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Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents, 24 J. Marshall L. Rev. 263 (1990)

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COMMENT

THE ELIMINATION OF PROCESS: WILL THE BIOTECHNOLOGY PATENT PROTECTION ACT REVIVE PROCESS PATENTS?

I. INTRODUCTION

With the encouragement of George Washington and Thomas Jefferson, Congress enacted the first patent act on April 19, 1790.[1] For two hundred years the patent system has been an important means of encouraging the advancement of the sciences.[2] However, due in part to the success of the patent laws in achieving this end, new technologies have emerged that may not "fit into" the patent code. One of these is biotechnology.

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1. H. TOULMIN, JR., INVENTION & THE LAW 10-11 (1936). On July 31 of the same year, the Commission for the Promotion of Useful Arts issued its first patent to Samuel Hopkins of Vermont for a process of making potash and pearl ash. Secretary of State Thomas Jefferson, an inventor himself, together with the Secretary of the Department of War and the Attorney General, formed the Commission. Graham v. John Deere Co., 383 U.S. 1, 6-7 (1966). Any two of these individuals could issue a patent. *Id.* at 7. Eventually, this function became too burdensome in combination with the officers' other duties, and the judiciary assumed the responsibility of issuing patents. *Id.* at 10.

2. Mr. Toulmin praises the United States' enlightened patent system for paving the road to America's success in industry. H. TOULMIN, JR., HANDBOOK OF PATENTS 4 (1949). Toulmin agreed with Abraham Lincoln, recipient of U.S. Patent No. 6,649 for 'A Device for Buoying Vessels over Shoals,' who said, "The patent system added the fuel of interest to the fire of genius." *Id.* at 31 n.39, iii. A solid patent system is a "highly significant component" of technological advancement. Adler, *Biotechnology Development and Transfer: Recommendations for an Integrated Policy*, 11 RUTGERS COMPUTER & TECH. L.J. 464, 478 (1985). "Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives . . . ." Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980); *see generally* C. JUMA, THE GENE HUNTERS: BIOTECHNOLOGY AND THE SCRAMBLE FOR SEEDS, 149-78 (1989) (analyzing effect of intellectual property protection on plant technology advancement).

But see Buttel & Belsky, *Biotechnology, Plant Breeding, and Intellectual Property: Social and Ethical Dimensions*, 12 SCIENCE TECH. & HUMAN VALUES 31 (1987). In their study of the seed industry, Buttel and Belsky concluded that while the Patent Act was effective in sparking economic growth (which led to the formation of U.S. and multinational seed companies), it was less effective in stimulating research and formation of new seed varieties. *Id.* at 35. Rather, the major companies actively discouraged the release of new varieties, which would mean increased competition. *Id.*

Biotechnology is the application of engineering and technological principles to living organisms or their components to produce new inventions or processes.[3] An important branch of biotechnology is genetic engineering,[4] or recombinant DNA technology,[5] which concerns the analysis and alteration of genes and proteins. These sciences are of vital importance to U.S. and world progress in innumerable fields.[6]

Biotechnology has the potential to eradicate thousands of diseases and feed millions of people. It promises advances to offset pollution and protect the environment.[7] As an industry it is a remarkable source of revenue, boasting a multi-billion dollar market.[8] The recombinant version of the protein erythropoietin

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3. *See* MCGRAW HILL DICTIONARY OF SCIENTIFIC TERMS 184 (3d ed. 1984); Note, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1327 n.3 (1988). Biotechnology subsumes many sciences, such as biochemistry, microbiology, chemical engineering, agronomy, and applied genetics. *Id.* Biotechnology research may relate to recombinant DNA and hybridoma technologies, pharmaceuticals, peptides, antibodies, vaccines, enzymes, cell lines, media, diagnostic pregnancy and cancer kits, and plant hybrids. Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407 (1985).

Congress defines a biotechnological material as a "biologically engineered organism that is essential for the production of a product [and] . . . includes any host cell, DNA sequence, or vector." H.R. 3957, 101st Cong., 2d Sess., 136 CONG. REC. E207 (1990) (section 2(b)(2) of proposed Biotechnology Patent Protection Act).

4. Genetic engineering is "the intentional production of new genes and alteration of genomes by the substitution or addition of new genetic material." MCGRAW HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 675 (3d ed. 1984).

5. Recombinant DNA technology is another name for genetic engineering. Deoxyribonucleic acid (DNA), the "molecule of life," resides on chromosomes in sequences which are found in the nucleus of every cell of a eucaryotic organism. J. WATSON, J. TOOZE & D. KURTZ, RECOMBINANT DNA, A SHORT COURSE 1-2 & 6-8 (1983) [hereinafter RECOMBINANT DNA]. In recombinant DNA technology, DNA, the genetic information, from one species may be "recombined" with the DNA of another species. *Id.* at 58-71.

6. *See infra* notes 7-10 and accompanying text (discussing advances in biotechnology); *see also* 134 CONG. REC. S8061 & S8064 (daily ed. June 17, 1988) (statement of Rep. Chiles) (Biotechnology will revolutionize many sectors and "have enormous impact on the next decades").

7. *See* Adler, *supra* note 2. Advances in biotechnology will allow scientists and consumers to tap into the genetically-rich resources of tropical plants and fauna. *Id.* at 471. This will help prevent resource reduction caused by gene depletion. *Id.*

8. *See* STATEMENT OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION IN SUPPORT OF THE BIOTECHNOLOGY PATENT PROTECTION ACT TO THE SUBCOMMITTEE ON COURTS, INTELLECTUAL PROPERTY, AND ADMINISTRATION OF JUSTICE OF THE HOUSE JUDICIARY COMMITTEE, September 25, 1990 [hereinafter IBA STATEMENT] (listed profit and investment figures and noted that biotechnology is one of the country's most intensive research and development industries). The U.S. Department of Commerce predicts that the market for biotech-related products will reach $40 billion by the year 2000. 134 CONG. REC. S8061 (daily ed. June 17, 1988) (statement of Rep. Chiles). The Japanese have estimated the market to be worth $100 billion by 2000. *Id.* In 1985, in the U.S., pharmaceutical compa-

("EPO"),[9] which prevents blood clotting, alone has an estimated value of $1 billion.[10] The United States currently leads the world in biotechnology innovation and production, but Japan and Germany are narrowing the gap.[11] The United States cannot afford to lose its edge in yet another technology to its world competitors.[12]

The biotechnology revolution is not unlike the industrial revolution, which itself spawned countless patents.[13] Inventors during the industrial revolution had to overcome hurdles in the patent system to obtain adequate protection. In fact, from as early as 1853[14] to as late as 1909,[15] the United States Supreme Court refused to recognize mechanical processes as patentable subject matter.[16]

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nies invested $4.1 billion in research and development; in 1986 they invested $4.6 billion. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, J. L. & TECH. 307, 308 (1987). In 1987, the pharmaceutical industry maintained 36,000 jobs, half of which were for scientists and engineers. *Id.* It takes an average of ten years and $125 million to produce a new marketable drug in the United States; *see also* The Chicago Tribune, Feb. 18, 1990, § 5, at 1 & 13, col. 1 (patented cell line for restoring white blood cells in treatment of cancer patients worth millions of dollars).

9. EPO is used for treatment of anemia, which is a reduction in the total quantity of red blood cells in circulation. MCGRAW HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 535 (6th ed. 1987). EPO is helpful because it stimulates the production of red blood cells. *Id.* at 536.

10. 12 Legal Times, Jan. 8, 1990, at 1, col. 2.

11. Griffen, *Exporting Biotechnology: The Pitfalls*, 3 AM. INTELL. PROP. L.A.Q.J. 542, 545 (1988-89).

12. *See* Corcoran, *Science and Business*, 262 SCI. AM. 82 (1990) (analyzing department of defense statistics that show Japan to be "significantly ahead" of the United States in some aspects of biotechnology, semiconductor and electrical sciences, photonics, superconductivity, and machine intelligence).

13. In 1869, George Westinghouse, Jr., received patent number 88,929 for his invention of the air brake. H. TOULMIN, *supra* note 2, at 31 n.39. In 1870, John and Isaiah Hyatt received a patent for "Improvements in Treating and Molding Pyroxyline," the foundation for the celluloid industry. *Id.* In 1873, patents issued to Louis Pasteur and Eli Janney, respectively, for their inventions of a process of making beer and car couplings. Alexander Graham Bell obtained a patent for the telephone in 1876. *Id.* at 32 n.39. In 1878, Thomas Edison received a patent for a "Phonograph or Speaking Machine," and in 1880 he obtained a patent for his electric lamp; in all Mr. Edison received 1101 patents. *Id.* This is just a sampling of the break-through inventions patented in the United States during the industrial revolution. Today, patent applications are on the rise: 1988 broke the record for patent applications filed, numbering 137,000; 152,000 applications were projected for 1989. Statement of Quigg, 38 PAT. TRADEMARK & COPYRIGHT J., 465, 466 (1989). Unfortunately, the backlog in patent applications was an average of 19.9 months in 1988; the PTO was shooting for an eighteen month backlog for 1989. *Id.*

14. *See, e.g.*, Corning v. Burden, 56 U.S. (15 How.) 252 (1853) (process that is function of a machine is not patentable).

15. *See, e.g.*, Expanded Metal Co. v. Bradford, 214 U.S. 366 (1909) (process involving mechanical operations may be patentable).

16. *See, e.g.*, Westinghouse v. Boyden Power Brake Co., 170 U.S. 537 (1898) (mechanical processes not patentable); Risdon Locomotive Works v. Medart, 158 U.S. 68 (1895) (same).

By 1935 the Court's approach had softened considerably.[17] Today, the patent system poses similar obstacles for inventors seeking biotechnological process patents.[18]

Myriad problems confront biotechnology in the procurement of protection for its inventions.[19] One problem is that the Patent Code requires that an invention not be obvious to one of ordinary skill in the field or science to which the invention pertains.[20] This requirement is troublesome to biotechnology where scientists utilize well-known processes, indispensable to the invention, to create completely new products.[21] Many of biotechnology's most important developments, such as insulin,[22] EPO,[23] and tissue plasminogen ac-

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17. *See, e.g.*, Waxham v. Smith, 294 U.S. 20 (1935) (process is not unpatentable merely because it is used in machine).

18. Those in the computer field have experienced the same phenomenon. *See* Note, *Computer Intellectual Property and Conceptual Severance*, 103 HARV. L. REV. 1046 (1990). Currently, patent protection for computer-related inventions is questionable and copyright protection is often inadequate. *Id.*

19. Judge Young noted that biotech raises issues that "rattle, ostensibly at least, the traditional foundations of patent law; that is [sic] how do putative proprietary interests in recombinant technology interact with traditional concepts of patent law?" Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 95 (D. Mass. 1989).

For example, there is no provision in the patent code that specifically addresses the patentability of living organisms. Biotechnology, by definition, concerns the manipulation of living organisms, for which inventors are naturally seeking patents. *See supra* note 3 and accompanying text (defining biotechnology). In 1980, the Supreme Court held that living organisms are patentable. Diamond v. Chakrabarty, 447 U.S. 303 (1980). In *Chakrabarty*, the Court held that living organisms are patentable subject matter in accordance with 35 U.S.C. § 101. *Id.*

In 1988, the Patent and Trademark Office issued a patent for a transgenic, cancer-prone mouse to Philip Leder's laboratory at Harvard. Erickson, *supra* note 7, at 102. Strong opposition to patenting living organisms has surfaced since the United States Supreme Court decided that viability does not preclude patentability. *See generally* Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551 (1988-89) (analyzes evolution of case law in granting patents for living organisms and discusses ensuing ethical and legal issues). As a result of *Chakrabarty* and its progeny, Congress is considering legislation, namely The Transgenic Animal Patent Reform Act. H.R. 4970, 99th Congress, 2d Sess., 134 CONG. REC. 7436 (1988).

20. 35 U.S.C. §§ 102-103 (1988). The novelty and nonobvious requirements are discussed at *infra* notes 48-49.

21. *See infra* notes 70-79 and accompanying text (discussing genetic engineering and monoclonal antibody techniques).

22. Insulin is used to treat diabetics. M. STRICKBERGER, GENETICS 167 (3d ed. 1985). Sugar levels normally controlled by the hormone insulin are not properly regulated in persons with diabetes. *Id.* The administration of insulin will protect diabetics from possible coma and death. *Id.* at 168.

23. The human kidneys produce EPO, which promotes the production of red blood cells in the bone marrow. MCGRAW HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 535 (6th ed. 1987). Individuals suffering from anemia—as a result of kidney disease, cancer, or AIDS—are unable to produce sufficient amounts of red blood cells. *Id.* Recombinant EPO ("rEPO") allows for the manufacture of far greater amounts of the protein than a human normally can

tivator ("TPA"),[24] are simply recombinant versions of their often indistinguishable natural counterparts. The present interpretation of the nonobvious requirement denies inventors, who develop processes yielding beneficial products, patent protection if the claimed process is based on a known process. This denial of patent protection occurs even if the process incorporates new starting materials or results in a new final product.[25]

Currently, U.S. laws inadequately protect patented inventions from the importation of products manufactured abroad using starting materials patented in the United States. The International Trade Commission does not have jurisdiction to exclude these infringing products from importation into the United States.[26] The nonobvious requirement as applied to process patents and the importation of products made from patented starting materials are the focus of this comment.

In response to the varied problems of applying the patent laws to biotechnology inventions, Congress has introduced numerous bills to encourage the advancement and protection of the science and its related industries.[27] Recently, Congressman Boucher introduced the Biotechnology Patent Protection Act ("BPPA").[28] If passed, the BPPA would accomplish two things: 1) extend patent

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produce. *Id.* The administration of rEPO boosts the patients' red blood cell production, thereby "vastly improving their lives and in some cases, saving them." *Id.*

24. TPA is a drug for heart attack victims: it saves lives by dissolving arterial blood clots quickly. 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

25. *See In re* Durden, 763 F.2d 1406 (1985). *Durden* and its progeny are discussed *infra* notes 109-31 and accompanying text. Courts generally have been encouraging to the biotechnology industry. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (court overruled PTO rejection and granted patent for living organism); Armitage, *The Emerging U.S. Patent Law for the Protection of Biotechnology Research Results*, 2 EUR. INTELL. PROP. REV. 47, 57 (1989) (federal circuit subscribes to a pro-biotech patent public policy). However, the impetus has not flowed over to process patents.

26. *See, e.g.*, Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990). This topic is discussed more thoroughly at *infra* notes 111-21 and accompanying text.

27. *See, e.g.*, H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H.R.7436-39 (daily ed. Sept. 13, 1988) (addresses legal and policy issues of patenting animals); 1114 Official Gazette 29 (U.S.P.T.O.) (May 15, 1990) (reprinting *Patent and Trademark Office Amendment to Regulations, 37 C.F.R. Part I: Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures*); *see generally* Hoffman, *The Biotechnology Revolution and its Regulatory Evolution*, 38 DRAKE L. REV. 471 (1988-89) (author outlines current issues in biotech and the legislative responses to these issues).

28. U.S. Representative Boucher introduced House Bill H.R. 3957 on February 7, 1990. 136 CONG. REC. E213 (daily ed. Feb. 7, 1990). The stated purpose of the bill is to eliminate barriers to U.S. biotechnology companies in obtaining patent rights. *Id.* at E207 (statement of Sen. Moorhead). The bill will work to eliminate unfair trade practices which disfavor American biotech companies. *Id.* The BPPA states in full:

Section 1. Patentability of Certain Processes. Section 103 of title 35, United States Code, is amended 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."

Section 2. Importation Prohibition; Infringement by Importation, Sale, or Use.

(a) Amendment to Tariff Act of 1930.—Section 37(a)(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1337(a)(1)(B) is mended—

(1) in clause (i) by striking "or" after the semicolon;

(2) in clause (ii) by striking out the period at the end and inserting "; or"; and

(3) by adding at the end the following:

"(iii) are made, produced, or processed under, or by means of, the uses of a biotechnological material (as defined under section 154

(b) of title 35;, United States Code) covered by a valid and enforceable United States patent."

(b) Amendments to Title 35, United States Code.—

(1) Infringement.—Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by sing a biotechnological material (as defined under section 154 (b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent."

(2) Contents and Term of Patent.—Section 154 of title 35, United States Code, is amended—

(A) by inserting "(a)" before "Every";

(B) by inserting "(1)" after "in this title";

(C) by striking "and, if the invention" and inserting "(2) if the invention";

(D) by inserting after "products made by that process," the following: "and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States, that product,"; and

(E) by adding at the end the following:

"(b) For purposes of this section, the term 'biotechnological material' means a biologically engineered organism that is essential for the production of a product. Such term includes any host cell, DNA sequence, or vector."

Section 3. Effective Date.

(a) Section 1.—The amendment made by section 1 shall apply to all United States patents granted before, on, or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

(b) Section 2.—(1) The amendment made by section 2(a) shall apply only to articles imported, or sold for importation, on or after the date of the enactment of this Act.

(2)(A) subject to subparagraph (B), the amendments made by section 2(b) shall take effect on the date of the enactment of this Act.

(B)(i) With respect to any article which is imported before February 6, 1990, and which, but for the amendment made by section 2(b), could be sold or used within the United States, no person shall be liable for infringement under section 271(h) of title 35, United States Code, for such sale or use.

(ii) With respect to any article which is imported on or after February 6, 1990, but before the date of the enactment of this Act and which, but for the

protection to processes[29] where novel and nonobvious[30] starting materials are used, even if the process itself is otherwise obvious; and 2) increase protection of U.S. patented starting materials used abroad to make products for importation into the U.S.[31]

The biotechnology industry welcomes these changes.[32] By increasing patent protection, the Act will provide the incentives necessary to enable biotechnology companies, particularly those dealing in pharmaceuticals, to commit the required resources for

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amendment made by section 2(b), could be sold or used within the United States, no person shall be liable for infringement under section 271(h) of title 35, United States Code—

(I) for the first such sale if it is made within 90 days after the date of the enactment of this Act; or

(II) for any such subsequent sale or for any such use.

H.R. 3957, 101st Cong., 2d Sess., 136 CONG. REC. E207 (1990).

29. A process patent relates to a method of making an article. Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 107 (D. Mass. 1989). A product patent relates to an invented or discovered article. *Id.* (citing *In re* Amtorg Trading Corp., 75 F.2d 826 (3d Cir.), *cert. denied sub. nom.* International AGR Corp. v. Amtorg Trading Corp., 296 U.S. 576 (1935). A product patent includes the right to restrict the use and sale of the product regardless of how and by whom it was manufactured. *Id.* A process patent covers only those products made by the patented process. *Id.*

30. The terms "novel" and "nonobvious" are defined and discussed at *infra* notes 46 & 49 and accompanying text.

31. Recent events in the biotech arena may have spurred this legislative action. For example, two major pharmaceutical companies—one American, the other Japanese—have been battling over the rights to the billion dollar drug, EPO. Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990); Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989); Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737 (1989); Amgen, Inc. v. Chugai Pharmaceutical Co., 11 U.S.P.Q.2d (BNA) 1466 (1989); *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906 (1989). The litigation has taken place in the U.S. District Court in Massachusetts, the U.S. International Trade Commission ("ITC"), the Food and Drug Administration, and the PTO. Morgan, *On the Political Frontiers of Biotechnology*, Legal Times, Jan. 8, 1990, at 1, col. 2. The litigation between Amgen, Inc., an American company, and Japan's Chugai Pharmaceutical Company, represents many of the problems facing U.S. companies in the biotech/legal arena.

In the *Amgen* case, Amgen owns the patent for the starting materials necessary to produce recombinant EPO ("rEPO"), but Genetics Institute owns the patent (and has licensed it to Chugai) for the purified version of EPO. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1741. Thus, neither may make EPO or rEPO without infringing the other's patent. *Id.* However, companies in these situations usually avoid litigation and enter cross-licensing agreements. Legal Times, Jan. 8, 1990, at 21, col. 4.

32. The Industrial Biotechnology Association ("IBA"), whose members include over a dozen major biotech firms and represent over 80% of the industry's financial resources, has endorsed the BPPA. IBA STATEMENT, *supra* note 9, at 1. Genetics Institute is the only IBA member to withold its support. *Id.* at Table 1. This is probably due to Genetics Institute's stance in its current litigation with Amgen, Incorporated.

progress.[33] The need for uniform standards with predictable applications is manifest. The patent system hinders biotechnology advancement because current inadequacies threaten to defeat investment incentives and damage American companies' abilities to develop new products.[34]

This comment analyzes the BPPA and the effect it will have on process patent applications and the importation of certain biotechnological products. Part II discusses the history and background of patent law, biotechnology, and related trade issues. Part III addresses the current inadequacies of U.S. patent and trade laws in protecting biotechnology process and starting materials inventions, and appraises the efficacy of the BPPA in resolving these inadequacies. Part IV examines the future of biotechnology and process patents and proposes alternative solutions to the problems addressed by the BPPA.

II. UNITED STATES PATENT AND TRADE LAWS AND THEIR APPLICATION TO BIOTECHNOLOGY

The United States Constitution grants Congress broad powers to regulate patents in order to promote the progress of the arts and science.[35] Under these powers, Congress established the patent sys-

33. Mossinghoff, *supra* note 8, at 307. Mossinghoff believes that patent protection is the only effective way to stimulate expansion. *Id.* He stated that currently incentive is low, and improvement is desperately needed. *Id.*

34. "[T]he deficiency in current law will severely weaken investment incentives and damage the ability of American companies to create new products." 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher). The backlog in patent applications averaged 19.9 months in 1988; the PTO was trying for an 18 month backlog for 1989. Address by PTO Commissioner Donald J. Quigg to the ABA Conference, *reprinted in* 38 PAT. TRADEMARK & COPYRIGHT J. 465, 466 (1989). In addition, patent applications are on the rise: 1988 broke the record for patent applications filed with 137,000; 152,000 were projected for 1989. *Id.*

One commentator stated that the patent system is stifling biotech progress. Adler, *supra* note 2, at 478-79. Adler, who clerked for Federal Circuit Judge Rich, stated that even after the breakthrough case of *Diamond v. Chakrabarty*, the Patent and Trademark Office has been overly conservative in issuing biotech patents. *Id.* Adler further admonishes the PTO for demonstrating erroneous judgment and an "unenlightened policy." *Id.* at 479. The Congress and the Department of Commerce do not fair much better; in Adler's opinion, they both are replete with inadequacy and oversight. *Id.* at 480.

But see Statement of Quigg, 38 PAT. TRADEMARK & COPYRIGHT J. 465, 466 (1989) (discusses improvements in patent law underway at PTO). The PTO has launched a thirteen-point plan to deal with biotech. *Id.* There were 100 examiners in the biotech examiners group, and the PTO formed the Biotech Institute to train examiners. *Id.* The PTO is concerned with "high quality examination" as opposed to large quantity turn-over when issuing patents. *Id.*

35. U.S. CONST. art. I, § 8, cl. 8. This constitutional provision grants Congress the power to regulate laws "[t]o promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *Id.* Congress may legislate

tem whereby the government grants an inventor certain exclusive rights to his or her invention for a period of time in exchange for the disclosure of the invention.[36] This reward system is designed to benefit the public by bringing forth new knowledge and stimulating research.[37]

Title 35 of the United States Code sets forth the requirements and guidelines for obtaining and enforcing patent rights.[38] Today, an inventor's exclusive right[39] to exclude others from making, using, and selling the invention extends for seventeen years.[40]

An inventor may obtain a patent in any or all of three categories: the final product obtained, the starting material used, or the process by which a final product is made or a starting material is

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to "best effectuate the Constitutional aims." Graham v. John Deere Co., 383 U.S. 1, 6 (1966). Thus, "Congress may set out conditions and tests for patentability." *Id.* When interpreting the patent laws, a court should not read in limits that Congress did not expressly intend. Diamond v. Chakrabarty, 447 U.S. 303, 303-08 (1980) (citing United States v. Dubilier Condenser Corp., 289 U.S. 178, 199 (1933)). The founders of this country recognized the importance of a system to encourage technological advancement. *Graham*, 383 U.S. at 5. Thomas Jefferson was a key figure in forging the first patent laws and his principles were embodied in the 1793 Patent Act. *Id.* at 7. Jefferson was concerned with achieving a proper balance between the evils of monopoly rights and the bonuses of incentive to advance science and development. *Id.* at 9-11.

In 1982, Congress created the United States Court of Appeals for the Federal Circuit. 2 D. CHISUM, PATENTS § 5.02[6] (1989). The Federal Circuit Court has exclusive jurisdiction over appeals arising under the U.S. patent laws. *Id.* Congress' primary goal in creating a federal appellate court for patent cases was to promote uniformity and predictability in the application of the patent laws. *Id.* (citing H.R. 97-312, 97th Cong., 1st Sess., CONG. REC. 20-23 (1981)).

All three branches of government are involved in technology transfer: the legislature in its power to regulate patents, interstate commerce, and international trade; the president in his treaty-making capacity; and the judiciary in its power to construe the applicable laws. U.S. CONST. art. I, § 8, cls. 3 & 8; art. II, § 2, cl. 2; art. III § 2, cl. 1.

36. Patent laws do not grant exclusive property rights in the patented subject-matter. Armitage, *U.S. Patent Law for Biotechnology Research Results*, 2 EUR. INTELL. PROP. REV. 47, 56 (1989). Rather, the statute grants the right to exclude others from making and using the patented invention. *Id.* A patent is a

> written contract between an inventor and the government. . . . The consideration given on the part of the inventor to the government is the disclosure of his invention. . . . The consideration on the part of the government given to the patentee for such disclosure is a monopoly for seventeen years of the invention disclosed to the extent of the claims allowed in the patent.

Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 99 (D. Mass. 1989) (quoting Marcyan v. Nissen Corp., 578 F. Supp. 485, 498 (N.D. Ind. 1982)).

37. Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974).

38. 35 U.S.C. §§ 1-376 (1988).

39. *See supra* note 36 (defining exclusive right).

40. 35 U.S.C. § 154 (1988). The practice in the U.S. is to reward patent rights to the first to invent, not the first to file an application. Ihnen, *supra* note 3, at 411.

used.[41] To obtain a patent, an inventor must demonstrate that the invention meets four basic requirements.[42] First, the invention must pertain to patentable subject matter.[43] An inventor must also

41. *See, e.g., In re* Pleuddemann, 910 F.2d 823, 825-26 (Fed. Cir. 1990) ("a single invention may be viewed legally as having three or more different aspects").

42. *See* Ihnen, *supra* note 3, at 422-30 (how to draft biotech patent claims).

43. 35 U.S.C. § 101 (1988). The subject matter requirement ensures that patentable subject matter includes any process, machine, manufacture, or composition of matter, or any improvement of any of these. *Id.* Section 101 states in full: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." *Id.*

The Patent Code defines "process" to be any "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 (1988). A "machine" is a "mechanical device or a combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1853). A "manufacture" is an article that has been changed or transformed, resulting in a new and different character or use. Diamond v. Chakrabarty, 447 U.S. 303, 307-08 (1980); Anheuser-Busch Brewing Ass'n v. United States, 207 U.S. 556, 562 (1908). "Composition of matter" includes "all compositions of two or more substances. . .and all composite articles." Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980); 1 E. LIPSCOMB'S WALKER ON PATENTS § 2:9 (3d ed. 1984). Abstract ideas, products and laws of nature, and physical phenomena are not patentable. *Chakrabarty*, 447 U.S. at 309; Parker v. Flook, 437 U.S. 584, 593 (1978); O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112-13 (1853). As for biotechnology, the patent office has issued patents for, *inter alia*, genes, DNA sequences, vectors and plasmids, hybridomas, monoclonal antibodies, single-celled organisms, multicellular organisms, and the processes for obtaining the products. Ihnen, *supra* note 3, at 408.

The United States Supreme Court opened the door for biotechnology patents in the case of Diamond v. Chakrabarty, 447 U.S. 303 (1980). *See* Ihnen, *supra* note 3, at 407 (*Chakrabarty* "released a tremendous log jam of patent applications" at the PTO and "assured the continued filing of large numbers of new applications.")

The issue in *Chakrabarty* was whether a living organism, in that case a genetically engineered bacterium, is patentable subject matter. *Chakrabarty*, 447 U.S. at 307. The genetically altered bacterium was capable of breaking down several components of crude oil and would be useful for cleaning oil spills. *Id.* at 305.

Emphasizing the broad language of section 101 of the Patent Code, the court held that living organisms are patentable. *Id.* at 309. The court noted that the broad terms in section 101, such as "manufacture" and "composition of matter," modified by "any," demonstrates that Congress intended a wide scope of patent coverage. *Id.* In fact, "anything under the sun" that is human-made is patentable. *Id.* at 316.

The proper focus of inquiry is whether the invention is a product of nature or whether it is human-made. *Id.* at 309-10. The court discounted the argument, which the dissent advanced, that Congress could not have foreseen applying the patent laws to living organisms. *Id.* at 314-15. The majority noted that it is the nature of inventions to be unforeseeable, especially 200 years in advance; this is the reason that Congress drafted the patent laws with broad and flexible language. *Id.* at 316. Any other interpretation of section 101 would undermine the purpose of the patent laws. *Id.*

The dissent further argued that because there was a separate body of law for plant patents, then there should be separate laws for living organisms. *Id.* at

show that the claimed invention is useful,[44] novel,[45] and nonobvi-

320. The dissent concluded that the court should defer the issue until the legislature has acted, and therefore the patent for the living organism should be denied. *Id.* at 321-22. The majority responded that the plant acts were not meant to limit patent protection and were not inconsistent with the patent act. *Id.* at 313-14.

Since *Chakrabarty*, Patent and Trademark Office Board of Appeals has held that plants are patentable subject matter outside of the plant acts. *Ex parte* Hibberd, 227 U.S.P.Q (BNA) 443 (P.T.O. Bd. App. 1984).

As demonstrated in cases such as *Ex parte Allen*, the subject matter requirement does not pose a significant problem for those inventors seeking biotechnology patents. 2 U.S.P.Q.2d (BNA) 1425 (P.T.O. Bd. App. 1987) (non-naturally occurring polyploid oysters are patentable subject matter); *see also Ex parte* Hibberd, 227 U.S.P.Q (BNA) 443 (P.T.O. Bd. App. 1984) (plants are patentable subject matter under 35 U.S.C. § 101).

For example, one may obtain a patent for a DNA sequence if it is transposed into another cell, because that is not how the sequence naturally exists. Armitage, *supra* note 26, at 49. Also, the PTO has granted a patent to Harvard University for a genetically-engineered mouse. U.S. Patent No. 4,736,866 (1988); SCIENCE NEWS, Apr. 16, 1988, at 244. The patent claims a genetically engineered "transgenic nonhuman mammal." *Id.*

Harvard researchers isolated a gene that causes cancer in mammals and then infected the gene into fertilized mouse eggs. N.Y. Times, Apr. 13, 1988, at A1, col. 5. The patented animal is highly susceptible to cancer which allows for more efficient testing of causes and cures for cancer. *Id.* The offspring of the mice will have the same properties. *Id.*

The focus of the patentable subject matter inquiry is whether human intervention produced the claimed product and whether the claimed product occurs naturally. *Chakrabarty*, 447 U.S. at 309-10; *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (P.T.O. Bd. App. 1987) (patent denied on other grounds). Most biotechnology inventions will qualify as patentable subject matter because the inventions are the result of human manipulation and do not exist in nature.

44. 35 U.S.C. § 101 (1988); *see generally* Brenner v. Manson, 383 U.S. 519 (1966). An invention must have some utility apart from research. *Id.* at 534-35 (if claim human therapy must demonstrate specific and substantial utility beyond laboratory).

If the invention is a process, the inventor must demonstrate that the product of that process is useful. *Brenner*, 383 U.S. at 535; Tennessee Valley Auth. v. Monsanto Chem. Co., 383 F.2d 973, 977 (5th Cir. 1967). Furthermore, to be considered useful under section 101, the utility of an invention must be definite and known, rather than contingent upon some future research. *In re* Kirk, 376 F.2d 936, 945 (C.C.P.A. 1967).

Another aspect of the utility requirement is that the claimed invention must have been actually made. *Id.* However, a court will not question whether the product has been acceptably reduced to practice unless one skilled in the art would have reason to question the objective truth of a claim. *Ex parte* Rubin, 5 U.S.P.Q.2d (BNA) 1461, 1462 (P.T.O. Bd. App. 1987) (holding that cancer treatment claims are no longer per se incredible).

The utility requirement poses special problems for biotech researchers because it may not be sufficient to demonstrate that an invention is effective in a culture dish. The PTO may require proof that the invention is effective in vitro. When human therapy is alleged, substantiating evidence will be required. *In re* Jolles, 628 F.2d 1322, 1327 (C.C.P.A. 1980). For example, a scientist claiming a cure for AIDS will have to demonstrate that the invention is effective for that purpose in humans. Thus, whether the biotechnology invention has definite and known utility outside of future research, which may be difficult to surmise in the early stages of research, is an issue that biotechnology inventors must overcome in order to receive patent protection for their inventions. *Compare*

Jolles, 628 F.2d at 1324 (utility sufficiently shown where treatment was effective on 53 of 100 human patients, and on lab animals) *with In re* Buting, 418 F.2d 540 (C.C.P.A. 1969) (utility insufficiently shown where treatment effective on only 2 types of cancer yet claimed effective for 7 types).

Also, in much of biotechnology the starting materials, such as the DNA sequence incorporated into a vector, are not useful until they actually produce the useful protein. Mossinghoff, *supra* note 8, at 311. However, courts have not adhered to a strict interpretation of the utility requirement in these instances thus far. Ihnen, *supra* note 3, at 412. For instance, the utility of intermediaries such as DNA vectors depends upon the utility of the final product. *Id.* Hence, the utility requirement hurdles are generally minimal but may prove more challenging for some invention types.

45. 35 U.S.C. § 102 (1988). Under section 102 of the Patent Code, a patentable invention must be novel, meaning that the claimed invention must not "exist" already. *Id.* Section 102 states:

> A person shall be entitled to a patent unless— (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or (c) he has abandoned the invention, or (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or (f) he did not himself invent the subject matter sought to be patented, or (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102 (1988); *see also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). All features of the claimed invention must have been disclosed in order to "anticipate" and hence invalidate the claimed invention (or deny the patent). American Seating Co. v. National Seating Co., 586 F.2d 611, 618 (6th Cir. 1978).

A product or process is novel, for purposes of the Patent Act, as long as it is not found in nature or other prior art in that *exact* form. PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (5th ed. rev. 1988). The underlying rationale for this requirement is that an inventor should not be permitted to monopolize something that the public is currently enjoying. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

This requirement usually is met readily because most naturally-occurring biotechnology-related products are "re-worked" to a state that is not found in nature. *See, e.g.*, Hormone Research v. Genentech, 708 F. Supp. 1096, 1101 (N.D. Cal. 1988) (HGH made by Genentech structurally different from natural HGH), *aff'd, vacated, and remanded*, 904 F.2d 1558 (9th Cir. 1990). Most human proteins are found in minute quantities in the human body. Consequently, if the protein is isolated and purified, it will be distinguishable from its natural counterpart and patentable due to its purity. *In re* Kratz, 592 F.2d 1169 (C.C.P.A.

ous.[46] These and other requirements pose potential problems in their application to biotechnology.[47] However, the most ominous of

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1979) (pure form of strawberry flavor not obvious) (citing *In re* Bergstrom & Sjovall, 166 U.S.P.Q. (BNA) 256, 262 (C.C.P.A. 1970)). "Pure material is necessarily different from *less* pure or impure materials, hence 'pure' materials are 'new' with respect to them." *Kratz*, 592 F.2d at 1173.

Although the novelty requirement readily may be met, the PTO has two tools it may use to deny a patent under the novelty requirement: anticipation and the one-year statutory bar. 35 U.S.C. § 102(a) (1988). A patent claim will be anticipated, and therefore unpatentable for lack of novelty, when all of its elements can be found in a single disclosure (description) that qualifies as prior art under section 102. *Id.* § 102(a)-(b).

Because many biotechnology products are reformed versions of a naturally occurring protein, the novelty hurdle is not as easy for biotechnology inventors to overcome. *See, e.g., Kratz*, 592 F.2d at 1174 (court addressed specific problem of patenting a product that may occur naturally). The court stated that a natural composition anticipates (and hence invalidates) an invention only if 1) the natural composition inherently contains the naturally occurring compound, and 2) the claim broadly encompasses both the known natural composition and the naturally occurring compound. Based upon this reasoning, the court held that the purified form of strawberry flavor was not anticipated by the naturally occurring strawberry flavor. *Id.* A biotechnology inventor can avoid problems with the anticipation issue if he or she diligently defines the differences between the invention and the prior art, including any naturally occurring versions. *See, e.g., Hormone Research*, 708 F. Supp. at 1101 (HGH made by Genentech structurally different from natural HGH).

46. 35 U.S.C. § 103 (1988). *See infra* notes 49-61 and accompanying text (discussing nonobvious requirements and problems the requirement poses to biotechnology).

47. Section 112 of the patent code dictates the disclosure requirements of a patent. 35 U.S.C. § 112 (1988). The disclosure requirements ensure that an inventor had possession of the claimed subject matter on the effective filing date of the patent application. *In re* Herschler, 591 F.2d 693, 700-01 (C.C.P.A. 1979). There are three issues within the section 112 requirement that a patent examiner or court will consider: enablement, best mode, and adequate description. 35 U.S.C. § 112 (1988).

To meet the requirement, there must be a sufficient teaching concerning the subject matter of the claims that would enable one skilled in the pertinent art to make and use the claimed invention. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) (citing Raytheon Co. v. Roper Corp., 724 F.2d 951, 960 (Fed. Cir. 1983)); *In re* Moore, 439 F.2d 1232, 1236 (C.C.P.A. 1971). The scope of the enablement should be commensurate with the scope of the protection sought by the claims. *Moore*, 439 F.2d at 1236. If the methods are known in the art, an inventor need not describe them in the patent in order to meet the enabling requirement. *In re* Wands, 858 F.2d 731, 735 (Fed. Cir. 1988).

To meet the description requirement, an inventor must provide a full, clear, and concise description of the invention in terms that enable one skilled in the pertinent art to make and use the invention without undue experimentation. *Id.* at 737; *In re* Moore, 439 F.2d 1232, 1236 (C.C.P.A. 1971). It is acceptable if some experimentation is still needed as long as it is not undue. *Wands*, 858 F.2d at 736-37; *see also Hormone Research*, 592 F.2d at 1115 (must show by clear and convincing evidence that invention is not enabling, which is a question of law as all claim interpretations are).

The inventor must also describe the best mode he or she knows for making and using the invention. The best mode denotes the one contemplated by the inventor at the time the application was filed. *Hybritech*, 802 F.2d at 1384; Kis-

tler Instrumente AG v. United States, 203 U.S.P.Q. (BNA) 511 (Ct. Cl. Tr. Div. 1979), *aff'd*, 628 F.2d 1303 (Ct. Cl. 1980).

One problem facing biotechnology inventors in meeting the disclosure requirements is describing how to "create" a living organism. *See, e.g., Ex parte* Forman, 230 U.S.P.Q. (BNA) 546 (P.T.O. Bd. App. & Int. 1986) (inventor insufficiently disclosed how to make genetically engineered bacteria since the process would require undue experimentation to make). Such problems are exacerbated if the starting materials are not available to the public or if undue experimentation would be necessary to make the invention. An inventor may meet the enablement and best mode requirements by depositing the living organism in a cell depository. *Wands*, 858 F.2d at 735-36. The cell depository may distribute samples of the organism once the patent issues. *Id.* at 735. A deposit of the organism in a culture bank may be necessary unless the starting organism is readily available to the public. *Id.* The deposited organism may be a starting material, such as a bacteria or phage, or the final patented organism, such as the altered microorganism with special abilities. However, depositing in a culture bank is not always necessary to meet the enablement requirement. *Id.* at 736; *Ex parte* Goeddel, 5 U.S.P.Q.2d (BNA) 1449, 1450 (P.T.O. Bd. App. 1987). If recreating the organism would not require undue experimentation, then a deposit will not be required. *Wands*, 858 F.2d at 736. If a comprehensive and detailed disclosure, which one skilled in the art could follow, is provided, then a deposit will not be necessary to meet the enabling requirement. *Goeddel*, 5 U.S.P.Q.2d (BNA) at 1450; *see also* Ihnen, *supra* note 3, at 427 (if no novel techniques required then deposit unnecessary, but prudent).

Biotechnology inventors may overcome disclosure problems if they draft the description of the invention, including how to make and use the invention, with great care and detail. When microorganisms are involved in the invention, prudence dictates that an inventor deposit several clones of the microorganism in a culture bank. However, the deposit route may not be the best answer for large multicellular animals, such as cows.

The one-year statutory bar also may prevent an inventor from obtaining a patent for her invention. An inventor would be barred if the invention was in "public use" more than one year before the inventor commenced the patent petition. 35 U.S.C. § 102 (b) (1988). However, if the questioned use was experimental in nature, then the one year statutory bar does not apply. Minnesota Mining & Mfg. v. Research Medical, 679 F. Supp. 1037, 1049 (D. Utah 1987). There are limitations to the experimental use doctrine. One may only "test" the product; one may not test the market. *Id.* Further, inventors should obtain confidentiality agreements, where feasible, from those exposed to the invention. *Id.*

An invention may be used in the public domain for experimental purposes for over a year and still be patentable. *Id.* at 571. The parameters of "public use" are hazy: when does experimental use cross over to the public realm? An ancient United States Supreme Court case appears to lay out the law. Egbert v. Lippman, 104 U.S. 333, 336 (1881). To constitute public use: 1) it may be sufficient that only one of the patented articles is publicly used; 2) it may be sufficient that only one person publicly uses the invention, if the use is without limitation, restriction, or agreement of confidentiality; and 3) these rules apply even if the invention is, by its nature, incapable of being used where it can be seen. *Egbert*, 104 U.S. at 336, *quoted in* Minnesota Mining & Mfg. v. Research Medical, 679 F. Supp. 1037, 1049 (D. Utah 1987).

The court in *Minnesota Mining* held that surgeons using a catheter similar to the claimed invention constituted public use. *Minnesota Mining*, 679 F. Supp. at 1049. This case demonstrates how public use, by one other than the inventor, of a device similar to the inventor's may be cited against the inventor. Such public use has the same negative effect on patentability as public use of the very same invention in question. In light of this prior art, the court denied the patent application on the grounds of obviousness. *Id.* at 1057. The court stated that "any non-secret use of the completed and operative invention or

these is the section 103 nonobviousness requirement.[48]

The Patent and Trademark Office ("PTO") will not grant a patent if the subject matter of the invention, taken as a whole, would have been obvious at the time of the invention to a person of ordinary skill[49] in the pertinent art, such as someone with a general understanding of the relevant science to which the invention pertains.[50] In *Graham v. John Deere Company*,[51] the United States Supreme Court formulated a tripartite approach to be followed when determining whether an invention is obvious.[52] First, a trial court or patent examiner at the PTO, whichever the case may be, must consider the scope and content of the existing teachings in the

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discovery in its natural and intended way is a public use . . . ." *Id.* at 1049. The application of this requirement to biotech is no less hazy than to other inventions.

If an inventor is careful about publicly using his or her invention, then this aspect of the utility requirement will not impede obtaining a patent. There is much debate concerning the conflict between the academic ethic of early disclosure and sharing research versus the patent and commercial practice of secrecy. *See generally* Note, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. LEGIS. 191 (1987) (thorough discussion of issues involved).

48. 35 U.S.C. § 103 (1988). Section 103 states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103 (1988).

Section 103 is essentially a codification of the principals enunciated in Hotchkiss v. Greenwood, 11 U.S. (How). 248 (1851). Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

49. This hypothetical person is assumed to be familiar with all the relevant prior art. Orthopedic Equip. Co. v. United States, 702 F.2d 1005 (Fed. Cir. 1983).

50. 35 U.S.C. § 103 (1988); *In re* Sovish, 769 F.2d 738, 742 (Fed. Cir. 1985); Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1012 (Fed. Cir. 1983). The nonobvious inquiry is distinguishable from the novelty inquiry in that it does not concern whether the claimed invention already exists in the prior art. *Orthopedic*, 702 F.2d at 1010-11. The novelty inquiry proceeds first. *Id.* If the prior art discloses every claim of the invention sought to be patented, then the patent would be denied and the nonobvious inquiry never confronted. *Id.*

The Federal Circuit framed the obviousness inquiry as "whether a person of ordinary skill in the art, having all of the teachings of the references before him, is able to produce the structure defined by the claim." *Id.* at 1013.

51. 383 U.S. 1 (1965).

52. *Id.* at 17. The approach outlined in *Graham* applies equally to both product and process patents. *See, e.g.*, Santa Fe-Pomeroy, Inc. v. P & Z Co., 569 F.2d 1084, 1091 (9th Cir. 1978) (applied *Graham* test in determining obviousness of claimed process).

sciences relevant to the invention ("prior art").[53] Second, the differences between the prior art and what the inventor claims as his or her invention must be determined. Third, the level of ordinary skill in the pertinent art must be assessed.[54] In making an obviousness determination, an examining court must view the claimed invention as a whole,[55] and avoid using hindsight.[56]

Additionally, the trial court or examiner must examine secondary considerations if present.[57] For example, evidence of a long felt need for the invention and the failure of others to discover the remedy would tend to prove that the invention was nonobvious.[58] The commercial success of the invention and copying by others demonstrate that the invention may not have been obvious.[59] Generating unexpected results should favor a finding that the invention was nonobvious.[60]

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53. *Graham*, 383 U.S. at 17. The "scope of prior art" refers to any references that are reasonably pertinent to the particular problem that the invention addresses. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535 (Fed. Cir. 1983). Sources of pertinent art include publications, common knowledge in the pertinent field, prior patents, and foreign patents. *Id.*

54. *Graham*, 383 U.S. at 17. There are several factors a court or patent examiner may consider in determining the "level of ordinary skill" in the art: 1) the education level of the inventor; 2) the type of problems encountered in the art; 3) prior solutions to those problems; 4) the rapidity with which innovations are made; 5) the sophistication of the technology; and 6) the education level of persons in the art. Environmental Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

55. Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 874-75 (Fed. Cir. 1985). As discussed *infra* note 141 and accompanying text, the *Durden* court improperly applied the rule of considering the invention as a whole. *See* Bender, Griffen & Lipsey, *Patent Decisions of the United States Court of Appeals for the Federal Circuit: The Year 1985 in Review*, 35 AM. U.L. REV. 995, 1005 (1986).

56. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1556-57 (Fed. Cir. 1983).

57. *Graham*, 383 U.S. at 17; *see also* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986) (secondary considerations must be considered before obviousness decision reached); Cable Elec. Prods. v. Genmark, Inc., 770 F.2d 1015, 1026 (Fed. Cir. 1985) (court must examine secondary considerations); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 895 (Fed. Cir. 1984) (evidence of secondary considerations support a conclusion of nonobviousness), *cert. denied*, 469 U.S. 857 (1984); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983) (if present, court must examine secondary considerations).

58. *Graham*, 383 U.S. at 17-18.

59. In Hybridtech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (1986), the claimant was seeking a patent for improving diagnostic kits for diseases. *Id.* at 1368-70. The court looked at the commercial success of these diagnostic kits as a determinative factor in allowing the claim. *Id.* at 1382. The court found that a doubling of sales in one year, from 6.9 million to 14.5 million, of one of the kits, and a 25% market share another kit obtained as a market leader, were important facts showing the nonobviousness of the kits. *Id.*

60. *Id.* at 1382. The *Hybritech* court found that the claimed invention "unexpectedly solved longstanding problems." *Id.* For example, the diagnostic kits performed with a higher degree of accuracy and fewer false positives when de-

In contrast to the United States' 200-year-old patent law,[61] biotechnology truly has prospered only in the last decade.[62] A significant biotechnology achievement involves the production of rare human proteins, such as insulin, in quantities accessible to millions of patients.[63] Other advances include the development of alpha interferon,[64] human growth hormone ("HGH"),[65] and an accurate means for the detection of cancer.[66]

A large part of biotechnology consists of isolating a gene sequence[67] that codes for a desired protein, and then transforming that gene sequence so that it will produce a protein in large, usable quantities.[68] Today there are two standard procedures that dominate biotechnology research.[69] The first is genetic engineering, or recombinant technology. Molecular biologists have developed ways to transfer human genes, which are composed of DNA, into the DNA of bacteria.[70] The resulting bacteria will produce the human

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tecting problems. *Id.* at 1383; *see also Perkin-Elmer*, 732 F.2d at 894 (determining obviousness involves a factual inquiry into unexpected results).

61. 35 U.S.C. §§ 1-376 (1989).

62. For an excellent discussion of the history of biotechnology, see Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1990) (in depth discussion of principals of genetic engineering); *see generally* J. ELKINGTON, THE GENE FACTORY 15-41 (1985) (background and history of biotech).

63. Insulin is used to treat diabetes. M. STRICKBERGER, GENETICS 167 (3d ed. 1985) In diabetics, sugar levels that the hormone insulin normally control are not properly regulated. *Id.* The administration of insulin protects diabetics from possible coma and death. *Id.* at 168.

Genetic engineering has allowed the production of insulin for treatment of diabetes in humans. Researchers have isolated genes that contribute to diabetes in their search for a cure for the disease. Atchison & MacLaren, *What Causes Diabetes*, 263 SCI. AM. 62, 68 (July 1990).

64. Alpha interferon is helpful in treating some cancers and other viruses by controlling the proliferation of dangerous cells. ELKINGTON, *supra* note 62, at 39.

65. HGH promotes body growth, fat mobilization, and inhibition of glucose oxidation. STEDMAN'S MEDICAL DICTIONARY 1302 (24th ed. 1976).

66. One biopharmaceutical company, Immunomedics, has developed a colon cancer detection method that is expected to be approved for the U.S. market. PR Newswire, May 24, 1990. The detection kit, based upon monoclonal antibodies, can detect minute cancers smaller than can be seen by x-rays. *Id.*

67. Deoxyribonucleic acid (DNA), the "molecule of life," resides on chromosomes in sequences which are found in the nucleus of every cell of a eucaryotic organism. RECOMBINANT DNA, *supra* note 5, at 6-8.

68. ELKINGTON, *supra* note 62, at 24-25. In protein synthesis, RNA transports genetic information from the DNA to cytoplasm, where protein production occurs. RECOMBINANT DNA, *supra* note 5, at 32-37 & 49-50; *see also* Crick, Barnett, Brenner & Watts-Tobin, *General Nature of the Genetic Code for Proteins*, 192 NATURE 1227 (1961).

69. Armitage, *supra* note 25, at 54-55. For a discussion of these two procedures, see *infra* notes 70-77 and accompanying text.

70. Armitage, *supra* note 25, at 55. Vectors are used for cloning foreign genes. RECOMBINANT DNA, *supra* note 5, at 67-68 & 189-97. Plasmids, a type of vector, are autonomously replicating "minichromosomes" that are circular and often mobile. *Id.* at 24.

protein coded for by the human DNA.[71] Scientists use these recombinant proteins to create new drugs for the treatment of deficiencies in humans.[72]

The second basic procedure in biotechnology concerns isolating and purifying monoclonal antibodies.[73] Antibodies are key elements in the human immune system and are used to develop vaccines.[74] The antibodies are termed monoclonal because they have been cloned from a single, isolated and purified antibody.[75] Monoclonal antibodies are used for the accurate and quick detection of cancer, viruses, and other antigenic substances.[76] By the 1990's, these two processes have become well-known to molecular biologists, and their use is widespread.[77] Because the biotechnology industry employs these "old" processes to create new products, the nonobvious requirement of section 103 often proves an insurmountable hurdle to obtaining patent rights.[78] The PTO has in fact denied process patents on this basis.[79]

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71. *See* RECOMBINANT DNA, *supra* note 5, at 9 (each protein and enzyme has a single corresponding gene).

72. *See generally* Barkstrom, *Recombinant DNA and the Regulation of Biotechnology: Reflections on the Asilomar Conference, Ten Years After*, 19 AKRON L. REV. 81, 81-87 (1985) (recounting history and description of genetic engineering).

73. An antibody is a disease fighting compound found in the body. ELKINGTON, *supra* note 62, at 28. The immune system responds to pathogens such as a bacterium or virus by producing antibodies. *Id.* For a detailed discussion of the genetic research on the AIDS virus, see Mills & Masur, *AIDS-Related Infections*, 263 SCI. AM. 50 (August 1990).

74. RECOMBINANT DNA, *supra* note 5, at 117-24; ELKINGTON, *supra* note 62, at 28.

75. ELKINGTON, *supra* note 62, at 29. Purifying a culture, usually blood or urine, that contains many antibodies to retrieve the specific antibody needed was virtually impossible ten years ago. *Id.* However, today's advances permit scientists to create an extremely pure antibody solution. *Id.*

76. *Id.*; *see, e.g.*, Stagnaro-Green, *Detection of At-Risk Pregnancy by Means of Highly Sensitive Assays for Thyroid Antibodies*, 11 J. AM. MED. A. 1422 (1990) (study showing efficacy of immunoassays in detecting at-risk pregnancies).

77. As researchers well know, retrieving a gene sequence is an arduous task requiring years of labor to accomplish. *See, e.g.*, Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989) (EPO took many years to develop).

78. *See supra* note 48 (citing 35 U.S.C. § 103 (1988)).

79. *See* IBA STATEMENT, *supra* note 8, at 4-6 (IBA conducted survey at Patent Office regarding *Durden* rejections of biotech claims). The IBA concluded that the application of *Durden* has had a chilling effect on the biotechnology industry. *Id.* at 6; *see also* Graham v. John Deere Co., 383 U.S. 1, 25 (1966). Some biotechnology inventions have been disqualified from patent protection because retrieving the gene would be obvious due to the fact that the method of retrieval is well-known and because certain properties of the protein may be known in the relevant art. *See, e.g.*, Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989) (process and product patents denied as obvious where recombinant DNA technology well-known in art and where product already disclosed in prior art).

Inadequacies in U.S. trade laws are also problematic to the biotechnology industry. The first Congress passed the Tariff Act of July 4, 1789 to encourage and protect manufacturers.[80] Since then, Congress has amended and supplemented the Act with over 200 statutes.[81] Congress recently amended section 337 of the Tariff Act of 1930[82] to extend protection to process patents.[83] Unfortunately, the amendment does not cover the importation of a product made overseas from a patented starting material.[84] This oversight opens the door for unfair trade practices.[85]

Because patent rights are key incentives to researchers, the present deficiency in patent protection will be detrimental to biotechnology advancement. Therefore, legislative action is necessary to eliminate, effectively and promptly, patent disincentives currently at work.

III. INADEQUACIES IN U.S. LAWS IN PROTECTING BIOTECHNOLOGY AND THE EFFICACY OF THE BPPA

A. Denial of Patent Protection for Processes Involving Nonobvious Starting Materials and Final Products

The PTO grants patents for new and useful processes and useful improvements thereof.[86] A process is a series of steps that leads to a useful result.[87] The scope of a process patent is more limited than that of a product patent in that process patent protection extends only to the specific process claimed, while product patent protection encompasses the product and its use and sale, regardless of

80. Speech by E. Re, Chief Judge of the United States Customs Court, *International Bar Association* Conference (Nov. 3, 1977), *cited in Litigation before the United States Customs Court*, 19 U.S.C.A. XVII (1978). Congress has the power to regulate commerce with foreign nations. U.S. CONST. art. I, § 8. Further, a State cannot impose imposts or duties on imports or exports without the consent of Congress. U.S. CONST. art. I, § 10.

81. E. Re, *supra* note 80.

82. 19 U.S.C.A. § 1337 (1989).

83. The ITC has the power to issue a temporary exclusion order if it has reason to believe a violation exists. *Id.* § 1337(e). It can issue a permanent exclusion order upon finding a section 1337 violation. *Id.* § 1337(d). Also, the ITC can issue a cease and desist order against anyone violating or believed to be violating section 1337. *Id.* § 1337(f).

84. *See, e.g.*, Amgen, Inc. v. International Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990).

85. *See, e.g., id.* (Congress did not even consider this issue in debating the BPPA); 4 F.J.S. 1001 (1986).

86. 35 U.S.C. § 101 (1988); *see also* Cochrane v. Deener, 94 U.S. 780 (1877).

87. 2 D. CHISUM, PATENTS § 1.03 (1990). "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 and reduced to a different state or thing." *Id.* (quoting *Cochrane*, 94 U.S. at 780).

how and by whom it is manufactured.[88] Process patents must meet the same requirements of utility, novelty, nonobviousness, and patentable subject matter, as do other utility patents. However, the section 103 nonobvious requirement is threatening to become an insurmountable obstacle for biotechnology researchers seeking process patents. The confused status of the law renders process patent protection for biotechnology processes questionable at best.

1. The Importance of Process Patent Protection

Process patents are a significant form of protection for several reasons.[89] First, U.S. law prohibits the importation into the U.S. of goods that have been "produced, processed, or mined under or by means of a process covered by the claims" of an unexpired U.S. patent.[90] Similar protection results from the expansion of the definition of infringement to include the importation of a product made abroad using a patented process.[91] Process patents may be crucial because certain foreign jurisdictions do not recognize product patents for pharmaceuticals but recognize process patents for making pharmaceuticals.[92]

Second, the additional protection of a process patent[93] would encourage a more complete disclosure of an invention, such as describing the process by which the starting materials interact most efficiently.[94] Some commentators have expressed a fear that grant-

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88. Amgen, Inc. v. Chugai Pharmacuetical Co., 706 F. Supp. 94, 103 (D. Mass. 1989) (citing United States v. Studiengesellschaft Kohle, 670 F.2d 1122, 1127 (D.C. Cir. 1981)).

89. *See* Murashige, *Section 102/103 Issues in Biotechnology Patent Prosecution*, 16 AM. INTELL. PROP. L.A.Q.J. 294, 309-10 (1988-89) (outlining reasons for importance).

90. Tariff Act of 1930, 19 U.S.C. § 1337(a) (1988) (as amended in 1988); *see also Certain Indomethacin*, Inv. No. 337-TA-183 (1986). If the ITC determines that there has been a violation of section 337, then it may issue an exclusion order or cease and desist order. Swecker, *U.S. ITC Law Is Amended to Strengthen Section 337 Protection*, 3 EUR. INTELL. PROP. REV. 95, 95 (1989). The penalty for violating an exclusion order is $100,000 per day or the value of the goods, whichever is greater. *Id.*

Other amendments to the Tariff Act include, inter alia: the complainant need not show the efficient operation of manufacture in the U.S., and the complainant need not show economic injury if it is a process patent that is being infringed. *Id.* A plaintiff must show only that the importation of an item is an unfair trade practice. 35 U.S.C. § 1337(a)(1)(B) (1988).

91. Omnibus Trade and Competitiveness Act, 35 U.S.C. § 154 (1988) (as amended in 1981); *see also* 35 U.S.C. § 271(g) (1988) (defines infringement as importation into or use or sale within the U.S. of a product made by a process patented in the U.S.).

92. Murashige, *supra* note 89, at 310. Such restrictions still exist in China, most of the Eastern bloc, and South America, although it is on its way out. *Id.*

93. This is in addition to patents covering starting materials and final products.

94. *In re* Mancy, 499 F.2d 1289, 1294 (C.C.P.A. 1974) (increased knowledge of discovery and access to new starting material serves public interest); *In re*

ing a process patent in addition to a product patent unjustifiably augments an inventor's exclusive rights; however, this type of patent protection exists already under section 271 of the Patent Code.[95] Thus a process patent will not be a significant extension of already existing patent rights.[96]

Third, the granting of process patents will reduce the incidence of "inventing around" patented starting materials. In the biotechnology field, it is relatively easy to modify patented starting materials to circumvent existing patent claims.[97] Possessing a process patent would allow a biotechnology inventor to block this sort of unfair practice. Finally, the added protection will eliminate unfair trade practices currently in operation that allow a company to manufacture abroad and import to the U.S. a product, often in the form of a drug or pharmaceutical, derived from patented starting materials.

2. *Current Law on Process Patents*

The present law on process patents for claims based on new starting materials used in old processes offers little guidance to attorneys and inventors. The Patent Code does not address the issue specifically, and the case law is disconsonant.[98] The confusion originates from several early decisions of the Court of Customs and Patent Appeals ("CCPA") that held that the mere existence or use,

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Kuehl, 475 F.2d 658, 666-67 (C.C.P.A. 1973) (disclosure increases "wealth of technical knowledge"). *But see* 2 D. CHISUM, PATENTS § 5.04(8) (1990). Professor Chisum questions whether method of use claims will necessarily "significantly increase" quality of disclosure, especially where the use is obvious. *Id.* § 5.04(8), at 5-361. He notes that some disclosure is already required to meet the section 101 utility requirement. *Id.* § 5.04(8), at 5-361 n.13.

95. 35 U.S.C. § 271 (1988); Bender, Griffen & Lipsey, *Patent Decisions of the U.S. Court of Appeals for the Federal Circuit: The Year 1985 in Review*, 35 AM. U.L. REV. 995, 1005 (1986); *see, e.g., Kuehl*, 475 F.2d at 666 (granting process patents does not materially increase scope of protection which already includes right to exclude others from making, using, or selling the claimed composition).

The possibility that double patenting may result may be eliminated by terminal disclaimers. 2 M. ADELMAN, PATENT LAW PERSPECTIVES § 2.8(5), at 792-93 (1990).

96. *But see* D. CHISUM, *supra* note 94, § 5.04(8), at 5-365 (discussing situations where process patent may provide additional protection).

97. IBA STATEMENT, *supra* note 8, at 2. For example, a scientist may use: 1) a different phage to transport the genetic information; or 2) different enzymes to splice the genetic information; or 3) a different host cell to manufacture the recombinant protein; or 4) the patented sequence attached to additional genetic information. *See* Daily Report for Executive (BNA) A-2 (Feb. 8, 1990) (quoting Sen. Boucher).

98. The subjective nature of a section 103 obviousness inquiry worsens the situation. Wiseman, *Biotechnology Patent Practice: A Primer*, 3 AM. INTELL. PROP. L.A.Q.J. 394, 409 (1988-89); *see also In re* Durden, 763 F.2d 1406, 1411 (Fed. Cir. 1985) (section 103 inquiry unpredictable and must be done on case-by-case basis).

in an otherwise obvious process, of novel and nonobvious starting materials is insufficient to render that process patentable.[99] In these cases, the PTO and courts assumed that the applicant's disclosure of the new material could be used to determine the obviousness of the process incorporating or resulting in the material.[100] In other words, these courts deemed the new starting materials or the final product part of the prior art for purposes of a section 103 inquiry for the claimed process.

A later line of precedent emerged that observed a more liberal standard. The CCPA in *In re Kuehl*[101] allowed patents for old processes that employed new and nonobvious starting materials if their use in that process would not have been obvious to one skilled in the art.[102] This and subsequent opinions emphasized the impropriety of considering the new material as part of the prior art when making a section 103 determination for the process.[103]

According to the *Kuehl* court, the focus of a section 103 inquiry should be whether it would have been obvious to one of ordinary skill in the art to use the nonobvious starting material to achieve the final product.[104] The court abolished the practice of considering

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99. For cases discussing the insufficiency of existence or use of novel or nonobvious starting materials, in an otherwise obvious process, to render the process patentable, see generally *In re* Neugebauer, 330 F.2d 353 (C.C.P.A. 1964); *In re* Albertson, 332 F.2d 379 (C.C.P.A. 1964); *In re* Hoeksema, 399 F.2d 269 (C.C.P.A. 1968); *In re* Kanter, 399 F.2d 249 (C.C.P.A. 1968); *In re* Larsen, 292 F.2d 531 (C.C.P.A. 1961); *In re* Saunders, 154 F.2d 693 (C.C.P.A. 1946); *Ex parte* Wagner, 88 U.S.P.Q. (BNA) 217 (P.T.O. Bd. App. 1950).

100. *See* D. CHISUM, *supra* note 94, § 5.04(8), at 5-360 (courts used inventor's teachings of new material in obviousness determination).

101. 475 F.2d 658 (C.C.P.A 1973) (opinion by Giles Rich, J., with Markey, Almond, Baldwin, and Lane, J.J., joining).

102. The court in *Kuehl* upheld the patentability of a conventional process that employed a novel starting material and resulted in a novel product. *Id.* The applicant in *Kuehl* obtained a patent for a novel zeolite, ZK-22, but the PTO rejected his process claim for using ZK-22 to crack hydrocarbons. *Id.* at 660. The examiner based the rejection on a prior art reference that disclosed the cracking of hydrocarbons using another class of zeolites, and the applicant's failure to show unexpected results using ZK-22. *Id.* at 660.

See In re Kerkoven, 626 F.2d 846 (C.C.P.A. 1980) (reversed section 103 rejection); *In re* Richman, 563 F.2d 1026 (C.C.P.A. 1977); *In re* Werthheim, 541 F.2d 257 (C.C.P.A. 1976) (reversed section 103 rejection), *later proceeding*, 646 F.2d 527 (C.C.P.A. 1981); *In re* Way, 514 F.2d 1057 (C.C.P.A. 1975); *In re* Wadlinger, 496 F.2d 1200 (C.C.P.A. 1974); *In re* Geerdes, 491 F.2d 1260 (C.C.P.A. 1974) (reversed section 103 rejection); *In re* Schneider, 481 F.2d 1350 (C.C.P.A. 1973) (reversed section 103 rejection).

103. The *Kuehl* court stated that *In re* Saunders, 154 F.2d 693 (C.C.P.A. 1946); *In re* Larsen, 292 F.2d 531 (C.C.P.A. 1961); and *In re* Albertson, 332 F.2d 379 (C.C.P.A. 1964) were inconsistent with section 103 standards in that the courts considered the properties of the compound to determine the obviousness of the process. *Kuehl*, 475 F.2d at 665. Thus, *Kuehl* effectively overruled *Saunders*. D. CHISUM, *supra* note 94, § 5.04(8), at 5-360.

104. *Kuehl*, 475 F.2d at 663.

the new starting material as prior art for purposes of this inquiry.[105] Specifically, the court in *Kuehl* found that, although it was known that zeolites were useful in cracking hydrocarbons, because the properties of a newly discovered zeolite would not have been known, its use for the cracking of hydrocarbons was not obvious.[106]

The logical extension of *Kuehl* is that if the starting materials are nonobvious, as determined by the PTO or a court, then the process employing the starting materials is necessarily nonobvious. However, the court avoided laying down a general rule and limited its holding to the fact pattern before it.[107]

Much later, in *In re Durden*,[108] the Federal Circuit, without stating so, regressed to the previous approach of considering any new materials as prior art in a section 103 inquiry concering the claimed process.[109] As a result, a more stringent nonobviousness standard has re-emerged, thwarting attempts to obtain process patents.[110]

The issue in *Durden* was whether a chemical process, otherwise obvious, was patentable because either or both the specific starting material employed and the final product obtained is novel and nonobvious.[111] The Federal Circuit affirmed the PTO's rejec-

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105. *Id.* at 662. The court quoted *In re* Prater, 415 F.2d 1393, 1393 (C.C.P.A. 1969), for the proposition that an invention "should be considered as part of '*the subject matter as a whole*' and *not* part of the prior art." *Id.* (emphasis in original).

106. *Id.* at 663. The court noted that ZK-22 was not a "homologue, isomer, or chemical analogue" of the prior art zeolites and pointed to two undisputed differences between ZK-22 and the prior art class of zeolites. *Id.* at 663. The court distinguished *In re* Albertson, 332 F.2d 379 (C.C.P.A. 1964), because the claimed (and rejected) process in that case involved the use of a common reducing agent to reduce the new and patented compound to create the new and patented reduced version of the compound. *Id.* at 665-66. While the invention in *Kuehl* involved the properties tied to the use of a new catalyst. *Id.*

107. *Id.* at 661-62 (court refused as too broad applicant's proposed rule that allowance of composition claims necessarily entitles applicant to patent for method of using composition).

108. 763 F.2d 1406 (Fed. Cir. 1985) (Rich, J., wrote the opinion with Markey and Nichols, J.J., joining).

109. PATENT LAW PERSPECTIVES § 2-796.1 (1989). The *Durden* court asserted that *Kuehl* was readily distinguishable from the facts in *Durden*. *Durden*, 763 F.2d at 1410. The process in *Kuehl* involved cracking hydrocarbons using a novel catalyst. *Id.* Presumably, a chemist of ordinary skill would not have predicted this cracking. Whereas the process in *Durden* supposedly would have been obvious (and predictable) to a chemist of ordinary skill. *See id.*

110. *See, e.g.*, *Ex parte* Kifer, 5 U.S.P.Q.2d (BNA) 1904 (P.T.O. Bd. App. 1987) (roof flashing process obvious despite use of nonobvious starting material); *Ex parte* Goodall, 231 U.S.P.Q. (BNA) 831 (P.T.O. Bd. App. 1985).

111. *Durden*, 763 F.2d at 1408. In *Durden* the inventor obtained patents for the starting materials, novel oxime compounds, and the final product when these were reacted, novel carbamate compounds. *Id.* at 1407. The PTO based its rejection on cited prior art that involved the same process completed with similar reactants. *Id.* (PTO cited *Punja*, U.S. Patent No. 3,843,669). The *Punja* process and the *Durden* process both involved reacting an oxime group to form a

tion of the process claim.[112] The court reasoned that the nonobviousness and novelty of starting materials and final products do not necessarily render an otherwise conventional process patentable.[113]

The court distinguished *Kuehl*, explaining that the process of concern in *Kuehl* was not predictable on the basis of "mere possession" of the novel starting material, while in *Durden*, the outcome of the process as applied to the novel compound was predictable.[114] The court found the facts before it indistinguishable from the facts in a 1964 case,[115] which involved the same reduction process.[116] It appears that the similarity of the fact patterns explains the otherwise superficial distinction.[117] Finally, the *Durden* court also declined the opportunity to announce a general rule, holding only for the specific facts before it.[118]

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carbamate ester. *Id.* at 1408. The compounds in *Punja* and *Durden* differed in structure in that the *Punja* compound was a 5-member ring and the *Durden* compound was a 6-member ring, and the location of the carbonyl groups differed. *Id.* Durden argued that the starting materials in the invention differed from those in the prior art. *Id.* However, Durden failed to show how these differences result in a product other than what one of ordinary skill in the relevant art would expect. *Id.* The PTO noted, and the Federal Circuit agreed, that the result of the claimed process using patented starting materials would have been obvious to a chemist of ordinary skill. *Id.* at 410.

112. *Durden*, 763 F.2d at 1407.

113. *Id.* at 1410. The court stated that the case was indistinguishable from *In re* Albertson, 332 F.2d 379 (C.C.P.A. 1964). *Id.* at 1409. In *Albertson*, the starting materials used and the product produced by the claimed process were novel and nonobvious; however the process claims were rejected as obvious in view of references demonstrating the same chemical process applied to other materials. *Albertson*, 332 F.2d at 382. The court noted that while a process might be *new* it is not necessarily *nonobvious*. *Durden*, 763 F.2d at 1410 (a process may become new with the use of new starting materials, however, this new process may be the expected result of what is done).

The dissent in the lower court *Durden* decision argued that *Albertson* was no longer "viable" after a contrary decision in *In re* Kuehl, 475 F.2d 658 (C.C.P.A. 1973). *Durden*, 763 F.2d at 1410. The majority below disagreed, and simply distinguished *Durden* from *Kuehl*. *Id.*

114. *Id.* at 1410.

115. *In re* Albertson, 332 F.2d 379 (C.C.P.A. 1964).

116. The court in *Albertson* held that the use of nonobvious starting material will not render a process nonobvious. *Id.* The claimed process involved reducing a new starting material to produce a new final product, both of which claims were allowed. *Id.* at 380.

117. For a discussion of why it would be improper to rely on *Albertson*, see *infra* notes 139-40 and accompanying text.

118. The court stated:

> We are sure that there are those who would like to have us state some clear general rule by which all cases of this nature could be decided. Some judges might be tempted to try it. But the question of obviousness under section 103 arises in such an unpredictable variety of ways and in such different forms that it would be an indiscreet thing to do. Today's rule would be likely regretted in tomorrow's case.

Durden, 763 F.2d at 1411. Unfortunately, it is the *Durden* ruling that is so regrettable.

The *Durden* decision is especially threatening to biotechnology, where there exist but a few indispensable processes by which an inventor may produce recombinant proteins.[119] In fact, the PTO often cites *Durden* in its rejection of biotechnology process claims.[120] For example, several issues in *Amgen, Incorporated v. Chugai Pharmaceutical Company*[121] spring from the PTO's rejection of process patent claims based on *Durden*. The PTO rejected Amgen's claim for a process of manufacturing recombinant EPO ("rEPO")[122] using Amgen's patented starting materials.[123]

Very recently the Federal Circuit analyzed the scope of *Durden* in *In re Pleuddemann*.[124] The *Pleuddemann* court reversed the PTO's rejection of the applicant's process claims.[125] The court distinguished *Durden* and found that the case was factually apposite to *Kuehl*.[126] The applicant's processes related to bonding materials and priming surfaces using newly patented compounds.[127]

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119. *See supra* notes 70-77 and accompanying text (discussing standard procedures used in biotechnology). The genius of biotechnology is the application of known processes (e.g., genetic engineering), to create new inventions (e.g., recombinant protein). One method is immunoassay, which determines the presence or amount of antigen in body fluids by employing the ability of an antibody to recognize and bind to an antigen. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1369 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

120. IBA STATEMENT, *supra* note 8, at 4-6; *see, e.g.*, Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 110 (D. Mass. 1989) (PTO rejected process involving recombinant DNA technology under authority of *Durden*). A court may refer to either or both of the following to reject a process patent: 1) prior art concerning the recombinant or immunoassay technology, and 2) general knowledge in the pertinent art of the properties of the desired protein, or final product. *Id.* In *Ex parte* Goodall, 231 U.S.P.Q. (BNA) 831 (P.T.O. Bd. App. 1986), the Board held that even if the applicant's hybridoma and antibody products were patentable, the patentability of the related processes would be in question in light of *Durden*. *Id.* at 831.

121. 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989); *see also* Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990); Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989).

122. Amgen did not obtain a patent for the resulting rEPO because purified EPO had already been patented by Genetics Institute. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1739. It is a fundamental concept in patent law that product patent protection is not limited by the process used to manufacture the product. *Amgen*, 706 F. Supp. at 104. It is the equivalence of the product's ingredients and the substantial similarity of the proportions of those ingredients to another product that determines infringement. *Id.*

123. *Amgen*, 706 F. Supp. at 109 (discussing but not analyzing rejection based upon *Durden*). The patented starting materials include a purified gene sequence, the sequence transformed into a vector, and the host cell transfected with the genetic sequence. *Id.* at 95.

124. 910 F.2d 823 (Fed. Cir. 1990) (Rich, J., again wrote the opinion, which Friedman and Mills, J.J., joined).

125. *Id.* The PTO based its rejection on *Kuehl*. *Id.* at 825.

126. *Id.* at 827.

127. *Id.* at 824. The applicant sought a patent for a process for bonding a polimerizable material to a mineral filler and a method for priming a surface to improve its bonding to certain organic resins. *Id.*

The same process involving similar compounds was well known in the art.[128]

In *Pleuddemann*, the court noted that when making a section 103 determination, the prior art does not include the applicant's new teachings, i.e., the properties of the new starting materials or final product. Unfortunately, the court refused to acknowledge that this was the flaw in *Durden*.[129] Instead, the court asserted that the "real difference" between *Durden* and *Kuehl* resides in the fact that the process in *Durden* was a method of *making* while the process in *Kuehl* was a method of *using*.[130] As discussed in Part IV of this comment, this distinction is superficial and unsatisfactory because, *inter alia*, it may be manipulated with skillful claim drafting.

3. *Durden Should Be Overruled in Favor of a General Rule*

As demonstrated in the previous section, the *Durden* decision further obfuscated an already confused state of law. Unless a reliable and consistent standard to determine the obviousness of a process is fashioned, the future of biotechnology developments may be compromised.[131] There is evidence that *Durden* has had a chilling effect on biotechnology process patent applications.[132] Because biotechnology research involves the use of known processes to create new products, *Durden* seriously threatens the attainability of biotechnology process patents.[133]

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128. *Id.* at 825.

129. *Pleuddemann*, 910 F.2d at 828.

130. *Id.* at 827. The court categorized *Kanter* and *Neugebauer* as process of making claims as well. *Id.* The Industrial Biotechnology Association ("IBA") concluded that *Pleuddemann* "offers no improvement in the current situation for biotechnology . . . ." IBA STATEMENT, *supra* note 8, at 7.

131. 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

132. IBA STATEMENT, *supra* note 8, at 6. Based on *Kuehl*, the PTO routinely rejects certain claims such as those concerning the production of proteins or of monoclonal antibodies. Murashige, *supra* note 89, at 310.

The IBA conducted an independent search at the Patent Office to determine the impact of the *Durden* decision on biotech patent applications. IBA STATEMENT, *supra* note 8, at 5. The IBA found that where product patents had issued but related process patents had been abandoned, 60% of the abandonments were linked to *Durden*, and 40% were dropped after interviews with the PTO. *Id.* Where process claims were issued, two-thirds of these applicants had to overcome initial *Durden* rejections; *Durden* was not at issue in the remaining one-third. *Id.* at 6. These and additional facts led the IBA to the conclusion that the PTO has applied *Durden* inconsistently and that *Durden* has had a chilling effect on the biotech industry. *Id.* at 5 & 6. The use of *Durden* is on the upswing. Wiseman, *Biotechnology Patent Practice: A Primer*, 16 AM. INTELL. PROP. L.A.Q.J. 394, 410 (1988-89).

133. *See supra* notes 70-77 and accompanying text (most biotech process patents revolve around recombinant DNA or monoclonal antibody immunoassay technologies).

Moreover, courts and the PTO have misapplied the decision,[134] while other courts have distinguished or limited *Durden's* application.[135] Commentators have been critical of the decision.[136] In short, the *Durden* decision is an anomaly, rendering the case law inconsistent and uninstructional. As one commentator noted, this issue should be resolved once and for all so that the judiciary may focus its resources on more compelling issues.[137]

It is apparent that *Durden* was wrongly decided. The *Durden* court improperly considered the properties of the new starting materials and final product in determining whether the process involving these compounds was obvious.[138] This approach was forbidden in *Kuehl*, and continues to be proscribed.[139] *Durden* must be overruled either by legislative action or with an *en banc* decision of the Federal Circuit.[140]

The proposed BPPA would overrule *Durden* by providing that a process does not fail for obviousness as long as an essential starting material used in the process is both novel and nonobvious.[141] This provision is not contrary to the protection and purpose of section 103.

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134. *See In re* Pleuddemann, 910 F.2d 823 (Fed. Cir. 1990) (court reversed PTO's rejection based on *Durden*); *In re* Dillon, 892 F.2d 1554 (Fed. Cir. 1989) (court held that PTO's reliance on *Durden* misplaced), *vacated and rev'd on other grounds on reh'g*, 919 F.2d 688 (Fed. Cir. 1990).

135. *See* Procter & Gamble v. Nabisco, 11 U.S.P.Q.2d (BNA) 1241, 1254 (D. Del. 1989) ("*Durden* may properly be viewed as only requiring an overall inquiry into the obviousness of a method or process claim . . .").

136. *See* Murashige, *supra* note 89, at 312 (holding in *Durden* "clearly aberrant"); PATENT LAW PERSPECTIVES § 2-795 (1989) (describing *Durden* as a "disappointing" decision); IBA STATEMENT, *supra* note 8, at 4 ("[v]irtually all legal commentators and practitioners have concluded that *Durden* was wrongly decided and is applied in a fashion that wrongly denies process patent protection").

137. PATENT LAW PERSPECTIVES § 2-792 (1989). The author noted that, since similar exclusive rights already inhere in the product patent, making the fine distinctions in cases such as *Durden* to determine whether a process is obvious, notwithstanding the obviousness of the relevant compound, is a waste of judicial resources. *Id.*

138. *Id.* § 2-796.1.

139. The *Durden* court obviously relied on *Albertson*, *Neugebauer*, and *Kanter* in reaching its decision. However, these three cases were decided before *Kuehl*, which proscribed this approach.

140. An opportunity presented itself in the en banc rehearing of *In re* Dillon, 892 F.2d 802 (Fed. Cir. 1989), where a three judge panel distinguished *Durden* and held that the claimed process was patentable. The Federal Circuit, rather than overrule *Durden*, weakened it by stating that the newness or obviousness of a starting material is just another factor in determining the obviousness of a claimed process. However, the new *Dillon* decision is unlikely to alleviate the deterious influence *Durden* has on biotech process patents.

141. H.R. 3957 § 1, 101st Cong., 2d Sess., 136 CONG. REC. E207 & E213 (daily ed. Feb. 7, 1990).

This provision of the BPPA will facilitate the obtaining of process patents in biotechnology. Molecular biologists using recombinant technology to develop new starting materials that produce useful proteins[142] will obtain adequate protection of the use of these starting materials.[143] Because courts have been reluctant to adopt a similar *per se* rule,[144] it is necessary for Congress to intervene.

The BPPA will not be a panacea for all of biotechnology's woes, and may create its own problems. For example, complications may arise when multiple patents issue that cover the same general process. Also, license arrangements may become more complex, perhaps allowing a patent holder to impose additional fees for the use of a process. Further, courts have cautioned that, based on this reasoning, even simple processes such as heating and dissolving, may be patented if performed on a new material.[145] However, this possibility is minimized because such processes must still meet the novelty and utility requirements of sections 101 and 102 of the Patent Code.[146]

B. Importance of Intellectual Property Protection World-Wide

Protection of intellectual property is crucial to U.S. international competitiveness and trade performance in the field of biotechnology.[147] U.S. pharmaceutical companies lose hundreds of millions of dollars each year as a result of inadequate protection of their patented products.[148] Measures are being taken world-wide, as well as in the U.S., to gain the protection biotechnology-related products need and deserve.[149] Unfortunately, there currently ex-

142. The protein may be patentable by way of its purity, or the protein may have been purified previously—and patented—so that the junior inventor will not get a patent for the final product, but only the process of making it. *In re* Kuehl, 475 F.2d 658 (C.C.P.A. 1973).

143. 136 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Sen. Moorhead). The bill would help U.S. biotech companies to achieve "parity" with international competitors that obtain similar process patents in their home countries. *Id.*

144. *See In re* Albertson, 332 F.2d 379, 381 (C.C.P.A. 1964); *In re* Larsen, 292 F.2d 531, 533 (C.C.P.A. 1961).

145. *See In re* Albertson, 332 F.2d 379, 382 (C.C.P.A. 1964); *In re* Durden, 763 F.2d 1406, 1410 (Fed. Cir. 1985) (quoting *Albertson*).

146. *See* 35 U.S.C.A. §§ 101-102 (1989); *see also supra* notes 45-46 (discussing novelty and utility requirements).

147. Winter, *The Role of the United States Government in Improving International Intellectual Property Protection*, 2 J. L. & TECH. 325 (1987).

148. Mossinghoff, *supra* note 8, at 308 (citing Pharmaceutical Manufacturers Association study).

149. *See generally* Griffen, *Exporting Biotechnology: The Pitfalls*, 3 AM. INTELL. PROP. L.A.Q.J. 542 (1988-89) (analyzing various export regulation); Fuller, *Intellectual Property Rights Associated with Biotechnology: An International Trade Perspective*, 3 AM. INTELL. PROP. L.A.Q.J. 529 (1988-89) (discussing various types of biotech inventions and protections available). The U.S. is involved

ists a serious "loophole" in the United States' intellectual property laws.[150]

While Congress has bolstered *process* patent protection,[151] the trade laws do not extend protection to patented *starting materials*.[152] Although the ITC may exclude from importation products made using patented processes, the ITC does not have jurisdiction to exclude a product that is made with a U.S. patented starting material.[153] In other words, the ITC cannot exclude goods that are derived from patented biotechnology products unless the process of making the final product is patented.[154] The Federal Circuit held that when amending the trade laws to cover process patents, Congress did not consider the possibility of protecting starting materials, thus it would be improper for a court to extend such protection.[155]

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in: 1) negotiations of a Draft Treaty on the Harmonization of Certain Provisions in Laws for the Protection of Inventions; 2) an exchange program of patent examiners with foreign patent offices; and 3) establishing minimum patent standards through the General Agreement on Tariffs and Trade (GATT). Address of Quigg, 38 PAT. TRADEMARK & COPYRIGHT J. 467 (1989).

150. "The trade laws have got to be updated so that the [biotech] pioneers don't take a [beating]." Legal Times, Jan. 8, 1990, at 21, col. 1 (quoting Stephan Lawton, Amgen lobbyist).

151. *See supra* notes 82-84 and accompanying text (describing new laws concerning protection of processes). The law amending 35 U.S.C. § 1335 overruled the Supreme Court's holding in Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527 (1972), where the court held that it is not an infringement under section 271 to make or use a patented product outside of the United States. In that case the court noted that a "clear and certain signal" from Congress is necessary before courts will expand patent protections. *Id.* at 531.

152. In one recent case, the applicant, arguing that the 1988 process amendment extended protection to starting materials, cited language from prior interpretations of section 337 of the Trade Act such that section 337 proscribed "manufactur[ing] abroad by a process which, if practiced in the United States, would infringe" a United States patent. *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906, 1909 (U.S. I.T.C. 1989) (the applicant was Amgen, Inc.), *vacated on other grounds sub nom.* Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990) (Federal Circuit affirmed holding of no protection for starting materials but reversed ITC's dismissal for lack of jurisdiction—dismissal should have been on the merits). The ITC responded that it did not intend to suggest that section 337 covers the use abroad of a process using a patented article. *Id.* at 1539.

153. Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990).

154. 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher). Amgen, Inc., argued that patent protection for a host cell necessarily covered the intracellular processes, such as the production of rEPO. *Amgen*, 902 F.2d at 1534. Thus, such host cells should be deemed processes for purposes of 35 U.S.C. § 1337. *Id.* at 1537. The Federal Circuit, analogizing a host cell with a machine, rejected this argument. *Id.* at 1537-38.

155. *Amgen*, 902 F.2d at 1539-40. The court indicated that Congress should resolve the problem. *Id.* Amgen had referred the court to the legislative history for the 1988 amendment to protect process patents: "[T]he continued broad jurisdiction of the International Trade Commission will help U.S. industry address the unfair activity of foreign competitors who, for example, import prod-

The inability on the part of the ITC to protect patented starting materials is one of the many issues raised in the litigation of *Amgen, Incorporated v. Chugai Pharmaceutical Company*[156] over the right to use and manufacture rEPO. Genetics Institute ("GI") owns the patent covering the purified,[157] "natural" form of EPO.[158] However, Amgen has the patent for the starting materials, including the genetic sequence that codes for rEPO.[159] Thus, neither party may manufacture EPO without infringing the other's patent.[160]

Chugai Pharmaceutical Company of Japan ("Chugai"), is the exclusive licensee of the GI patent and has manufactured rEPO in Japan using Amgen's patented host cells; Chugai has imported the final product to the primed U.S. market.[161] Whereas GI's production of rEPO, under the tradename Marogen, infringes Amgen's patent, Chugai's production abroad and subsequent importation of Marogen does not infringe because section 271 does not cover materials manufactured outside of the U.S. using patented starting materials.[162] Also, the United States Code does not grant the ITC jurisdiction to prevent Chugai from importing Marogen.[163] This policy is inequitable and tantamount to unfair trade practices.

The BPPA will protect biotechnology companies that manufacture their products in the U.S. from similar unfair trade practices in

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ucts manufactured using patented genetic engineering technology." *Id.* at 1539 (quoting statement of Sen. Lautenberg).

156. 706 F. Supp. 94 (D. Mass. 1989); *see also* Amgen, Inc. v. United States Int'l Trade Comm'n, 902 F.2d 1532 (Fed. Cir. 1990); Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989); Amgen, Inc. v. Chugai Pharmaceutical Co., 11 U.S.P.Q.2d (BNA) 1466 (D. Mass. 1989); *In re* Certain Recombinant Erythropoietin, 10 U.S.P.Q.2d (BNA) 1906 (D. Mass. 1989).

157. GI purified the protein based on natural EPO, while Amgen purified EPO by means of genetic engineering. Legal Times, Jan. 8, 1990, at 21, cols. 3-4. The purified protein is the commercially valuable form. *Id.*

158. *Amgen*, 706 F. Supp. at 94. Natural in this sense means that the protein was taken from its natural source and then purified. This is a very inefficient method of obtaining a protein and its uses are limited.

159. *Id.* The starting materials that Amgen has patented include the host cell that winds up expressing for the production of large quantities of EPO. Legal Times, Jan. 8, 1990, at 21, cols. 3-4. Amgen lost its argument that it also has process patent rights to the process of making EPO through recombinant technology. *Id.* Amgen's EPO product, Epogen, accounts for 89% of Amgen's revenues. Los Angeles Times, June 3, 1990, Business Section, at 1, col. 5.

160. "Put simply, Amgen cloned the stuff, but couldn't purify it. Genetics Institute purified the protein; won the first patent on the isolated, pure, homogeneous molecule; but lost the race to clone it." Legal Times, Jan. 8, 1990, at 21, cols. 3-4.

161. The magistrate determined that Chugai's use of host cells to produce rEPO comes within the scope of Amgen's patent. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1779-80. Chugai has entered into a joint venture with Upjohn to sell the EPO product, Marogen. Los Angeles Times, June 3, 1990, Business Section, at 1, col. 5. Sales are pending FDA clearance. *Id.*

162. 35 U.S.C. § 271 (1988).

163. 19 U.S.C.A. § 1337 (1989).

two ways.[164] First, the BPPA will empower the ITC to exclude the importation of products made using a patented biotechnological material.[165] Second, the BPPA will make it an act of infringement to import products made abroad using patented starting materials.[166]

The BPPA will not put U.S. biotechnology companies at an advantage, but merely will allow them to compete on a level playing field. In short, all products sold in the U.S.—including previously exempt imports—will have to respect *all* U.S. patents.[167] American companies will no longer have to compete with foreign companies who have appropriated patented information without permission. The BPPA will serve to remedy the inequities confronting U.S. biotechnology companies. As a matter of simple fairness Congress should enact this provision of the BPPA.

The BPPA will stimulate research and development in the biotechnolgy industry. However, it is not clear why similar import protection should not extend to all patented starting materials.[168] While the need for protection in biotechnology is more urgent, similar protection would be valuable to those in other industries, such as chemistry. In addition, the futures of other sciences may reveal unexpected potential for new products or new cures to diseases. It would be wise to protect such future developments from unfair use as well.

IV. ALTERNATIVE APPROACHES TO THE BPPA

If Congress does not pass the BPPA, several viable alternatives are available. However, none of the alternatives would be as efficacious as the enactment of the BPPA.

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164. H.R. 3957, 101st Cong., 2d Sess., 136 CONG. REC. E207 & E213 (daily ed. Feb. 7, 1990) (statements by Sen. Moorhead and Rep. Boucher, respectively). The BPPA also amends 35 U.S.C. § 271(h) to grant district courts jurisdiction over infringement involving importation. H.R. 3957 § 2(b)(1) (1990).

165. H.R. 3957 § 2(a) (1990).

166. H.R. 3957 § 2(b)(1) (1990).

167. 136 CONG. REC. E207 (daily ed. Feb. 7, 1990) (statement of Sen. Moorhead).

168. "It is not a function of the patent system to favor or disfavor particular technologies." Transgenic Animal Patent Reform Act of 1989: Hearings on H.R. 1556 Before the Subcommittee on Courts, Intellectual Property and the Administration of Justice, 91-92 (1989) (statements of Donald Chisum). Professor Chisum noted that the neutrality of the patent system (i.e., by not making specific exclusions or exceptions for a particular technology) has played a significant role in its success. *Id.*

The IBA has no objection to expanding this provision to include all starting materials. IBA STATEMENT, *supra* note 8, at 9. The IBA, however, noted that legislation enacted to benefit a specific industry is not necessarily unfair. *Id.*

A. Durden Is Distinguishable from Biotechnology Inventions

The reasoning in *Durden* may be distinguished from biotechnology related claims in two ways. For instance, the *Durden* holding appears to apply only to defined chemical reactions.[169] Because biotechnology processes typically are not analyzed as defined chemical reactions, the *Durden* rationale is inapplicable. Further, courts may distinguish *Durden* in that the rationale of *Durden* is inapplicable to biotechnology processes, because, at least at this stage of biotechnological development, scientists have not unraveled the precise processes relating to many biotechnological phenomena.[170]

Based upon current technology, scientists cannot determine the function of a DNA sequence until the sequence has been isolated properly. Only at this point does it become potentially "obvious" that incorporating this sequence into the proper process will produce the expected results. However, even at this juncture, a molecular biologist would not be able to predict what the sequence will do given only the nucleotide sequence, or chemical composition. Genetic technology has not advanced to this level of sophistication.

In effect, too much hindsight is necessary to make the jump that a given genetic sequence will code for a given protein. For this reason a court may readily distinguish the *Durden* case, which apparently concerns predictability on a precise chemical level. Perhaps once genetic technology attains the level whereby scientists can predict the function of a genetic sequence based upon its chemical composition, then the *Durden* reasoning will be applicable. However, the *Kuehl* line of cases adapts much better to biotechnology process claims.

The *Kuehl* reasoning mandates that the novel starting materials used in the claimed process should not be considered in a section

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169. Murashige, *supra* note 89, at 311. *But see Ex parte* Kifer, 5 U.S.P.Q.2d (BNA) 1904, 1906 (P.T.O. Bd. App. 1987) (*Durden* is not limited to chemical cases).

170. Rejections of biotech claims based on *Durden* may have been reasoned in the following manner. All genetic sequences, which are composed of a limited variety of chemicals, are deemed one "class" of compounds. Then, because it is known that when genetic sequences are incorporated into a new host cell, the result is that the sequence will code for and produce its requisite protein, the process may be deemed obvious and not patentable. In simplified terms, it is obvious that a genetic sequence will code for a protein.

However, these simplifications demonstrate that the *Durden* reasoning as applied to biotechnology is flawed. First, many genetic sequences do not code for anything at all (e.g., introns, improperly or randomly isolated sequences, or sequences containing a stop signal). Second, given a random sequence of DNA, it is impossible, at least as technology exists today, to determine what the sequence will do. It may code for a protein. More likely, the sequence is "nonsense" and does not code for anything. To compare the predictable chemical processes at issue in *Durden* with the complex processes involved in protein synthesis is inane.

103 prior art inquiry. Thus, without considering the properties of the new DNA sequence it would be impossible to predict the outcome of using that sequence in a known biotechnology process. The level of technology is such that it is impossible to predict the function of a genetic sequence.[171] Thus, based on the *Kuehl* rationale, in biotechnology when a starting material is novel and nonobvious, its use in an otherwise obvious process would be novel and nonobvious.[172] Therefore, if necessary, a patent applicant should urge that the reasoning in *Kuehl* applies, and that the *Durden* rationale does not.

B. Secondary Considerations

The existence of secondary considerations such as the long felt need for the invention, the failure of others to discover a remedy, commercial success of the invention, unexpected results, and copying by others favor a finding of nonobviousness.[173] As an example, in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,[174] the claimed process concerned the use of monoclonal antibodies in a conventional process usually performed with polyclonal antibodies.[175] The court, in upholding the validity of the process patent, based its holding in large part on the patentee's showing of commercial success and unexpected results.[176]

By showing that his or her invention has generated secondary considerations, an inventor may avoid an obviousness rejection. However, when the patentability of an invention is still being disputed at the PTO, it may be too early for the invention to have generated any secondary considerations.

C. Claim Drafting

Recently, courts and the PTO have been characterizing

171. In contrast, chemists may predict chemical reactions based upon the chemical components of a compound.

172. *Accord In re* Mancy, 499 F.2d 1289 (C.C.P.A. 1974). The *Mancy* court held that an otherwise obvious process for producing an antibiotic using a new microorganism was patentable. *Id.* at 1290. The court noted that the only way the process could be deemed obvious would be by using, improperly, the applicant's very own disclosures concerning the new microorganism. *Id.* at 1293.

173. Graham v. John Deere Co., 383 U.S. 1, 17 (1965); *see also* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). *But see* Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805 (1988) (criticizing increased importance Federal Circuit has given to secondary considerations).

174. 802 F.2d 1367 (Fed. Cir. 1986).

175. *Id.*

176. *Id.* at 1382-83.

processes as either methods of using or methods of making.[177] The former they hold are patentable, the latter are not.[178]

An inventor may avoid *Durden* rejections by characterizing the process claims as a method of *using* a new material, rather than a method of *making* a new material. For example, when claims involve novel DNA sequences, vectors, or host cells, it would be better to claim the method of using these starting materials, as opposed to claiming a method of making a protein (albeit using the new starting materials).

V. CONCLUSION

In view of the tremendous economic and social benefits biotechnology has to offer, in addition to the incentive of staying ahead of international competitors, Congress' priorities should be to advance progress in the biotechnology sciences. Increased patent protection is one available means to promote biotechnology development. The Biotechnology Patent Protection Act, by increasing patent protection, would serve this end.

Congress should pass this Act because the Act would: 1) eliminate confusion regarding the application of the section 103 nonobvious requirements to process patents; 2) allow patents for known processes that employ novel and nonobvious starting materials; and 3) by prohibiting the importation of products manufactured with

177. *See In re* Pleuddemann, 910 F.2d 823 (Fed. Cir. 1990). The *Pleuddemann* court asserted that the "real difference" between *Durden* and *Kuehl* resides in the fact that the process in *Durden* was a method of *making* while the process in *Kuehl* was a method of *using*. *Id.* at 827; *see also In re* Dillon, 892 F.2d 1554, 1570 (Fed. Cir. 1989) (distinguishable from *Durden* because facts concerned method of use of new material, while *Durden* concerned method of making new material), *vacated and rev'd on other grounds on reh'g*, 919 F.2d 688 (Fed. Cir. 1990). Wiseman, *Biotechnology Patent Practice: A Primer*, 3 AM. INTELL. PROP. L.A.Q.J. 394, 410 (1988-89). Mr. Wisemann, a supervisory patent examiner at the PTO, states that in analyzing biotech process claims, an examiner must decide whether the claim falls within the facts of *Durden* and *Larsen* or of *Kuehl* and *Mancy*. *Id.* Then the examiner tellingly explains that under the first pair of cases, a certain biotech process would have been obvious, but not obvious under the second pair. *Id.* Such reasoning is erroneous, and painfully demonstrates the problems *Durden* instigated. An invention is obvious or it is not. The prior art has not changed, thus it is a mystery how the outcome can change. This underscores the importance of claim drafting to avoid phraseology that may connect the process with the *Durden* case.

178. *Plueddemann*, 910 F.2d at 827. The confusion created in making this distinction is evident in this case. The court appears to confuse the issue, or was not careful in its word choice. It quotes the following excerpt: "[I]n our view it is in the public interest to permit appellant to claim the *process* (of use) as well as the *product* . . . to encourage a more detailed disclosure of the specific methods of using the novel composition . . . ." *Id.* at 826 (quoting *In re* Kuehl, 475 F.2d 658, 666 (C.C.P.A. 1973)) (emphasis added). Because the court's decision was based upon the fact that the claimed process was a method of using new starting materials, the court probably did not intend "product" to mean final product, but rather as the starting material compounds.

starting materials patented in the United States, prevent unfair trade practices that hurt U.S. biotechnology companies. In sum, the Act will stimulate and encourage biotechnology advancement by providing needed and deserved protection for biotechnology advancements.

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