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BIOTECHNOLOGY PATENT PROTECTION ACT

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I. SUMMARY

Current United States patent and trade laws are inadequate to protect the creative and scientific genius of American inventors who use recombinant techniques to produce proteins that are useful as human therapeutics.¹ The potential for unfair foreign competition, the need for enhanced incentives to develop new biotechnology-derived pharmaceutical products, and basic notions of fairness and economic certainty dictate that Congress should enact amendments to our patent law.

II. INTRODUCTION

The promise of modern biotechnology can only be assured by strong intellectual property protection. Patent protection for breakthrough inventions secures for inventors, and the financial sponsors of the research, sufficient rewards to stimulate further innovation. During the past Congress,² and again this Congress,³ legislation was introduced to improve the degree of patent protection offered to biotechnology-derived products and processes. This article outlines the case for such legislation, describes the legislative process to date, and offers suggestions for further action.

III. GENERAL BACKGROUND ON THE PROBLEM

Biotechnology is a singular contribution to the modern age. This technology, in its recent incarnation, represents an opportunity to create dramatic breakthroughs in pharmaceuticals, medical devices, veterinary products and agricultural products. The promise offered by biotechnol-

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1. Similar problems and possibilities exist for recombinant polypeptides which are useful as animal drugs, in manufacturing and for other commercial purposes.

2. H.R. 3957, 101st Cong., 2d Sess. (1990), *see also* 136 CONG. REC. E213-14 (daily ed. Feb. 7, 1990)(statement of Rep. Boucher); S. 2326, 101st Cong., 2d Sess., 136 CONG. REC. S3107-08 (daily ed. Mar. 22, 1990)(statement of Sen. DeConcini); and H.R. 5664, 101st Cong., 2d Sess. (1990)(introduced by Rep. Boucher Sept. 18, 1990). For a more complete discussion of this proposed legislation, *see infra* sections V.B. and V.C.

3. H.R. 5664 has been reintroduced as the Biotechnology Patent Protection Act of 1991, H.R. 1417, 102d Cong., 1st Sess. (1991), S. 654, 102d Cong., 1st Sess., 137 CONG. REC. S3286 (daily ed. Mar. 13, 1991). *See also* 137 CONG. REC. E946 (daily ed. Mar. 14, 1991)(statement of Rep. Boucher); 137 CONG. REC. S3284-86 (daily ed. Mar. 13, 1991)(statement of Sen. DeConcini).

ogy is virtually limitless. It has already produced significant improvements in human health care,⁴ and will result in similar changes in agriculture. These developments are threatened, however, by the existence of a set of patent law rules that thwart innovators' receipt of a full and fair reward for their scientific contribution.

In an era of demonstrably increased competition, the United States should act affirmatively to protect those industries that are on the technological frontier and that offer the greatest hope for competitive advantage. Biotechnology is just such an industry. Since the discovery of DNA technology, the majority of breakthrough research has occurred in the United States.⁵ Moreover, American biotechnology companies appear to be ahead of their foreign competition in most respects—for the moment.

Unfortunately, this American leadership may not persist over time for two basic reasons. First, United States patent law appears to have fallen behind industrial needs. Second, American companies may face unfair foreign competition from imported products based on American inventions.

One long term consequence of inadequate patent protection for biotechnology-derived products is the likelihood that some promising therapies will not be pursued. A second consequence of patent uncertainty is the proliferation of patent litigation in this area.⁶ The high costs of such litigation may seriously drain the research budgets of biotech companies.⁷ Moreover, the absence of legal certainty for biotechnology has a dampening effect on venture capital investments.

IV. SPECIFIC DEFICIENCIES OF UNITED STATES PATENT AND TRADE LAW

A. *Product Patents and Naturally Occurring Proteins*

Product patents are patents which cover a composition of matter. As explained in *United States v. Studiengesellschaft Kohle*:⁸

The essential difference between [process and product patents] relates to scope. A product patent gives the patentee the right to restrict the use and sale of the product regardless of how and

4. Examples of biotechnology-derived human health care products include insulin, human growth hormone, erythropoietin (a protein which stimulates the production of red blood cells) and tPA (a protein used to dissolve clots). See NAT'L ACADEMY OF ENG'G, ENGINEERING AND THE ADVANCEMENT OF HUMAN WELFARE: 10 OUTSTANDING ACHIEVEMENTS 1964-1989, at 42-45 (Dec. 5, 1989), reprinted in *The Process Patent Amendments of 1990: Hearings on H.R. 3957 and H.R. 5664 Before the Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House Comm. on the Judiciary*, 101st Cong., 2d Sess. 33, at 260 (Sept. 25, 1990) [hereinafter *Hearings*].

5. The United States leads in research, but Japan has a strong commercial base in biotechnology. OFFICE OF INDUS., U.S. INT'L TRADE COMM'N, AN OVERVIEW OF COMMERCIAL BIOTECHNOLOGY IN THE UNITED STATES at v (1990).

6. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, 5 NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE—SPECIAL REPORT 56-58 (1989).

7. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 403 (1984).

8. 670 F.2d 1122 (D.C. Cir. 1981).

by whom it was manufactured. A process patentee's power extends only to those products made by the patented process. A process patent thus "leaves the field open to ingenious men to invent and to employ other processes."

A sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process that infringes the patent.⁹

In the field of pharmaceuticals, the patented product is usually described in terms of the structure of an active ingredient of the drug substance. Product patents are generally considered to provide better protection for drugs than process or use patents because the latter two types usually can be circumvented more easily or with less visibility. Inventors of some recombinant versions of naturally occurring products have found it difficult to obtain adequate patent protection because of the mere existence of literature disclosing incomplete information about the natural protein.¹⁰

When the scientific literature or other available information reveals that the naturally occurring version of the protein has been purified to some extent, even if it has not been definitively characterized, a patent for the recombinant version may be denied for lack of novelty; in patent law terms, the product has already been discovered.¹¹ This may occur even when the amount of the natural product that has been isolated is insufficient for any practical use and the method employed cannot provide practical quantities of the material.

A second hurdle inventors must overcome is that a patent may be denied because the recombinant product is deemed unpatentably obvious despite its novelty. In many cases, although the protein has never before been isolated in a substantially pure form or the product was not well characterized prior to the recombinant synthesis, if its basic properties and some aspects of its structure are known, the Patent and Trademark Office (Patent Office) may assert that the use of recombinant technology to make a pure form of such a product is obvious. Most lay persons would be astonished to learn that scientific breakthroughs, including those leading to international scientific recognition, have been denied patent protection because they were held to be obvious. Yet that is the current state of affairs.¹²

9. *Id.* at 1127-28 (citations omitted).

10. A natural protein is a protein encoded by DNA that occurs in nature. A recombinant protein is a protein encoded by DNA that has been produced by combining genetic material from at least two different sources.

11. See generally Murashige, *Section 102/103 Issues in Biotechnology Patent Prosecution*, 16 A.I.P.L.A. Q.J. 294, 303-04 (1988-89); Andrews, *Unaddressed Question in the Amgen Case*, N.Y. Times, Mar. 9, 1991, § 1, at 30, col. 5.

12. A researcher's ability to obtain a patent for a purified version of a protein to block the use of a process to make commercially viable quantities of a recombinant version of the protein has been criticized. See Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 903-04 (1990). See also *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987), modified on reconsideration, 678 F. Supp. 1429 (N.D. Cal. 1988); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 707 F. Supp. 1547 (N.D. Cal. 1989); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 724 F.

The existing law, as it is being applied, has the effect of offering an incentive to firms who lag behind in research and technology development to attempt to leapfrog the innovators by patenting, or otherwise disclosing, an allegedly purified protein, thereby blocking the scientific leaders' ability to obtain a patent. This occurs even though the innovative contribution of the leaders is essential to make the protein available as a practical matter. This technique produces little, if any, public good and thwarts beneficial developments in public health.¹³

The mere existence of a previously discovered protein should not, by itself, preclude the issuance of a patent for a recombinantly created version of the same protein. The rationale under which a patent may be granted for a product existing in nature is that in its natural form, such a product was not available and useful to the public without further isolation and purification. By the same rationale, if a product is made available in virtually unlimited quantities and in a highly purified state by the application of recombinant technology, the recombinant product should be patentable if its natural counterpart was available for the intended use only in impractical quantities or with undesirable impurities or contaminants. Therefore, Congress should enact an amendment to the patent law that creates an appropriate incentive to use recombinant technology to produce proteins.

B. *Process Patents*

1. Misapplication of *In re Durden*

The second major defect in the United States patent law is the erroneous and inconsistent application of *In re Durden*,¹⁴ a nonbiotech patent case, to important biotechnology-derived processes. As recognized by a Patent Office supervisor, the use of this case as a basis for rejecting process patent claims in biotechnology is on the rise.¹⁵ This is so because many examiners have been incorrectly applying *Durden* to biotechnology.¹⁶

Supp. 690 (N.D. Cal. 1989), *aff'd in part, rev'd in part, vacated in part*, Scripps Clinic & Research Found. v. Genentech, Inc., Nos. 89-1541, -1542, -1543, -1646, -1647 (Fed. Cir. Mar. 11, 1991) (LEXIS, Genfed library, U.S. App. file 3925)(reserving for further analysis by the district court the issue whether a patent on a purified protein should serve to block a patent on a recombinant version of the same protein).

13. This is not to suggest that all, or even most, disclosures of isolated or purified proteins are made with this motive; however, the potential for abuse exists.

14. 763 F.2d 1406 (Fed. Cir. 1985).

15. Wiseman, *Biotechnology Patent Practice—A Primer*, 16 A.I.P.L.A. Q.J. 394, 411 (1988-89). See generally Litman, *Obvious Process Rejection Under 35 U.S.C. 103*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 775 (1989); Wegner, *Much Ado About Durden*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 785 (1989).

16. *Durden* involved a challenge to the denial of a patent for a process to make a novel chemical. The process was similar to that of a previously issued patent; however, the *Durden* process utilized a novel, but related, starting material and produced a novel, but related, end product. It appeared predictable once the new starting material and new product were disclosed, that the old process would work with the new starting material to produce the new product. The court in *Durden* concluded, in the narrow, factual context of that case, that a chemical process, otherwise obvious, is not patentable even if either or

The Patent Office has cited *Durden* in denying patents to processes for producing proteins which use as starting materials, DNA, vectors or biological microorganisms made by recombinant DNA technology. This denial of process claim protection is routine even if the starting materials are found by the Patent Office examiner to be novel and nonobvious and, therefore, patentable in their own right.

The rote application of *Durden* in the biotechnology context involving the use of microorganisms as starting materials is in direct conflict with *In re Mancy*.¹⁷ In *Mancy*, the court held that a new microbe could not be treated as prior art in determining the patentability of a method of using the microbe to produce an antibiotic therefrom by an otherwise standard process.¹⁸ In other words, novelty and nonobviousness of the microbe imparted patentability to a method of using it. *Mancy* is a much more appropriate case to the biotechnology industry than *Durden*. The net result of the present Patent Office practice has been to delay severely or to prevent the issuance of process patent protection to deserving inventors.

Moreover, inventors have been forced to suffer inconsistent results regarding process patent protection. The United States Court of Appeals for the Federal Circuit (Federal Circuit) acknowledges that there have been conflicting views on this issue both in the Patent Office Board of Appeals and in the Federal Circuit Court's predecessor, the United States Court of Customs and Patent Appeals (C.C.P.A.).¹⁹ But, *Durden* is indefensible especially when applied to biotechnology.²⁰

Without appropriate process claims in their patents, biotechnology inventors cannot take advantage of the benefits of the Process Patent Amendments Act of 1988,²¹ thereby nullifying this Act's advantages for the biotechnology industry. Resolution of these conflicts should be accomplished by additional legislation that will enable inventors to benefit from the provisions of the 1988 Act.

The law as currently expressed provides that to be considered obvious:

the differences between the subject matter sought to be patented and the prior art [must be] such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.²²

both the specific starting material employed and the product obtained, are novel and unobvious.

17. 499 F.2d 1289 (C.C.P.A. 1974); see also *In re Kuehl*, 475 F.2d 658 (C.C.P.A. 1973); *MacAdams*, 206 U.S.P.Q. (BNA) 445 (PTO Bd. App. 1978); *Glaister*, 201 U.S.P.Q. (BNA) 255 (PTO Bd. App. 1975).

18. *Mancy*, 499 F.2d at 1289.

19. *Durden*, 763 F.2d at 1409.

20. See generally Litman, *supra* note 15; McAndrews, *Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 1188 (1990); Wegner, *supra* note 15; Wiseman, *supra* note 15.

21. Pub. L. No. 100-418, 102 Stat. 1563 (codified as amended in scattered sections of 35 U.S.C.).

22. 35 U.S.C. § 103 (1988)(emphasis added).

The Federal Circuit court and the C.C.P.A. have reiterated many times that an applicant's disclosure in a patent application cannot be treated as prior art in determining the obviousness of the claimed invention.²³ The court has also emphasized that the invention as a whole must be considered in assessing obviousness.²⁴ Finally, the court has cautioned that a patentability determination must be made as of the time the invention was made, and not as part of a hindsight reconstruction of the invention given the applicant's disclosure.²⁵

The denial of process claims in circumstances where either the starting material in a process, the product of the process, or both, are novel and nonobvious (and therefore patentable) is contrary to all of these principles. The essential elements, without which the claimed process could not have been described, were unknown before their disclosure by the applicant. They are not prior art and cannot be treated as such. The essential elements are incontrovertibly a part of the subject matter as a whole; without their presence in the claim, the claim cannot be properly described. Furthermore, at the time the invention was made, the claimed process could not have been obvious; its essential elements being known only to the inventor.

2. The Effect of *In re Pleuddemann* on the Need for Legislation

*In re Pleuddemann*²⁶ is a recent case that may have a significant impact on biotechnology patent litigation. Both *Pleuddemann* and *Durden* deal with process (method) patent claims involving a novel composition. The *Durden* decision illustrated that a claimed process of *making* a novel composition is not automatically patentable but must be analyzed on a case-by-case basis in light of the prior art.²⁷ *Pleuddemann* dealt with the process of *using* a novel compound. The Patent Office examiner had rejected Pleuddemann's claims for using patented organosilanes as bonding or priming agents to bond to a mineral filler or to prime a surface to improve bonding to organic resins. Pleuddemann's compound was incorporated into the products made. The Patent Office examiner and the Patent Office Board of Patent Appeals and Interferences used a *Durden* argument to reject Pleuddemann's process-of-using claims, asserting that such a method was obvious based upon the prior art.²⁸ That is, it was obvious to use the Pleuddemann compound for bonding or priming because other analogous compounds had been similarly used.

The Federal Circuit court reversed the Patent Office's rejection saying that *Durden* did not apply, in part because Pleuddemann's process

23. See *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1567-88 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987); *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982).

24. See *John Deere Co. v. Graham*, 333 F.2d 529 (8th Cir. 1964), *aff'd*, 383 U.S. 1 (1966).

25. *In re Kuehl*, 475 F.2d 658, 663-65 (C.C.P.A. 1973).

26. 910 F.2d 823 (Fed. Cir. 1990).

27. *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985).

28. *Pleuddemann*, 910 F.2d at 825.

was a process-of-using, not a process-of-making.²⁹ The court repeated aspects of the *Durden* decision, emphasizing that obviousness under the patent laws must be decided on the basis of each fact situation and that there is no generally applicable rule.³⁰ "It is the properties of [Pleuddemann's] compounds as bonding/priming agents for certain polymers . . . that give them their utility. As stated above, the compounds and their use are but different aspects of, or ways of looking at, the same invention"³¹

Pleuddemann does not reverse the *Durden* analysis rejecting process-of-making claims; therefore, *Durden* presently stands as good law applicable to any process-of-making claims, despite the presence of a novel starting material or novel product. Indeed, the Federal Circuit court explicitly distinguished the *Durden* process-of-making rejection from the *Pleuddemann* process-of-using rejection.³²

The Patent Office and the courts continue to apply *Durden* and reject claims involving methods of using novel DNA sequences and other recombinant intermediates to make protein products. The classic *Durden* rejection maintains that a process of making a protein using a novel DNA sequence is obvious, because others have previously used the same process with other DNA sequences to make other proteins. It might be asserted that recombinant DNA patent applications no longer need fear such a *Durden* rejection of process-of-making claims which are based upon a novel DNA sequence encoding a desired protein *X*. Unfortunately, the situation is not clear.

A prudent attorney certainly would seek to use *Pleuddemann* to the client's advantage by rephrasing "a recombinant DNA process of making protein *X*" into a *Pleuddemann*-style process-of-using claim, such as, "contacting DNA with cellular enzymes or with a transcription/translation apparatus." This approach was successful in U.S. Patent 5,004,690, issued April 2, 1991. However, it is not clear that such a semantic change would always be successful. For example, the Patent Office examiner could assert that such a claim was really a process-of-making claim in disguise. Such arguments would not apply to the situation in *Pleuddemann*, where the method-of-using was totally unrelated to any method-of-making. Thus, the examiner might claim that *Pleuddemann* does not apply to methods of using DNA sequences and other recombinant intermediates, which would still be governed by the newly reaffirmed *Durden* analysis.

Additionally, if *Pleuddemann*-style using recombinant DNA claims were allowed, the question of enforcement against those practicing the claimed method outside the United States would remain. If the claim only covered using the recombinant DNA in an expression vector (which is not imported) then there would be little enforcement advantage over

29. *Id.* at 826-27.

30. *Id.*

31. *Id.* at 827.

32. *Id.*

the claim to the recombinant DNA itself. The United States International Trade Commission (ITC) and the Federal Circuit court found such claims unenforceable against imports in a recent decision regarding erythropoietin.³³ Claims to *using* the recombinant DNA in a method of protein synthesis could, however, be enforced against those who would practice the synthetic method outside the United States and import the protein product.

Alternatively, some have argued that given the right case on appeal, the Federal Circuit court might, at some future date, reverse *Durden* by applying a *Pleuddemann*-type analysis finding that *making* is also not obvious because the *Durden*-type rejection presumes the new starting material or novel product to be prior art. While this possibility is consistent with the analysis in *Pleuddemann*, there clearly is no certainty that such a future decision will ever occur.

Some had hoped the November 9, 1990 rehearing of *In re Dillon*³⁴ would provide guidance regarding *Durden* and perhaps overrule it. In very clear dicta, the Federal Circuit court summarized its attitude regarding *Durden* as follows:

Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old *type of process*, such as mixing, reacting, reducing, etc. The materials 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*.³⁵

Therefore, *Durden* is very much alive, but weakened and unpredictable in its application by the individual patent examiner.

Durden-type rejections remain an even greater problem following *Pleuddemann* because the Federal Circuit court explicitly avoided questioning *Durden* as good law, and distinguished *making* and *using* as two different types of process claims.³⁶ A patent applicant may ask what new route to protect a recombinant DNA process claim is available after *Pleuddemann*? The answer is not clear because *Pleuddemann* does not ad-

33. Certain Recombinant Erythropoietin, USITC Pub. 2186, Inv. No. 337-TA-281, 10 U.S.P.Q.2d (BNA) 1906 (ITC Apr. 10, 1989), *vacated and remanded sub nom.* Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990).

An Administrative Law Judge (ALJ) at the ITC had determined that Amgen's patent did not "cover" a foreign company's process for producing a certain recombinant product, and thus there was no trade law violation. The ITC adopted the ALJ's analysis of the patent issue, but dismissed Amgen's complaint for lack of subject matter jurisdiction. The Federal Circuit court found that the ITC had subject matter jurisdiction and vacated and remanded.

34. 919 F.2d 688 (Fed. Cir. 1990) (en banc).

35. *Id.* at 695 (emphasis in original).

36. *Pleuddemann*, 910 F.2d at 827.

dress that question. One could rephrase *making* claims as *using* claims and then wait years to see whether the Patent Office and the courts will accept this semantic manipulation as a means of avoiding a *Durden*-style obviousness rejection. Certainly, however, congressional passage of clear statutory language that explicitly removes the *Durden*-style rejection is a more direct and unambiguous route to protect recombinant DNA method-of-making protein claims.

C. *Unfair Imports*

The third and final deficiency in our law is best seen by examining the glaringly unfair practice of permitting a foreign manufacturer to use host cells, DNA isolates or vectors to produce a product and to ship it into the United States without legal recourse for the holder of the patent on the host cell. This practice has been endorsed by the ITC on the basis of a crabbed reading of the trade law's Tariff Act provisions.³⁷

The importance of process claim protection is illustrated by Amgen, Inc.'s inability to prevent importation of erythropoietin (EPO) into the United States from Japan by Chugai Pharmaceutical Company. Amgen's patent did not contain a claim to a process of making EPO using patented host cells. The ITC refused to interpret the claims to the host cells alone as constituting a process claim under existing law. Consequently, Amgen was denied relief based upon its patented host cells since the ITC held that such claims to "host cells" per se were not process of making claims. When amendments to the Tariff Act were adopted in 1988,³⁸ Senator Lautenberg, a sponsor of the bill, observed:

The continued broad jurisdiction of the International Trade Commission will help U.S. industry address the unfair activity of foreign competitors who, for example, import products manufactured using patented genetic engineering technology. Merely moving manufacture offshore does not absolve the wrongdoer from the requirement to compete fairly. This Trade Act protection prohibits the foreign enterprise from taking jobs from American workers by doing offshore that which they could not lawfully do in the United States.³⁹

If at the end of a long and uncertain period of discovery of innovated drug products and development of patented technology, a United States innovator must watch helplessly as infringing foreign imitators reap the harvest to which the innovator is entitled, there will be a substantial diminution or elimination of the economic incentives intended to encourage those efforts.

The most controversial and public patent dispute in biotechnology⁴⁰ involves the innovative product, recombinant erythropoietin

37. 10 U.S.P.Q.2d (BNA) at 1906.

38. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107 (codified in scattered sections of 19 U.S.C.).

39. 134 CONG. REC. 20,086 (1988).

40. See, e.g., Andrews, *Mad Scientists*, BUS. MONTH, May 1, 1990, at 54.

(rEPO), as litigated in *Amgen, Inc. v. Chugai Pharmaceutical Co.*⁴¹ In this case, Amgen conducted ground-breaking scientific research enabling it to produce commercially viable commodities of rEPO.⁴² This major scientific and medical advance did not, however, give Amgen sufficient patent rights to prevent importation of competing products from Japan even though Amgen's competitors could not produce rEPO within the United States without infringing Amgen's patents. The fundamental unfairness of this situation served, in part, to motivate congressional interest in the problem of patent protection for biotechnology.⁴³

Genetics Institute, Amgen's competitor, held the legal rights to a product patent on nonrecombinant EPO.⁴⁴ This patent, standing alone, would not have permitted Genetics Institute to create enough EPO to introduce a new pharmaceutical product to the market. To reach a viable product stage it was necessary to have the ability to determine the DNA sequence of the protein, to locate a host cell to produce the protein, and to develop a method for producing the end product. Amgen made all of these scientific contributions.

When Amgen attempted to enforce what it thought were its superior rights, it was denied relief in two separate forums. Both the ITC and the Federal Circuit court denied Amgen's attempt to bar the importation of rEPO.⁴⁵ The denial was based on the ground that the jurisdictional statute for enforcement actions, section 337 of the Tariff Act of 1930,⁴⁶ required that the petitioner hold a valid United States process patent. The court declined to decide whether, on the basis of a different record, a more expansive reading of the statute was possible which would thereby extend the scope of the host cell patent to products produced by the host cell.⁴⁷

41. 706 F. Supp. 94 (D. Mass. 1989)(Young, J., granting partial summary judgment for Chugai and Genetics Institute).

42. Amgen is currently alone on the market with its version of EPO, EPOGEN, because the provisions of the Federal Food, Drug, and Cosmetic Act, § 527, 21 U.S.C. 360cc (1988). Under this Act, the sponsor of a new drug or biologic can, if certain market criteria are met, obtain market exclusivity for a period of seven years. In this case, Amgen obtained market exclusivity because it established that rEPO was a safe and effective therapy for treatment of chronic renal failure, the relevant patient population of which is less than 200,000.

43. See *supra* notes 2 & 3.

44. After this article was already set for publication, the Federal Circuit court handed down an opinion which, in essence, upheld Amgen's patent claims with respect to its host cell patent and invalidated Genetics Institute's patent with respect to the product, EPO. See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, Nos. 90-1273, -1275 (Fed. Cir. Mar. 5, 1991) (LEXIS, Genfed library, U.S. App. file 3481; WESTLAW, CTAF database 27262), *aff'g in part, rev'g in part, vacating in part* 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989) (The district court had upheld the validity of both parties' patents and had found mutual infringement.).

45. Certain Recombinant Erythropoietin, USITC Pub. 2186, Inv. No. 337-TA-281, 10 U.S.P.Q.2d (BNA) 1906 (ITC Apr. 10, 1989), *vacated and remanded sub nom.* *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990).

46. 19 U.S.C. § 1337 (1988).

47. This argument was explicitly raised for the first time in an amicus brief by Genentech, Inc. The Federal Circuit court, however, declined permission to file this brief, apparently because other parties objected that new untimely raised arguments would prejudice their position.

Genetics Institute has filed a motion for a rehearing en banc of the Federal Circuit's recent ruling that Amgen's product patent on the host cell for making EPO was valid and infringed, while Genetics Institute's product patent on purified EPO was invalid. The result of this case, even if upheld, would not alter the lack of remedies to permit Amgen to enforce its valid host cell patent in a manner to prevent importation of the end product, EPO.

V. PROPOSED SOLUTIONS

A. *General Background*

Legislation should be proposed in Congress to provide that a person who has undertaken the research and supplied the inventive skills to meet the underlying purposes of the patent law can be granted a patent. A person who has the genius to make a significant technical advance deserves to enjoy the maximal benefits of the incentives offered by the patent laws.

The American patent law is largely a product of the fertile mind of Thomas Jefferson who said, "ingenuity should receive a liberal encouragement."⁴⁸ To enable Jefferson's vision, the Founders included specific authority in the Constitution for Congress to enact patent laws "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."⁴⁹

The Constitution vests Congress with the right to create incentives for inventors to undergo the often enormous cost of developing new products.⁵⁰ As the Supreme Court has construed the patent clause, the "public interest" must be preserved by the patent laws Congress enacts.⁵¹ One of the primary public purposes served by the patent laws is, to paraphrase patent owner Abraham Lincoln, to add fuel to the fire of genius in the discovery of new and useful things.⁵² The proposed bill⁵³ meets this challenge by recognizing two important facts. First, unlike some other industries (including some in high-technology areas), the biotechnology industry is very dependent on patent protection. The economics of the pharmaceutical industry demonstrate the essential nature of patent protection to secure adequate rewards for the significant research and development costs involved in creating a new drug. Second, biotechnology poses unique, even ingenious, patent law problems as outlined above.

48. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980) (quoting 5 WRITINGS OF THOMAS JEFFERSON 75-76 (Washington ed. 1871)).

49. U.S. CONST. art. I, § 8, cl. 8.

50. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).

51. *United States v. Masonite Corp.*, 316 U.S. 265, 277-78 (1942).

52. A. LINCOLN, *Discoveries, Inventions and Improvements*, in 5 COMPLETE WORKS OF ABRAHAM LINCOLN 99-113 (J. Nicolay & J. Hay eds. 1984).

53. See *infra* section V.B.

B. *A Proposed Remedial Bill: Section-By-Section Analysis*

In the following discussion, this article outlines a proposed remedial bill to address the patenting problems faced by the biotechnology industry. This proposed remedial bill consists of two sections. The language of proposed Section 2 has been previously introduced in the United States House of Representatives and in the Senate.⁵⁴

1. Proposed Section 1

Proposed Section 1 would add the following new paragraph at the end of 35 U.S.C. § 112:⁵⁵

A recombinant biological process to make a product may be expressed as a claim to such recombinant product when prepared by a specified recombinant biological process, and such claim shall be limited to such recombinant biological process for determination of patentability under section 102 and section 103 and infringement under section 271 of this title.

This additional language provides that the mere existence of a purified naturally occurring protein in the literature or in a previous patent does not per se act to block the issuance of a patent on a product produced by recombinant methods.⁵⁶

Under current law, Patent Office examiners reject, on the grounds of obviousness or anticipation, claims to a recombinantly produced polypeptide if it has been previously disclosed.⁵⁷ Thus, current policy has the direct result of providing an incentive merely to purify naturally occurring proteins; it does not offer an incentive to create a practical method to produce such proteins in useful quantities. In addition, this view tends to favor the creation of new proteins that differ only slightly from the naturally occurring protein solely to secure patent protection.

Some may argue that virtually all of the useful naturally occurring proteins have already been found and characterized. This claim seems astonishing in light of the existence of more than 50,000 such proteins. Very few of these proteins have been produced in quantities that permit evaluation of their utility in human therapies. Under the current law, however, scientists and research-based companies have little incentive to use sophisticated recombinant techniques to produce a protein once it has been purified and the results have been published or patented.

The traditional pharmaceutical industry may be critical of proposed Section 1 and express concern about the apparent deviation it makes

54. See *infra* note 65 and accompanying text.

55. 35 U.S.C. § 112 (1988).

56. This proposed section does not alter the existing patent law doctrine that permits the patenting of *purified* proteins. See, e.g., *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912) (L. Hand, J., upholding a patent for purified adrenalin).

57. Proposed Section 1 establishes a more liberal standard of patentability for product-by-process claims in the area of recombinant technology. See, e.g., *In re Fitzgerald*, 619 F.2d 67, 70 (C.C.P.A. 1980); *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977); *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985).

from settled patent law doctrines.⁵⁸ Such an argument fails to recognize that the courts and Congress have previously modified product patent law to benefit the traditional, small-molecule pharmaceutical industry.⁵⁹

This proposal heeds the Supreme Court's cautionary note by not recapturing any invention already in the public domain⁶⁰ and by balancing disclosure with reward.⁶¹ Under this proposal, the person who has a pre-existing patent on a purified product or on a nonrecombinant method of making the product continues to have dominant rights. The proposed legislation expands the storehouse of knowledge by providing an appropriate incentive to create these naturally occurring proteins in a more pure form, for less cost, in larger quantities, and by more sophisticated technology.

The proposed bill appropriately moves from a single focus on protein structure to a combined focus on protein structure, practicality of use or function, and cost. The reduction in cost of producing a protein may be the only method by which the protein can be delivered in sufficient quantity to a patient population. Thus, in a sense, permitting the Patent Office to grant patents on such products by a recombinant process is, in reality, merely a reward for a new use.

It should be noted that nothing in this proposal eliminates the general existing patent law requirements that a new product-by-process claim must itself be nonobvious. Thus, if a previously granted patent or publication would have led an ordinary person skilled in the art to use recombinant technology, and that previous disclosure had provided sufficient information to make the use of recombinant technology obvious,

58. For example, the traditional "phenomena of nature" rules enunciated by the Supreme Court in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948).

59. These doctrinal changes in the law de-emphasize a focus on mere structure in determining patentability of small molecules. The doctrine that permits patents to be issued even if there is close structural similarity to prior art if the compound exhibits surprisingly good effectiveness for a therapeutic application is an example of this shift in focus. See, e.g., *Eli Lilly & Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096 (5th Cir. 1972); *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986); *Pfizer, Inc. v. International Rectifier Corp.*, 545 F. Supp. 486 (C.D. Cal. 1980), *aff'd*, 685 F.2d 357 (9th Cir. 1982), *cert. denied*, 459 U.S. 1172 (1983). Secondly, section 100(b) of the 1952 Patent Act, 35 U.S.C. § 100(b)(1988), explicitly permits process claims for new uses of old compounds. Finally, the Supreme Court in *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980), permitted product-like protection over nonstaple products sold by a patentee in conjunction with a patented "method of use." In each of these instances the law was altered to meet new economic necessities.

60. See generally *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989). This proposed bill also meets the four-part test for new intellectual property legislation suggested by former Representative Robert Kastenmeier. See Kastenmeier & Remington, *The Semiconductor Chip Protection Act of 1984: A Swamp on Firm Ground?*, 70 MINN. L. REV. 417, 440-41 (1985) (outlining harmony, clear definition, honest analysis of costs and benefits, and enhancement of aggregate public domain as test factors).

61. Important distinctions between patent law and trade secrets involve length of term and disclosure. The failure of current patent law to offer sufficient proprietary protection to biotechnology creates a greater temptation to rely on trade secrets. In turn, greater reliance on trade secret protection in this field has high costs in terms of a reduced pace of scientific advance, duplicative research and, perhaps, increased transaction costs. See H.R. REP. NO. 888, 100th Cong., 2d Sess., 53-54 (1988).

then a patent would not lie. For example, if a scientist has previously purified a protein-like growth factor and has discovered both its genetic sequence and potential uses, and routine recombinant steps would produce the protein, then a Patent Office examiner could reasonably conclude that the use of recombinant technology was obvious. The underlying purpose to this proposed section is to permit assessment of patentability on a case-by-case basis rather than to sanction the continued denial of such claims solely on the ground that a protein has been disclosed previously, albeit in a form or quantity making its practical utilization unlikely.

Finally, this proposal does not eliminate the requirement to examine the claims under the established enablement standards.⁶² Thus, the breadth and scope of such claims will still be determined based on the amount and sufficiency of disclosure, the amount of prior art, and the predictability and level of skill in the art.⁶³ Nor does this proposal at all prevent patentability of improved methods of recombinantly preparing the product. Even if a broad claim is warranted under the examination standards of section 112, others can still obtain patent protection for improved processes. The obtained claim to a broad product-by-process would then be dominant or superior to the subsequent claim.

2. Proposed Section 2

Section 2 of the proposed legislation would amend 35 U.S.C. § 103⁶⁴ by adding at the end the following new paragraph:

A process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise nonobvious under section 103.⁶⁵

This addition legislatively overrules *Durden* and codifies the holding of *Mancy*.

There is general agreement in the biotechnology patent bar that *Durden* should not apply to biotechnology, yet some may assert that this legislative solution to the so-called *Durden* problem is unnecessary and that the ordinary appeal process should be sufficient. While this argument has superficial appeal, it ignores the real-world transactional costs of such an approach. For companies wishing to obtain rapid FDA approval and marketing of a new drug, the luxury of pursuing a process

62. 35 U.S.C. § 112 (1988). The enablement standards in the first paragraph of section 112 provide:

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

63. See, e.g., *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); Forman, 230 U.S.P.Q. (BNA) 546 (PTO Bd. Pat. App. & Int'l 1986).

64. 35 U.S.C. § 103 (1988).

65. S. 2326, 101st Cong., 2d Sess. § 1, 136 CONG. REC. S3108 (daily ed. Mar. 22, 1990); H.R. 3957, 101st Cong., 2d Sess. § 1 (1990).

claim through a multiyear appeals process may not be available.⁶⁶ Second, this argument misses the point that all such appeals would be decided on a case-by-case basis. Thus, there is no certainty that a "test" case would solve the problem on anything other than an individual basis.

The best argument in favor of legislation addressing the *Durden* problem is the total absence of such a limitation in Western Europe or Japan.⁶⁷ Both of these legal systems have a strong tradition of protecting process patents. Removal of the *Durden* limitation will fully avail the United States biotech industry of the benefits afforded by the Process Patent Amendments Act of 1988.⁶⁸

When the availability of process claims is limited or delayed by *Durden* problems, that 1988 Act is as much as non-existent, especially to innovators in the biotechnology industry. The present proposal therefore corrects an unintended effect of the Patent Office's policy: denying a promising nascent United States industry the advantages of legislation intended for its benefit.

Proposed Section 2 provides certainty and protects the rights not only of biotechnology innovators but of innovators in other United States industries as well. While *Durden's* effects are perhaps most visible in the biotechnology field, they lead to irrational decisions as to obviousness in all fields.

The proposed text of Section 2 of the bill addresses virtually all of the problems that are likely to occur with respect to the protection of biotechnology-derived products. If, as proposed here, the innovator is able to obtain a valid process patent free from the impediments and delays arising as a result of *Durden*, there is little need for a remedy specific to the products of patented host cells. This is so because under current law⁶⁹ the holder of a process patent can obtain adequate remedies at the border through the use of the International Trade Commission, or domestically under United States patent law.⁷⁰

In the earlier versions of the legislation, a specific remedy was proposed for making, using, or selling the product of a patented "essential biological material" (i.e., a host cell or other similar essential biological intermediate).⁷¹ While this proposal would have served to meet the

66. For example, Amgen, Inc. deferred pursuit of its process claims on EPO when a *Durden* objection was raised by the Patent Office.

67. S. BENT, R. SCHWAAB, D. CONLIN & D. JEFFERY, *INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE* 504-05 (1987).

68. See *supra* note 21 and accompanying text.

69. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107. This policy orientation was also a motivating function when Congress overruled *Deep South Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972) as part of the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383.

70. 35 U.S.C. § 271(g) (1988).

71. H.R. 3957, 101st Cong., 2d Sess. § 2 (1990) and companion bill S. 2326, 101st Cong., 2d Sess. § 2, 136 CONG. REC. S3108 (daily ed. Mar. 22, 1990) are identical except the Senate bill uses the term "an essential biotechnological material" where the House bill uses the term "a biotechnological material."

specific needs of the biotechnology industry, it proved to be broader than generally necessary and extremely controversial.⁷² As a result of that controversy and of a recognition by proponents of the legislation that the vast majority of the problems addressed by this legislation could be resolved without resort to an industry-specific provision, this section of the bill was deleted.⁷³

This is not to say that there will not be a narrow range of circumstances in which an innovator will be unable to obtain complete protection from unfair offshore competition. This narrow problem could occur with respect to innovators who have been denied process patent protection because of *Durden* and who cannot take advantage of the proposed legislation because they can seek reissuance under United States law.⁷⁴

There could also be parties who could lose the benefits of this remedial legislation if they are, or were, unable to obtain a process patent in a timely fashion because of non-*Durden* problems—such as questions arising from issues of “first to invent.” This may be the case temporarily for Amgen which is currently in an interference in the Patent Office concerning the validity of its claim for priority for a method of making EPO. Amgen’s claim to a process patent appears to be strong in light of the factfinding by the district and Federal Circuit courts. If, as a result, Amgen obtains a process patent, there is no need for a “host cell” remedy. Such a process patent, if acquired, would provide Amgen with all the rights necessary to obtain a remedy that would prevent the importation of EPO.

3. Legislation

When the original Biotechnology Patent Protection Act was introduced in early 1990,⁷⁵ it generated substantial support from the industry⁷⁶ and academia.⁷⁷ Over time, however, the legislation provided a

72. Unfortunately, earlier proposals to address these situations proved to be controversial. The Bush Administration in particular objected to providing a specific fix for the biotechnology industry. It also feared that to tread on amendments to section 337 of the Tariff Act could complicate the already delicate international trade talks in the General Agreement on Tariff and Trade. See letter from Wendell L. Willkie, II, General Counsel of the U.S. Dep’t of Commerce to Rep. Robert W. Kastenmeier, Chairman, Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House Comm. on the Judiciary (July 5, 1990) [hereinafter Willkie Letter], reprinted in *Hearings*, *supra* note 4, at 108-13.

73. Compare H.R. 3957, 101st Cong., 2d Sess. (1990) with H.R. 5664, 101st Cong., 2d Sess. (1990). See also *Hearings*, *supra* note 4, at 17-33 (statement of Harry F. Manbeck, Jr.).

74. 35 U.S.C. § 251 (1988) (relating to reissuance).

75. The Biotechnology Patent Protection Act of 1990 (H.R. 3957 and its companion bill S. 2326) was introduced in the House of Representatives in February, see 136 CONG. REC. E213-14 (daily ed. Feb. 7, 1990) and in the Senate in March, see 136 CONG. REC. S3107-08 (daily ed. Mar. 22, 1990).

76. See *Hearings*, *supra* note 4, at 115-28 (statement of the Industrial Biotechnology Association) and at 118 (table indicating that of 11 top biotech companies, 9 support the legislation, 1 has no position, and only 1 opposes it).

77. See, e.g., letter from Katharine Ku, Pres. Ass’n of Univ. Technology Managers to Rep. Rick Boucher (Dec. 15, 1989), reprinted in *Hearings*, *supra* note 4, at 129-30; letter from Sheldon E. Steinbach, Vice Pres. & Gen. Counsel, Am. Council on Educ. to Rep. Robert

degree of controversy, especially regarding the effective date.⁷⁸ Opponents, such as Genetics Institute, argued that the bill would have affected the outcome of a pending case involving EPO.⁷⁹ This controversy effectively derailed the detailed consideration of the original bill.

After the bill was introduced, the relevant congressional committees asked the Bush Administration for its views of the pending measures. In a July 1990 letter, the Department of Commerce, speaking for the Administration, offered its views.⁸⁰ The letter reasoned that special remedies for products of patented host cells were unnecessary because sufficient remedies were available if the inventor secured a process patent. The Department of Commerce argued that if *Durden* was the only impediment to obtaining process patents, then the solution lay with amendments that addressed only that issue. In addition, the Administration expressed strong opposition to the effective date provisions of the original bill.

As a result of the objections of the Administration and others, a second bill, the Process Patent Amendments of 1990,⁸¹ was introduced in September of 1990 by Representative Boucher. This bill was largely crafted in response to the recommendations of the Administration.

C. Congressional Hearings

A congressional hearing on H.R. 3957 and H.R. 5664 was held in September of 1990.⁸² The witnesses at this hearing were far from uniform in their views. The Administration testified in favor of H.R. 5664, but against H.R. 3957. Representatives of biotechnology firms were similarly divided. Genetics Institute and Upjohn, parties to the dispute about EPO, testified against H.R. 3957. Amgen's Chairman and CEO testified in favor of H.R. 3957. The witness representing Genentech, one of the authors of this article, testified in favor of legislation to address this problem generally. Finally, a witness representing some large

W. Kastenmeier (April 4, 1990), *reprinted in Hearings, supra* note 4, at 150-51; letter from Karl J. Hittelman, Ph.D., Assoc. Vice Chancellor Academic Affairs, Univ. of Cal., San Francisco to Rep. Robert W. Kastenmeier (June 27, 1990), *reprinted in Hearings, supra* note 4, at 201; letter from Glenn Harlan Reynolds, Assoc. Professor of Law, Univ. of Tennessee, Knoxville to Rep. Robert W. Kastenmeier (July 17, 1990), *reprinted in Hearings, supra* note 4, at 206-09; letter from Thomas J. Bennett, Director, Research Services, Loyola Univ., Chicago to Rep. Robert W. Kastenmeier (Aug. 3, 1990), *reprinted in Hearings, supra* note 4, at 211; letter of Richard L. Wallace, Vice Pres. for Academic Affairs, Univ. of Missouri to Rep. Robert W. Kastenmeier (Aug. 20, 1990), *reprinted in Hearings, supra* note 4, at 212.

One of the underlying reasons for the support of the university community is that universities appear to suffer disproportionately from *Durden* rejections. *See Hearings, supra* note 4, at 122 (statement of the Industrial Biotechnology Ass'n discussing forfeiture of process patent protection by deserving universities).

78. *See Andrews, Disputed Provision in Gene Bill*, N.Y. Times, Feb. 17, 1990, § 1, at 36, col. 5. *See also Hearings, supra* note 4, at 33-38 (testimony of Bruce M. Eisen, Vice President-Chief Patent Counsel, Genetics Institute, Cambridge, Mass.).

79. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94 (D. Mass. 1989).

80. Willkie Letter, *supra* note 72.

81. H.R. 5664, 101st Cong., 2d Sess. (1990). *See supra* note 3.

82. *Hearings, supra* note 4.

industrial companies testified in favor of letting these issues be resolved by further judicial developments.

The hearing clearly established the fault lines for further consideration in the next Congress. Some parties will continue to push for congressional resolution of a judicially created problem, while others will continue to insist on awaiting further judicial action. The second major issue of division concerns the competing equities of Congress involving itself in an ongoing commercial dispute. Unfortunately, this latter issue has come to dominate the discussion. Fair and complete resolution of the problems associated with the effective date of this legislation will be difficult to achieve without further compromise by the parties and by further judicial decisions.

VI. CONCLUSION

International competition, industrial competitiveness, and fundamental fairness demand the enactment of new laws to enhance the incentives for biotechnology-derived products. This initiative will work to benefit high risk, high cost, innovative scientific research and will stimulate investment in new technologies leading to dramatic advances in biotherapeutics beneficial to public health.