. n273 As enacted, a process is deemed nonobvious solely on the basis of the novel and nonobvious composition of matter involved therein and it is logical that the process should not be presumed nonobvious when the composition of matter is later held obvious. Otherwise, the process patent would be an "unsinkable" patent. n274

To benefit from the Act, a novel and nonobvious composition of matter and the process linked to it must be either in the same application or, if they are in separate applications, have the same filing date. n275 The purpose of this provision is to ensure that the patent rights derived from a composition of matter and a process patented under the Act terminate on the same date. n276 This seems to resemble the judicially-created obviousness-type double patenting doctrine. n277 Since in most cases once the products are known, the process claims would become obvious, expiration of the two different rights at different dates would result in unjustifiable extension of patent terms. Therefore, if the disclosure of a patentable biotechnological product does not make the process of using or making the product obvious, the inventor is better off to take the traditional approach and not use the Act. This is because the "same application" or "same effective filing date" requirement need not be met under the traditional conditions of patentability.

To take full advantage of the Act when applying for a patent on a composition of matter, an applicant should be careful to include all possible methods of using or making claims. Inadvertently leaving out a method from the application can mean forfeiting rights to that method

[*438] which otherwise would have been available under the Act. Under certain circumstances, the inventor of a product invention may want to postpone a patent application on the product until he or she has fully explored all possible methods of using or making the product. Thus, to this extent, the Act would encourage inventors to delay the disclosure of their invention. Of course, applicants may take advantage of the various procedures such as continuation applications, continuation-in-part applications, or provisional applications, under which later-developed method claims may be included. n278

The Biotechnology Process Patent Act is silent about the use of a terminal disclaimer under 35 U.S.C.

253 to make product and process patents expire at the same date. n279 Logically, where the product and process claims are filed in separate applications, such a terminal disclaimer should be available for an application directed at method claims filed after the application on product claims but before the product patent is issued. n280

If the benefits of the Act are desired, an applicant must make a timely election in order to proceed under the provisions of the Act. n281 Further, under the Act the patentable subject matter linked to an analo-

[*439] gous process is limited to a composition of matter. n282 Thus, a patentable machine or apparatus would not make an otherwise obvious biotechnological process per se nonobvious. Such exclusion of machines from the Act is essential in limiting the Act to biotechnology. Nevertheless, presumably, if a machine is used in a conventional way (for example, microinjection of DNA into cells or Drosophila eggs), to produce a patentable new cell line or organism, the whole process including the use of machines would be patentable under the Act.

It should be noted, as the House Committee on Judiciary stated, the real purpose of the Biotechnology Process Patent Act of 1995 is only to ensure that those patentable biotechnological processes using or resulting in a patentable composition of matter are in fact patented. n283 It does not intend to make otherwise obvious biotechnological processes nonobvious and patentable, even though its practical consequence may seem to be so. n284 Novelty and utility are still required under the Act. n285 Furthermore, the limitations included in the Act narrow its scope, and thus reduce the negative effects discussed above that are inherent in any per se rule of nonobviousness. n286

D. Ochiai, Brouwer and Their Significance

The legislative history of Public Law 104-41 clearly indicates that the per se nonobviousness rule enacted by Congress is limited to biotechnology only and should not apply outside that industry. n287 Thus, examiners and the courts must still undertake traditional fact-specific analysis when theyare presented with "analogous process" claims directed to inventions in other fields. Given the conflicting case law and the difficult nature of analogous processes, courts and the PTO still face the difficult task of enunciating and applying a new and coherent rule for determination of nonobviousness. In this respect, Ochiai and Brouwer are clearly the beginning steps.

Ochiai and Brouwer are significant, as both decisions emphatically mandate fact-specific analysis of each claim and denounce all per se

[*440] obviousness rules. n288 Under Ochiai and Brouwer, each case must be decided based on particularized inquiries. n289 Finding an analogous process claim obvious or nonobvious by merely relying on one particular case precedent is not likely to be sustainable. Thus, any particular rule applied by the court in a particular case should be mere guidance in a subsequent case. This case- by-case approach is plausible not only because it has been traditionally mandated by the court, n290 but also because it is more realistic in light of the nature of determination of obviousness and the complexity of processes. Indeed, the concept of "process" itself is so vague and flexible that it may be used to describe inventions that are extremely diverse. n291 A process may be mechanical, biological, or chemical. It may involve a single step or multiple steps of using or making a composition of matter, steps of manufacture, or a machine. Thus, it would be unwise to generate per se rules.

Further, the semantic distinction between method of using and process of making claims made by the court in Pleuddemann is illogical and arbitrary. n292 Almost all processes employ certain materials and produce certain physical results. Processes invariably involve steps of using and steps of making, and are capable of being described as both method of making and method of using. Thus determining obviousness of an invention based on an arbitrary characterization by the examiner or the court, or based merely on a party's admission, n293 necessarily leads to conflicts and inconsistency. In this sense, Brouwer is significant in breaking the framework of the semantic analysis in Pleuddemann and unequivocally holding that an otherwise obvious method of making a novel and nonobvious product can be no nobvious.

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The Ochiai court tried with great effort to reconcile the allegedly inconsistent precedents by extracting a general principle from the previous cases. n294 It is true that all cases reiterated the 35 U.S.C.

103 fact-intensive determination requirement. n295 However, many cases incorrectly applied the Graham tests and some are in direct conflict with the analytical approach taken by the Ochiai court. For example, the fact patterns in Durden and Albertson are almost identical to that in Ochiai while the rulings in Durden and Albertson are contrary to the holding in Ochiai. n296 Likewise, both Larsen and Brouwer involve methods of making novel and nonobvious chemicals, but the holdings are opposite.

Yet the court has left the old cases standing as good law, asserting that "[t]hey present . . . applications of a unitary legal regime to different claims and fields of art to yield particularized results." n297 This may have again left the law in a state of uncertainty and confusion, as the supporters of per se nonobviousness rules believed. n298 Furthermore, the fact that the appellate courts have not been able to make consistent rulings in the past, even under the same "unitary legal regime," not only illustrates the complexity of the issue but also indicates that more concrete rules and guidance adapted for this particular issue are needed from the courts, especially the Federal Circuit.

Section 103 of the Patent Act requires one to consider the invention "as a whole" in determining the obviousness of the invention. n299 One inconsistency in the case law regarding obviousness of an analogous process lies in the question of how to define the scope of prior art and the scope of the invention. In some cases, the courts have regarded the novel and nonobvious starting or resulting materials as part of prior art. n300

[*442] Almost invariably, the courts with this view have held the processes as being obvious. n301 In other cases, the courts included the starting or resulting materials in the claimed processes, and held the processes to be nonobvious. n302

The court in Ochiai adopted the latter view based on the particular facts and included the patentable starting materials in the processes. n303 Consequently, because "one cannot choose from the unknown," the court concluded the process was nonobvious. n304 Likewise, in Brouwer, the court found that without first knowing the resulting novel and nonobvious product there was no suggestion in prior art to practice the claimed process. n305 The court corrected the flaws in the precedents and observed the requirement of the statute to consider obviousness of an invention "as a whole" over the prior art available under 35 U.S.C.

103. When determining the obviousness of an analogous process under the Ochiai and Brouwer approach, the conclusion hinges upon the question of whether the novel and nonobvious starting or resulting materials ought to be treated as part of the process at issue. If the answer is yes, the process is most likely nonobvious. If the answer is no, the process is likely to be held obvious.

However, the case-by-case approach is not without drawbacks. Any time the court reiterates a holding in a particular case, there is always the danger that the holding will be adapted to a different situation by examiners, lawyers, the lower courts, and even the Federal Circuit itself. This is especially true when one faces an analogous process such as that in Durden, where the issue is complex and the teachings of the courts appear inconsistent. n306 This is evident from the conflicting per se rules the

[*443] courts and the Board have adopted in various cases. Thus, to ensure the proper analysis of Durden-type processes, the court must enunciate more concrete guidance.

The Ochiai and Brouwer approach is simple, logical, and straightforward: if the novel and nonobvious starting material is a part of the otherwise obvious process, the process is nonobvious because, without the knowledge of the starting material, one would not have been able to choose it to make the product in the process. n307 Likewise, if the novel and nonobvious resulting material is a part of the otherwise obvious process, the process is nonobvious because, without the knowledge of the resulting material, it would not have been obvious to one of ordinary skills in the art to make that resulting material. Yet this rule must be qualified and narrowly tailored. Otherwise, it would likely become a vehicle toward a per se nonobviousness rule which considers all claims involving a method of using or making novel and nonobvious material nonobvious simply because the presence of a novel and nonobvious material. Several factors are proposed below that should be considered, including the proper scope and content of an analogous process, traditional secondary considerations for nonobviousness analysis, and potential extension of market power.

1. Scope and Content of An "Analogous Process"

When applying the Ochiai analysis, it is critical to clearly define the scope and content of the process in question. In the context of an analogous process linked with novel and nonobvious materials, the nexus between the material and the process should be examined. The product and process must be closely linked together in order to include the product in the process. Examiners and courts may consider various factors that reasonably aid in the determination of the nexus.

a) Active Elements

Where a novel and nonobvious material is an active element of an analogous process, or constitutes a part of the manipulative steps of the process, the nexus is closest. This was the case in In re Kuehl. n308 There, the novel and nonobvious catalyst was the central element of the catalytic reactions (or processes), and the process could be used to crack

[*444] various hydrocarbons into smaller molecules. n309 Thus, the novel and nonobvious catalyst was an integral part of the process and the use of the catalyst essentially made the processes new and nonobvious. Similarly, as in In re Way, n310 if a novel and nonobvious material is used as part of the apparatus of an otherwise known process, that material may also be logically considered part of the process. n311 In such cases, an argument can be made that the process is a new and useful improvement of the known processes, and thus patentable under 35 U.S.C.

101. n312

b) Alternative Means for Claiming the Product Invention

Another relevant factor is whether the novel character of the product confers new characteristics on the process and dictates the nature of the process so that the process and the product are alternative expressions of the same invention. n313 In a method of using case, as Judge Rich stated in In re Pleuddemann, the novel character of the starting material may determine the use of the material. n314 In a method of making a novel and nonobvious product, such as the roof flashing in Ex parte Kifer, n315 the

[*445] novel and nonobvious features of the product may dictate the features of the method for making the product. Without first knowing such features, one of ordinary skill in the art would not be able to modify the conventional process to develop a process for making the new product. Thus, the process adapted to the novel and nonobvious product would not be obvious.

c) Multiple Separable Steps

A process may be an act or a series of acts. n316 The relationship among a series of acts may have some bearing on the nexus between the novel product and the process. Downstream and upstream steps or acts that are conceptually separated and remotely linked to a novel material may be excluded from the process in determining whether the novel product makes the otherwise obvious process nonobvious. For example, a process for making leather belt from a new and nonobvious variety of patented oxen must necessarily include many separate steps such as breeding or raising the oxen, sacrificing the oxen, preparation and treatment of oxen leather, cutting and sewing, and fixing buckles on the belt, etc. It certainly may not be very convincing to argue that the whole process, consisting of conventional steps remotely linked to the starting novel and nonobvious oxen, is made nonobvious because of the patentable oxen. n317 In contrast, in a simple chemical process like that at issue in Durden or Ochiai, it would be sound to say that the starting and resulting compounds are in the same single chemical process.

d) Contained in the Same Application

In addition to the nexus to be determined, the claimed material and process must be disclosed in the same application. The nature or the processes in the present discussion is such that disclosure of the patentable material would make the use of the process obvious. Thus, once the materials are disclosed to the public, they become part of prior art and it would be unfair to let the inventor recapture the claims to the processes that have been made obvious by the disclosure of the materials.

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These are merely some sample factors that may aid the application of the Ochiai and Brouwer approach to determine the scope of an analogous process. They should be considered flexible guidance to be viewed in light of the relevant circumstances.

2. Economic Considerations

The court should also consider the effect of a ruling on the market power conferred to the patent owner. If extension of the patent owner's market power is significant and is disproportional to the benefits which the invention brought to the public, then granting patent rights may not be justifiable under the policies underlying patent law. As discussed above, there is the danger of extending excess market power when granting a patent on an obvious conventional process. Holding an obvious conventional method of use nonobvious abridges the traditional exhaustion doctrine and thus extends market power and monopoly of the patent owner. The degree of such extension of market power largely depends on the spectrum of potential uses for the patented product. n318 When a patented product has many conventional uses, the extension is great; where there is only a single practical use of the patented product, and the product and the claimed process are but alternative expression of the same invention, the extension of market power is limited. n319 Because the exhaustion doctrine does not apply to making a patented product, and a patent owner has the right to exclude others from making the product, the potential for extension of market power is not significant where an analogous process of making a patented product is held nonobvious and patentable. n320

VI. Conclusion

The purpose of patent law as defined by the Constitution, requires a proper balance between maximizing the benefit to society from the disclosure of an invention and minimizing overreaching monopoly of an inventor. In respect to otherwise obvious analogous processes that involve patentable starting or resulting materials, neither a per se obvious rule nor a per se nonobvious rule can ensure such a proper balance. Nevertheless, given the unique nature of the biotechnology art and the interest

[*447] in protecting the emerging biotechnology industry, the Biotechnology Process Patent Act of 1995 may be justifiable. In addition, the limitations imposed on the Act effectively narrow its scope and reduce the negative effects inherent in a per se rule. Thus, the benefits derived from the Act likely outweigh the costs, and the Act is, at least for now, justified in that it provides protection to the United States biotechnology industry against unfair foreign competition.

Outside the field of biotechnology, In re Ochiai and In re Brouwer are the latest steps of the CAFC in formulating a coherent and workable rule of obviousness for analogous processes. Ochiai emphatically mandates fact-specific analysis of the obviousness of each claim and denounces all per se obviousrules. The significance in the court's analysis of an analogous process in Ochiai and Brouwer is that the court correctly excluded the inventors' novel and non-obvious starting and resulting products from the prior art, and instead, regarded them as parts of the claimed processes. However, this case-by-case approach has the inherent danger of leading to a per se rule. To prevent this, the CAFC should offer more concrete guidance. Courts faced with these issues should consider the above mentioned factors when determining the scope and obviousness of an analogous process.

n1 *35 U.S.C. 101* (1996).

n2 *Cochrane v. Deener, 94 U.S. 780, 788 (1876)* (emphasis added).

n3 *35 U.S.C. 101*-103 (1996).

n4 *35 U.S.C. 100* uses the term process in defining process and states that "[t]he term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

n5 See, e.g., Harold Wegner, Much Ado About Durden, 71 J. Pat. & Trademark Off. Soc'y 785 (1989); Kevin Kelly, The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents? *24 J. Marshall L. Rev. 263 (1990);* Isabelle McAndrew, Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664, 72 J. Pat. & Trademark Off. Soc'y 1188 (1990); David Beir & Robert H. Benson, Biotechnology Patent Process Act, *68 Denv. U. L. Rev. 173 (1991);* Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation To The Procrustean Bed, 17 Rutgers Computer & Tech L.J. 1, 54 (1991); Rochelle K. Seide & Aimee H. Weiss, The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn, J. Proprietary Rts., Mar. 1992, at 6; Carlos A. Fisher, Unfair Trade Practices in Biotechnology: the Legacy of In re Durden, *21 Sw. U. L. Rev. 1103 (1992);* Nelson Johnson, The Foreign Use of U.S. Patents: Damming the Flow of Downstream Products, *30 Colum. J. Transnat'l L. 145 (1992);* Jeremy Cubert, U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge, 77 J. Pat. & Trademark Off. Soc'y 151 (1995); Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 342-46 (1995).

n6 Hereinafter a process that is analogous to an old known process except for novel and nonobvious materials involved will be called an "analogous process."

n7 *763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).*

n8 *Id. at 1408, 226 U.S.P.Q. (BNA) at 360.*

n9 See supra note 5.

n10 See Burk, supra note 5 at 54 (citing *Ex parte Kifer, 5 U.S.P.Q.2d (BNA) 1904* (Bd. Pat. App. & Intf. (1988)).

n11 See generally Beir & Benson, supra note 5.

n12 See, e.g., Hearings on H.R. 587 Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 104th Cong., 1st Sess. (March 29, 1995) (statement of Steven M. Odre of Amgen, Inc.).

n13 See infra notes 140-200 and accompanying text

n14 Id.

n15 Id.

n16 *In re Ochiai, 71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).*

n17 *Id. at 1569, 37 U.S.P.Q.2d (BNA) at 1130.*

N18 Id.

n19 *In re Brouwer, 77 F.3d 422, 37 U.S.P.Q.2d (BNA) 1663 (Fed. Cir. 1995).*

n20 See infra notes 26-85 and accompanying text.

n21 *902 F.2d 1532, 14 U.S.P.Q.2d (BNA) 1734 (Fed. Cir. 1990).*

n22 See infra notes 86-114 and accompanying text.

n23 See infra notes 115-197 and accompanying text.

n24 See infra notes 198-240 and accompanying text.

n25 See infra notes 241-286 and accompanying text.

n26 *In re Larson, 292 F.2d 531, 532, 130 U.S.P.Q. (BNA) 209, 210 (C.C.P.A. 1961).* Although the starting materials were known in the prior art, without the knowledge of the resulting compound, the selection of the starting materials would have been nonobvious.

n27 Id. The organic compounds, esters of substituted benzoic acids, were novel and nonobvious, and the relevant compound claims were allowed. The preparation of the compounds by "reacting an alkali metal salt of such an acid and an appropriate halohydrin or epoxide" was the subject of the process claims. Id. Compounds with chemical structures similar to the appellant's compounds and produced by the same mechanism employed by the appellant were disclosed in prior art. Id.

n28 Id.

n29 *Id. at 533, 130 U.S.P.Q. (BNA) at 210-11.*

n30 Id.

n31 *Id. at 534-36, 130 U.S.P.Q. (BNA) at 211-13* (Rich, J., concurring).

n32 *Id. at 536, 130 U.S.P.Q. (BNA) at 213* (Smith, J., dissenting).

n33 Id.

n34 *In re Neugebauer, 330 F.2d 353, 141 U.S.P.Q. (BNA) 205 (C.C.P.A. 1964).*

n35 *Id. at 357-58, 141 U.S.P.Q. (BNA) at 209.* The court stated that the "fact that the final product is novel is not controlling of obviousness of the method." *Id. at 358, 141 U.S.P.Q. (BNA) at 209.*

n36 *763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).*

n37 *332 F.2d 379, 141 U.S.P.Q. (BNA) 730 (C.C.P.A. 1964).*

n38 *763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).*

n39 *In re Albertson, 332 F.2d at 379-80, 141 U.S.P.Q. (BNA) at 730-31.*

n40 Id.

n41 Id.

n42 Id.

n43 *Id. at 381, 141 U.S.P.Q. (BNA) at 732.*

n44 Id.

n45 *Id. at 382, 141 U.S.P.Q. (BNA) at 732.*

n46 Id. (Smith, J., dissenting). Section 100(b) of the Patent Act defines process as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *35 U.S.C. 100*(b) (1996) (emphasis added).

n47 *399 F.2d 249, 158 U.S.P.Q. (BNA) 331 (C.C.P.A. 1968).*

n48 *In re Larsen, 292 F.2d 531, 130 U.S.P.Q. (BNA) 209 (C.C.P.A. 1961).*

n49 *In re Neugebauer, 330 F.2d 353, 141 U.S.P.Q. (BNA) 205 (C.C.P.A. 1964).*

n50 *In re Albertson, 332 F.2d 379, 141 U.S.P.Q. (BNA) 730 (C.C.P.A. 1964).*

n51 *Kanter, 399 F.2d at 250, 158 U.S.P.Q. (BNA) at 332.*

n52 Id.

n53 Id.

n54 *Id. at 251, 158 U.S.P.Q. (BNA) at 333.*

n55 *In re Neugebauer, 330 F.2d 353, 141 U.S.P.Q. (BNA) 205 (C.C.P.A. 1964).*

n56 *Kanter, 399 F.2d at 251, 158 U.S.P.Q. (BNA) at 333.*

n57 *Id. at 250-51, 158 U.S.P.Q. (BNA) at 332-33.*

n58 *Id. at 251, 158 U.S.P.Q. (BNA) at 333.*

n59 *Id. at 251-53, 158 U.S.P.Q. (BNA) at 333-34* (Smith, J., dissenting).

n60 *Id. at 252, 158 U.S.P.Q. (BNA) at 333.*

n61 Id.

n62 *475 F.2d 658, 177 U.S.P.Q. (BNA) 250 (C.C.P.A. 1973).*

n63 *499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974).*

n64 *Kuehl, 475 F.2d at 659, 177 U.S.P.Q. (BNA) at 251.*

n65 *Id. at 660, 177 U.S.P.Q. (BNA) at 251-53.*

n66 Id.

n67 Id.

n68 *Id. at 661-67, 177 U.S.P.Q. (BNA) at 253-56.*

n69 *Id. at 662, 177 U.S.P.Q. (BNA) at 253.*

n70 *383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 466-67 (1966).*

n71 *Kuehl, 475 F.2d at 662, 177 U.S.P.Q. (BNA) at 253.*

n72 Id.

n73 *Id. at 663, 177 U.S.P.Q. (BNA) at 253.*

n74 Id.

n75 *Id. at 665, 177 U.S.P.Q. (BNA) at 255.*

n76 Id.

n77 *Id. at 665-66, 177 U.S.P.Q. (BNA) at 255-56.*

n78 *Id. at 667, 177 U.S.P.Q. (BNA) at 256.*

n79 Id.

n80 *499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974).*

n81 *Id. at 1290-91, 182 U.S.P.Q. (BNA) at 304.*

n82 *Id. at 1291, 182 U.S.P.Q. (BNA) at 304.*

n83 Id.

n84 *Id. at 1292-94, 182 U.S.P.Q. (BNA) at 305-06.* The court stated that "under 103 neither a novel product made by, nor a novel starting material used in, the process can be treated as prior art." *Id. at 1293, 182 U.S.P.Q. (BNA) at 306.*

n85 *Mancy, 499 F.2d at 1293, 182 U.S.P.Q. (BNA) at 306.* We think that there is a significant difference between a method of making a novel product and a method of using a novel product. . . . In the method-of-use cases, such as Kuehl, the novelty of the starting material may lend nonobviousness to the process. In the cases where the invention is a process for making a new product, however novel the product may be, the claimed process steps and starting materials may themselves still be old and the process therefore obvious. Id.

n86 *In re Durden, 763 F.2d 1406, 1410, 226 U.S.P.Q. (BNA) 359, 360 (Fed. Cir. 1985).*

n87 *Id. at 1407, 226 U.S.P.Q. (BNA) at 359.*

n88 *Id. at 1408, 226 U.S.P.Q. (BNA) at 359.*

n89 Id.

n90 *Id. at 1407, 226 U.S.P.Q. (BNA) at 359.*

n91 *Id. at 1409, 226 U.S.P.Q. (BNA) at 360.*

n92 *Id. at 1409-10, 226 U.S.P.Q. (BNA) at 361.*

n93 *Id. at 1410, 226 U.S.P.Q. (BNA) at 361.*

n94 Id.

n95 *Id. at 1411, 226 U.S.P.Q. (BNA) at 361.*

n96 Id.

n97 *Id. at 1411, 226 U.S.P.Q. (BNA) at 362.*

n98 See generally supra note 5.

n99 See supra notes 69-75 and accompanying text.

n100 See Bier & Benson, supra note 5 at 176-77.

n101 See David Beir & Robert H. Benson, Biotechnology Patent Process Act, *68 Denv. U. L. Rev. 173, 176-77 (1991).*

n102 A common technique in biotechnology is to culture genetically engineered microorganisms such as bacteria, which contain and express genes of interest, to produce a large amount of proteins. Often these proteins are known and not patentable but the engineered host cells are. For a brief introduction to molecular biology and biotechnology, see D. Benjamin Borson, The Human Genome Projects: Patenting Human Genes and Biotechnology. Is The Human Genome Patentable? 35 IDEA 461, 461-67 (1995).

n103 *35 U.S.C. 154* (1996).

n104 *19 U.S.C. 1337* (1996). See Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 342-46 (1995).

n105 See Bier & Benson, supra note 5 at 176-77.

n106 *Amgen v. United States Int'l Trade Comm'n, 902 F.2d 1532, 14 U.S.P.Q.2d (BNA) 1734 (Fed. Cir. 1990).* See also Hearings on H.R. 587 Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 104th Cong., 1st Sess. (March 29, 1995) (statement of Steven M. Odre of Amgen, Inc.).

n107 *Amgen v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 U.S.P.Q.2d (BNA) 1016* (Fed. Cir.), cert. denied, *502 U.S. 856 (1991).* Erythropoietin is hormone capable of stimulating production of blood cells. rEPO was granted by the Federal Drug Administration for seven years of exclusive marketing approval in the United States as an orphan drug for treatment of anemia associated with chronic renal failure.

n108 Hearings on H.R. 587, supra note 106 (statement of Steven M. Odre of Amgen, Inc.).

n109 *Amgen, 902 F.2d at 1533, 14 U.S.P.Q.2d (BNA) at 1734.*

n110 *Id. at 1534, 14 U.S.P.Q.2d (BNA) at 1736.*

n111 Id.

n112 Id.

n113 Id.

n114 See Hearings on H.R. 4307 before the House Subcomm. on Intellectual Property and Judicial Administration of the House Judiciary Comm., 103d Cong., 2d Sess. (May 5, 1994) (statement of Richard G. Waterman of Dow Chemical Co.). See also Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 132-34 (1995).

n115 *910 F.2d. 823, 15 U.S.P.Q.2d (BNA) 1738 (Fed. Cir. 1990).*

n116 *Id. at 824-25, 15 U.S.P.Q.2d (BNA) at 1739.*

n117 Id.

n118 *Id. at 825, 15 U.S.P.Q.2d (BNA) at 1739.*

n119 Id.

n120 Id. The Board also relied on In re Kanter and In re Neugebauer in addition to In re Durden. *Id. at 827, 15 U.S.P.Q.2d (BNA) at 1741.*

n121 *Id. at 825-28, 15 U.S.P.Q.2d (BNA) at 1739-41.*

n122 Id.

n123 *Id. at 827, 15 U.S.P.Q.2d (BNA) at 1741.*

n124 Id.

n125 Id.

n126 See *In re Larsen, 292 F.2d 531, 536-37, 130 U.S.P.Q. (BNA) 209, 212-13* (Smith, J., dissenting). Judge Smith stated "Therefore, I view the product and process claims as but different ways of claiming the disclosed invention." *Id. at 536, 130 U.S.P.Q. (BNA) at 213;* see also *In re Kanter, 399 F.2d 249, 251-53, 158 U.S.P.Q. (BNA) 331, 332-33 (C.C.P.A. 1968)* (Smith, J., dissenting), where Judge Smith opined "both types of claims should be allowed to issue on the basis that they are but alternative, statutorily-recognized expressions for defining the invention." *Id. at 252, 158 U.S.P.Q. (BNA) at 333.*

n127 See supra note 87 and accompanying text.

n128 *Pleuddemann, 910 F.2d at 827, 15 U.S.P.Q.2d (BNA) at 1741.*

n129 See Kevin Kelly, The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?, *24 J. Marshall L. Rev. 263, 295 (1990).*

n130 *Pleuddemann, 910 F.2d at 827, 15 U.S.P.Q.2d (BNA) at 1741-42.*

n131 *919 F.2d 688, 16 U.S.P.Q.2d (BNA) 1897 (Fed. Cir. 1990)* (en banc), cert. denied, *500 U.S. 904 (1991).*

n132 *Id. at 695, 16 U.S.P.Q.2d (BNA) at 1903.*

n133 Id.

n134 Id.

n135 Id.

n136 See *id. at 698* (Archer, J., concurring) & 718 (Newman, J., dissenting); *Ex parte Ochiai, 24 U.S.P.Q.2d (BNA) 1265, 1268* (Bd. Pat. App. & Intf. 1992), rev'd *71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).*

n137 H.R. 3957, 101st Cong., 2d Sess., 136 Cong. Rec. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

n138 S. 2326, 101st Cong., 2d Sess., 136 Cong. Rec. S3107 (daily ed. Mar. 22, 1990) (statement of Sen. DeConcini).

n139 Biotech companies Genetech and Amgen were instrumental in lobbying for the introduction of the H.R. 3957, and the original bill was intended to apply to the biotechnology industry only. However, at the insistence of major pharmaceutical and chemical companies, industry-specific language was later dropped. See Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation To The Procrustean Bed, 17 Rutgers Computer & Tech L.J. 1 (1991).

n140 H.R. 3957, supra note 139.

n141 Id.

n142 Id.

n143 See Rochelle K. Seide & Aimee H. Weiss, The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn, J. Proprietary Rts., Mar. 1992, at 6, 14 nn.51-52. The biotechnology companies, represented by two major trade associations of the biotech industry, the Association of Biotechnology Companies ("ABC") and the Industrial Biotechnology Association ("IBA") were clearly divided over the Bill. In protesting IBA's endorsement of H.R. 3957, Genetics Institute and Cetus resigned from IBA and joined ABC, which vigorously opposed the bill. Id.

n144 See Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation To The Procrustean Bed, 17 Rutgers Computer & Tech L.J. 1, 77-79 (1991).

n145 Id. at 78.

n146 Id.

n147 Id. The Committee believed that the pending case In re Pleuddemann might well clarify the Durden problem. However, the case actually went against the Committee's wish. Id.

n148 Id. at 80-81.

n149 David Beir & Robert H. Benson, Biotechnology Patent Process Act, *68 Denv. U. L. Rev. 173, 189 (1991).*

n150 Id. See also Rochelle K. Seide & Aimee H. Weiss, The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn, J. Proprietary Rts., Mar. 1992, at 6.

n151 H.R. 5664, 101st Cong., 2d Sess., 136 Cong. Rec. E2909 (daily ed. Sept. 19, 1990).

n152 Id.

n153 Id.

n154 Id.

n155 Id.

n156 Id.

n157 H.R. 1417, 102d Cong., 1st Sess. (1991), 137 Cong. Rec. E946 (daily ed. Mar. 14, 1991) (statement of Rep. Boucher) and S. 654, 102d Cong., 1st Sess. (1991), 137 Cong. Rec. S3284 (daily ed. Mar. 13, 1991) (statement of Sen. DeConcini). See also Rochelle K. Seide & Aimee H. Weiss, The Biotechnology Patent Protection Act of 1991: The Battle Lines Have Been Drawn, J. Proprietary Rts., Mar. 1992, at 6, 9.

n158 Amgen argued to further expand the bill to amend *19 U.S.C. 1337* to protect products made using patented biological materials, as in Boucher I. See Seide & Weiss supra note 157 at 10.

n159 See Seide & Weiss supra note 157 at 10.

n160 Id.

n161 Id.

n162 S. Rep. No. 260, 102d Cong., 2d Sess. (1992).

n163 These opponents included the Patent, Trademark and Copyright sections of the American Bar Association, Intellectual Property Owners, Inc., and the American Intellectual Property Law Association.

n164 Seide & Weiss, supra note 157 at 11.

n165 S. 654, 102d Cong., 2d Sess., 138 Cong. Rec. S14313-01 (daily ed. Sept. 21, 1992).

n166 Id.

n167 Id. The biotechnological process was defined to be "any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products." Id.

n168 Id.

n169 139 Cong. Rec. E256-03 (daily ed. Feb. 3, 1993) (statement of Rep. Boucher).

n170 139 Cong. Rec. S1148-02 (daily ed. Feb. 3, 1993) (statement of Sen. DeConcini).

n171 H.R. 760, 103d Cong., 1st Sess. (1993); S. 298, 103d Cong., 1st Sess. (1993); S. Rep. No. 82, 103d Cong., 1st Sess. (1993); see also Jeremy Cubert, U.S. Patent Policy and Biotechnology: Growing Pains on the Cutting Edge, 77 J. Pat. & Trademark Off. Soc'y 151 (1995).

n172 H.R. Rep. No. 728, 103d Cong., 2d Sess. (1994).

n173 Id.

n174 Id.

n175 Id.

n176 Id.

n177 See Hearings on H.R. 4307 before the House Subcomm. on Intellectual Property and Judicial Administration of the House Judiciary Comm., 103d Cong., 2d Sess. (May 5, 1994) (statement of Richard G. Waterman of Dow Chemical Co.).

n178 Id.

n179 Id.

n180 Id.

n181 Id.

n182 Id.

n183 Id. (statement of Roger S. Smith).

n184 Id.

n185 140 Cong. Rec. H9281-02 (daily ed. Sept. 20, 1994). A second title on copyright reform was inserted into H.R. 4307 before voting and was also passed. Id.

n186 140 Cong. Rec. S14433-01 & S14569-01, (daily ed. Oct. 6, 1994). See also The Biotechnology Patent Protection Act of 1995, 141 Cong. Rec. S11201-02 (daily ed. Aug. 2, 1995) (statement of Senator Hatch).

n187 141 Cong. Rec. E129-02 (daily ed. Jan. 19, 1995) (Congressman Moorhead stated that the purpose of the Bill was to help biotech companies in obtaining process patents and stimulate the growth of the biotech industry).

n188 141 Cong. Rec. S11201-03 (daily ed. Aug. 2, 1995) (statement of Senator Hatch).

n189 S. 1111, Biotechnological Processes Patents, 104th Cong., 1st Sess., 141 Cong. Rec. S14569-03 (daily ed. Sept. 28, 1995); H.R. 587, Biotechnical Process Patents, 104th Cong., 1st Sess., 141 Cong. Rec. H10095-02 (daily ed. Oct. 17, 1995).

n190 At the hearing, Mr. H. Dieter Hoinkes of the PTO applauded H.R. 587 for simplifying the biotechnological process patent application, providing certainty for the patent applicants, and making U.S. patent practice consistent with those of Europe and Japan in the biotechnology field. However, as Mr. Hoinkes stated, while accepting an industry specific amendment to *35 U.S.C. 103*, the PTO would prefer a generic bill applicable to other fields in addition to biotechnology. The PTO believed that legal

uncertainties in other fields would continue to exist regarding the patentability of processes making or using patentable materials. Hearings on H.R. 587 Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 104th Cong., 1st Sess. (March 29, 1995) (statement of H. Dieter Hoinkes). Biotech company Amgen also rendered its strong support to H.R. 587 and urged the Subcommittee to supplement the bill with provisions that would make persons who use, sell, or import products made outside the U.S. using biological materials patented in the U.S. liable as infringers. Id. (statement of Steven M. Odre).

n191 S. 1111, Biotechnological Processes Patents, 104th Cong., 1st Sess., 141 Cong. Rec. S14569-03 (daily ed. Sept. 28, 1995); H.R. 587, Biotechnical Process Patents, 104th Cong., 1st Sess., 141 Cong. Rec. H10095-02 (daily ed. Oct. 17, 1995); S. 1111, Biotechnology Process Patents, 104th Cong., 1st Sess., 141 Cong. Rec. S15220-02 (daily ed. Oct. 17, 1995).

n192 141 Cong. Rec. H10095-02 (daily ed. Oct. 17, 1995).

n193 Biotechnological Process Patents, Pub. L. No. 104-41, 1996 U.S.C.C.A.N. 404-1 (1995) (statement of the President of the United States).

n194 Pub. L. No. 104-41, 109 Stat. 361, 1 (1995).

n195 Id. [T]he term "biotechnological process" means (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to (i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subpara- graph (A) or (B), or a combination of subparagraphs (A) and (B). Id.

n196 Id. 2.

n197 Id. 3.

n198 *71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).*

n199 *73 F.3d 380, 37 U.S.P.Q.2d (BNA) 1663 (Fed. Cir. 1996).*

n200 *Ex parte Ochiai, 24 U.S.P.Q.2d (BNA) 1265, 1266* (Bd. Pat. App. & Int. 1992).

n201 Id.

n202 Id.

n203 *Ochiai, 71 F.3d at 1568, 37 U.S.P.Q.2d (BNA) at 1129* (quoting examiner's answer to Ochiai's appeal to Board).

n204 *Ochiai, 24 U.S.P.Q.2d (BNA) at 1267.*

n205 *Id. at 1267-70.*

n206 *919 F.2d 688, 16 U.S.P.Q.2d (BNA) 1897 (Fed. Cir. 1990).*

n207 *Ochiai, 24 U.S.P.Q.2d (BNA) at 1268.*

n208 *Id. at 1268-70.*

n209 *Id. at 1267.*

n210 *Id. at 1268.*

n211 *383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467 (1966).* In applying this factor, the Court stated that "[u]nder Section 103 . . . differences between the prior art and the claims at issue are to be ascertained . . . ." Id.

n212 *Ochiai, 71 F.3d at 1569, 37 U.S.P.Q.2d (BNA) at 1131.*

n213 Id.

n214 Id.

n215 *Id. at 1569-70, 37 U.S.P.Q.2d (BNA) at 1131-32.*

n216 Id.

n217 *Id. at 1570, 37 U.S.P.Q.2d (BNA) at 1132.*

n218 Id.

n219 Id.

n220 Id.

n221 Id.

n222 *Id. at 1571, 37 U.S.P.Q.2d (BNA) at 1132.*

n223 Id.

n224 Id.

n225 Id.

n226 *Id. at 1572, 37 U.S.P.Q.2d (BNA) at 1133.* The court specifically stated that "[a]ny conflicts as may be perceived to exist derive from an impermissible effort to extract per se rules from decisions that disavow precisely such extraction." Id.

n227 Id. In attempting to clarify this point, the court stated "reliance on per se rules of obviousness is legally incorrect and must cease. . . . We once again hold today that our precedents do not establish any per se rules of obviousness, just as those precedents themselves expressly declined to create such rules." Id.

n228 *77 F.3d 422, 37 U.S.P.Q.2d (BNA) 1663 (Fed. Cir. 1995).*

n229 Initially the Brouwer opinion was not published and the Federal Circuit indicated in December 1995 that it was a nonprecedential opinion and could not be cited. *In re Brouwer, 73 F.3d 380 (Fed. Cir. 1995).* However, the Federal Circuit later changed its position and the opinion was published in *February. Brouwer, 77 F.3d at 422, 37 U.S.P.Q.2d (BNA) at 1663.*

n230 *Brouwer, 77 F.3d at 423-24, 37 U.S.P.Q.2d (BNA) at 1664-65.*

n231 *Id. at 424, 37 U.S.P.Q.2d (BNA) at 1665.*

n232 Id.

n233 *In re Larsen, 292 F.2d 531, 130 U.S.P.Q. (BNA) 209 (C.C.P.A. 1961).*

n234 *Brouwer, 77 F.3d at 424, 37 U.S.P.Q.2d (BNA) at 1665.*

n235 Id.

n236 Id.

n237 *Id. at 425, 37 U.S.P.Q.2d (BNA) at 1666.*

n238 Id. (citation omitted).

n239 *292 F.2d at 536, 130 U.S.P.Q. (BNA) at 214* (Smith, J., dissenting). See also supra notes 32-33 and accompanying text.

n240 *Brouwer, 77 F.3d at 426, 37 U.S.P.Q.2d (BNA) at 1666.*

n241 U.S. Const. art. I, 8, cl. 8.

n242 *Graham v. John Deere, 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 466-67 (1966).*

n243 Id.

n244 See id.

n245 Id.

n246 Id.

n247 Id.

n248 Id.

n249 Id.

n250 Id.

n251 See *35 U.S.C. 154*(a)(1) (1996).

n252 See generally Scott A. Chambers, Exhaustion Doctrine in Biotechnology, 35 IDEA 289, 290- 312 (1995).

n253 Id. at 312.

n254 Id. at 307.

n255 Id.

n256 *35 U.S.C. 154*(a)(1) (1996).

n257 Supra notes 252-55 and accompanying text.

n258 See Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 141 (1995).

n259 Id. at 140-41.

n260 Supra note 78 and accompanying text (discussing that the court argued that method of use patent coupled with product patent would encourage inventor to disclose in detail use of the patented product).

n261 *In re Ochiai, 71 F.3d 1565, 1572, 37 U.S.P.Q.2d (BNA) 1127, 1133 (Fed. Cir. 1995).*

n262 *35 U.S.C. 154*(a)(1) (1996).

n263 Supra notes 257-59 and accompanying text.

n264 Since not all analogous processes that use or make patentable products are nonobvious, a case-by-case analysis would be the best approach. See Hearings on H.R. 4307 before the House Subcomm. on Intellectual Property and Judicial Administration of the House Judiciary Comm., 103d Cong., 2d Sess. (May 5, 1994) (statement of Richard G. Waterman). Further, the ultimate solution against foreign competition such as Amgen faced in Amgen v. Int'l Trade Comm'n would be to obtain a product patent in the importer's country. This would further preclude infringement of the product patent even in the foreign country. As the trend of world cooperation in intellectual property right protection continues, foreign patent solicitation should become easier. Another approach Congress could have taken in amending the Patent Act to accommodate the biotech industry would have been to grant the owner of a product patent the right to exclude others from importing into the United States products made using that patented product. See Nelson Johnson, The Foreign Use of U.S. Patents: Damming the Flow of Downstream Products, *30 Colum. J. Transnat'l L. 164-78 (1992).* This is also the approach Amgen urged Congress to adopt. See, e.g., Hearings on H.R. 587 Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 104th Cong., 1st Sess. (March 29, 1995) (statement of Steven M. Odre of Amgen, Inc.). This strategy would eliminate the need for granting a patent on an "obvious" process.

n265 See 141 Cong. rec. E129-02 (daily ed. Jan. 19, 1995) (Congressman Moorhead's statement of the purpose of introducing H.R. 587); see also Dan L. Burk, Biotechnology and Patent Law: Fitting Innovation To The Procrustean Bed, 17 Rutgers Computer & Tech L.J. 1, 70 (1991).

n266 See Burk, supra note 265 at 18, 22.

n267 Id.

n268 See supra notes 137-193 and accompanying text.

n269 Public L. No. 104-41, 109 Stat. 361 (1995).

n270 Id. at 1.

n271 Id.

n272 H.R. Rep. No. 178, 104th Cong., 1st Sess. at 5 (1995).

n273 See supra notes 137-192 and accompanying text.

n274 See Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 342-46 (1995).

n275 Pub. L. No. 104-41, 109 Stat. 361, 1 (1995).

n276 See H.R. Rep. No. 178, 104th Cong., 1st Sess. at 5 (1995).

n277 Obviousness-type double patenting "is a judge-made criterion adopted out of necessity where the courts were faced with a situation in which claims in two applications or patents were not drawn precisely to the same invention, but were drawn to inventions so very much alike as to render one obvious in view of the other and to effectively extend

the life of the patent that would have the earlier of the two issue dates." *Gerber Garment Technology, Inc. v. Lectra Sys., Inc., 916 F.2d 683, 686, 16 U.S.P.Q.2d (BNA) 1436, 1439 (Fed. Cir. 1990).* A second patent that is obvious over the first one may be granted if a proper terminal disclaimer is filed to cause the two patents to expire at the same time. See, e.g., *In re Goodman, 11 F.3d 1046, 1052, 29 U.S.P.Q.2d (BNA) 2010, 2015-16 (Fed. Cir. 1993).*

n278 "A continuation is a second application for the same invention claimed in a prior nonprovisional application and filed before the original becomes abandoned or patented." Manual of Patent Examining Procedure, 201.07 (6th ed. 1995) [hereinafter MPEP]. "A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application by the same applicant, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application." MPEP 201.08 (6th ed. 1995). An inventor may obtain an early filing date by filing a provisional application under *35 U.S.C. 111*(b). A provisional application must contain a specification and a drawing if necessary, but need not include a claim. See *35 U.S.C. 111* (1996); see also MPEP 201.04(b) (6th ed. 1995).

n279 Under *35 U.S.C. 253*, "any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted." *35 U.S.C. 253* (1996).

n280 However, if the application containing method claims is filed after the product patent issues and the method claims are obvious over the product claims, a terminal disclaimer should not be available, and the method claims should not be patentable.

n281 Pub. L. No. 104-41, 109 Stat. 361, 1 (1995). The PTO has taken the position that *35 U.S.C. 103*(b) elections will be treated on a case-by-case basis by way of petition under 37 C.F.R. 1.182: "The petition must establish that all the requirements set forth in section 103(b) have been satisfied." An election must be "made no later than the earlier of either (1) the payment of the issue fee, or (2) the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under *35 U.S.C. section 102* or 103." Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and *35 U.S.C. section 103*(b), *1184 O.G. 86* (Comm'r Pat. & Trk. March 26, 1996).

n282 See H.R. Rep. No. 178, 104th Cong., 1st Sess. at 5 (1995).

n283 Id.

n284 Id.

n285 Id. at 4.

n286 See supra notes 245-50 and accompanying text.

n287 H.R. Rep. No. 178, at 4, 104th Cong., 1st Sess. (1995).

n288 See *In re Ochiai, 71 F.3d 1565, 1570, 37 U.S.P.Q.2d (BNA) 1127, 1132 (Fed. Cir. 1995).* In an effort to clearly convey this teaching, the court emphasized that "there are not 'Durden obviousness rejections' or 'Albertson obviousness rejections,' but rather only section 103 obviousness rejections." Id.

n289 Id.

n290 Id.

n291 "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *35 U.S.C. 100* (1996). The Supreme Court has taught that a "process is a mode of treatment of certain materials to produce a given result. It is an act or a series of acts, performed upon the subject matter to be transformed or reduced to a different state or thing." *Cochrane v. Deener, 94 U.S. 780, 788 (1876).*

n292 See *In re Pleuddemann, 910 F.2d 823, 15 U.S.P.Q.2d (BNA) 1738 (Fed. Cir. 1990).*

n293 Part of the basis of the court's holding in Durden was the appellant's admission that the process claim in question was directed to a method of making. *In re Durden, 763 F.2d 1406, 1408, 226 U.S.P.Q. (BNA) 359, 359 (Fed. Cir. 1985).*

n294 *In re Ochiai, 71 F.3d 1565, 1570-72, 37 U.S.P.Q.2d (BNA) 1127, 1131-33 (Fed. Cir. 1995).* The general principle is, according to the court, "that section 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another per se rule." *Id. at 1571, 37 U.S.P.Q.2d (BNA) at 1132.*

n295 Id.

n296 Unlike the Ochiai court, both the Durden and Albertson courts included the novel and nonobvious starting and resulting compounds in the prior art.

n297 *Ochiai, 71 F.3d at 1571, 37 U.S.P.Q.2d (BNA) at 1132-33.*

n298 Hearings on H.R. 587 Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 104th Cong., 1st Sess. (March 29, 1995) (statement of H. Dieter Hoinkes).

n299 See *35 U.S.C. 103* (1996).

n300 See, e.g., *In re Larsen, 292 F.2d 531, 130 U.S.P.Q. (BNA) 209 (C.C.P.A. 1961); In re Albertson, 332 F.2d 379, 141 U.S.P.Q. (BNA) 730 (C.C.P.A. 1964); In re Neugebauer, 330 F.2d 353, 141 U.S.P.Q. (BNA) 205 (C.C.P.A. 1964); In re Kanter, 399 F.2d 249, 158 U.S.P.Q. (BNA) 331 (C.C.P.A. 1968);* and *In re Durden, 763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).*

n301 See Id.

n302 See e.g. *In re Kuehl, 475 F.2d 658, 177 U.S.P.Q. (BNA) 250 (C.C.P.A. 1973); In re Mancy, 499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974);* and *In re Pleuddemann, 910 F.2d 823, 12 U.S.P.Q.2d (BNA) 1738 (Fed. Cir. 1990).*

n303 *In re Ochiai, 71 F.3d 1565, 1569, 37 U.S.P.Q.2d (BNA) 1127, 1131 (Fed. Cir. 1995).*

n304 *Id. at 1570, 37 U.S.P.Q.2d (BNA) at 1131* (citing *In re Mancy, 499 F.2d at 1293, 182 U.S.P.Q. (BNA) at 303).*

n305 *In re Brouwer, 77 F.3d at 425, 37 U.S.P.Q.2d (BNA) at 1665.* It appears that the court also implicitly based its conclusion on the fact that the selection of the starting materials was also nonobvious.

n306 This is demonstrated by the Board in deciding Ochiai. The Board was unable to reconcile the conflicting holdings of the Federal Circuit and the Court of Claims and Patent Appeals, and instead relied on Durden to make its decision.

n307 *In re Ochiai, 71 F.3d 1565, 1569, 37 U.S.P.Q.2d (BNA) 1127, 1131 (Fed. Cir. 1995).*

n308 *475 F.2d 658, 177 U.S.P.Q. (BNA) 250 (C.C.P.A. 1973).*

n309 Id.

n310 *514 F.2d 1057, 185 U.S.P.Q. (BNA) 580 (C.C.P.A. 1975).* In In re Way, the patent application claimed a metal piercing method, wherein a novel and nonobvious alloy was incorporated in the piercer point of the piercing apparatus which was used to manufacture seamless metal tubing by rolling a round bar or billet of steel over the piercing point. *Id. at 1058-59, 185 U.S.P.Q. (BNA) at 581.* The rejection based on obviousness was reversed by the court. *Id. at 1062-63, 185 U.S.P.Q. (BNA) at 584-85.* According to the court, had the patentable alloy been a part of the tubing to be processed, the process application might have been properly rejected. *Id. at 1062, 185 U.S.P.Q. (BNA) at 584.*

n311 Id.

n312 *35 U.S.C. 101* (1996). See also *In re Kanter, 399 F.2d 249, 251-53, 158 U.S.P.Q. (BNA) 331, 332-33 (C.C.P.A. 1968)* (Smith, J., dissenting).

n313 See Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 138-39 (1995). Burchfiel argues that both making and using new and nonobvious materials should be treated the same and that both could be characterized as statutorily-recognized expressions, alternative to the materials themselves, for defining an invention.

n314 *In re Pleuddemann, 910 F.2d. 823, 825-28, 15 U.S.P.Q.2d (BNA) 1738, 1739-41 (Fed. Cir. 1990).*

n315 *5 U.S.P.Q.2d (BNA) 1094* (Bd. Pat. App. & Intf. 1987). In Kifer, the process claim at issue was a two-step molding process for making a novel roof flashing of the type used on stack pipe passing though the roof of a house. The flashing was composed of two parts with novel shapes, and the molding process steps were adapted to the novel shapes. *Id. at 1095.* The examiner's rejection of the process claim based on obviousness was affirmed by the Board and was not appealed to the Federal Circuit. *Id. at 1097.*

n316 *Cochrane v. Deener, 94 U.S. 780, 788 (1876).*

n317 However, in light of the above discussion, the opposite may be true if the new character of the oxen led to the subsequent series steps that are different from the conventional steps.

n318 Kenneth J. Burchfiel, Biotechnology and the Federal Circuit, 142 (1995).

n319 Id. at 141.

n320 Id.