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Biotechnology Process Patents: Is Special Legislation Needed?*

Timothy P. Linkkila & Timothy E. Tracy**

Introduction

The human genome project is the largest focused U.S. scientific endeavor since the push to put a human on the moon. Hundreds of millions of taxpayer dollars fund research at the Department of Energy and the National Institutes of Health.¹ The ultimate goal is to develop and deliver diagnoses and treatments for alleviating human suffering. Initially, research was publicly funded, but, as treatments are developed, there is an opportunity to shift funding from the public to the private sector. For this shift to occur, firms in the biotechnology industry must be able to recoup their research investments and a fair return (in view of the risks) on those investments.

Due to its relative youth, the field is still highly speculative. Industry analysts have estimated that the average cost of discovering and bringing even a conventional drug to market exceeds \$359 million.² Companies cannot be expected to advance such sums without some assurances of return. The biotechnology industry is nevertheless one of the fastest growing in the U.S., with sales of \$2.9 billion in 1990 alone.³ While the U.S. currently leads the world in

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¹ See, e.g., Robert M. Cook-Deegan, *Origins of the Human Genome Project*, 5 Risk 109 (1994) (Table 1).

² See, e.g., Nancy A. Nichols, *Scientific Management at Merck: An Interview with CFO Judy Lewent*, 72 Harv. Bus. Rev. 89 (1994).

³ Senate Comm. on the Judiciary, *Biotechnology Patent Protection Act of 1993*, S. Rep. No. 82, 103d Cong., 1st Sess., at 4 (1993) (hereafter S. Rep. No. 82).

biotechnology research, Germany and Japan are said to have had greater commercial success.⁴

As discussed in more detail by Dr. Murashige,⁵ the two basic ways for private firms to recover costs and a reasonable return on R&D investments are trade secrets and patents. Trade secrets are especially useful for processes, but they are sometimes difficult to maintain.⁶ Also, compared with patents, they may interfere with broad dissemination of information and further research. Unlike owners of trade secrets, patentees must tell others how to practice claimed inventions,⁷ and, while patents can prevent commercial exploitation of claimed subject matter for seventeen years, researchers can build on their disclosures long before.⁸ Thus, patents deserve careful attention from both public and private perspectives.

This paper examines proposed changes to tailor patent law for the domestic biotechnology industry. First, it examines the problem as seen by some members of the industry and bills that have already twice passed the Senate. Then, it reviews major bases for organized opposition; e.g., some feel that, *if* there is a problem, the cures are worse than the disease. Finally, it provides further reasons for believing that passage of current bills is unwarranted.

Background on the Proposed Legislation

The U.S. patent system provides coverage for a host of inventions, including living organisms.⁹ However, while a new microorganism is patentable, its value usually derives not from the microorganism itself

⁴ David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 Denv. U. L.Rev. 174 (1991).

⁵ Kate H. Murashige, *Overview of Potential Intellectual Property for Biotechnology*, 5 Risk 119 (1994).

⁶ *Id.*, e.g., at 131.

⁷ 35 U.S.C. §112 ¶ 1.

⁸ Indeed, research may even be for commercial purposes. *See, e.g.*, 35 U.S.C. § 271 (e) — largely designed to overcome the holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).

⁹ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

but from something it makes. In understanding the problem that concerns members of the biotechnology industry, it is important to distinguish three things: (1) a living entity that may be patentable if it is new and unobvious to those practicing in the field (PT₁), (2) its product (PT₂), and (3) the process whereby PT₁ produces PT₂ (PR). Often, PT₂ is a product such as insulin. If PT₂ and its function are both known, that product is unpatentable. Thus, R&D costs can be recouped only with patent claims covering PT₁ or PR.

Moreover, as also mentioned by Dr. Murashige,¹⁰ if someone holds a U.S. patent on PR, it can be used to prevent others from not only practicing the process in the U.S. but also importing PT₂. However, the Federal Circuit has found that one who holds a patent on PT₁, but *not* on PR, cannot prevent importation of PT₂.¹¹ Thus, inventors of PT₁-type products, to exclude unpatentable end products made abroad, also need protection for PR.

Yet, another Federal Circuit case, *Durden*,¹² has raised obstacles. There, the Court held that patentable starting materials (or novel end products) do not render an otherwise obvious process patentable. While the Court limited its holding to the specific facts of that case,¹³ and the case appears to be inconsistent with an earlier decision more directly applicable to biotechnology processes,¹⁴ the U.S. Patent and Trademark Office (PTO) has used *Durden* regularly to deny claims on processes.¹⁵ Moreover, the Federal Circuit has been unable to resolve the apparent inconsistency in its cases. Although two recent

¹⁰ *Supra* note 5 at 127.

¹¹ *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990) (Amgen filed a complaint with the ITC to prevent importation of an unpatented product, manufactured in Japan using patented genetically engineered host cells. The ITC terminated its investigation for lack of subject matter jurisdiction. The Court vacated and remanded, holding that the ITC should have treated the complaint on the merits and that the claims of Amgen's patent did not cover a *process* for producing the imported product.).

¹² *In re Durden*, 763 F.2d 1406 (Fed. Cir. 1985).

¹³ 763 F.2d, at 1410.

¹⁴ *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974) (a standard technique of culturing microorganisms to produce antibiotics could not be used to render a similar method obvious when the process used a patentable microbe).

¹⁵ *See, e.g., Beier & Benson, supra* note 4, at 176; *see also*, S. Rep. No. 82, at 8.

cases, *Pleuddemann*¹⁶ and *Dillon*,¹⁷ cast doubt on the continuing vitality of *Durden*, neither reverses it. Further, the discussion in *Dillon* was dicta.¹⁸

Moreover, while *Pleuddemann* reversed a PTO rejection of process claims for a known bonding technique using a novel compound, the Court distinguished *Durden* on the basis that it concerned a process of *making* whereas *Pleuddemann* sought a process of *using*.¹⁹ Unfortunately, the process of interest for reasons given above, involves both *using* and *making*, i.e., PT_1 uses PR to *make* PT_2 . Critics maintain that one cannot predict what examiners, members of the PTO Board of Patent Interferences and Appeals (BPAI) or the Federal Circuit will do.

While some two-thirds of PTO process claim rejections based on *Durden* can be overcome,²⁰ this requires a showing of "unexpected results" and often means additional scientific experimentation and negotiation with the PTO. Not only are the costs of such experimentation and negotiation particularly disadvantageous to universities and smaller firms, but the uncertainty is regarded as generally detrimental to the domestic biotechnology industry.²¹

¹⁶ In re *Pleuddemann*, 910 F.2d 823 (Fed. Cir. 1990).

¹⁷ In re *Dillon*, 919 F.2d 688 (Fed. Cir. 1990) (en banc).

¹⁸ "Dicta" indicates that the court did not need to address the issue. Process claims were not before the court, but it stated, 919 F.2d, at 695:

Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old type of process, such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered....
[W]hen any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of Durden. (Emphasis added)

¹⁹ 910 F.2d, at 828.

²⁰ Lisa J. Raines, *Protecting Biotechnology's Pioneers*, Issues in Sci. & Tech., Winter 1991-92, at 33, 35.

²¹ *Id.*

Critics unsatisfied with the way that things have been handled in the courts and agencies, have turned to Congress²² for specially crafted relief.²³ As summarized by Herbert Wamsley in 1992:²⁴

Rep. Rick Boucher... and Sen. DeConcini are sponsoring legislation to amend... the patent code to make it easier to obtain claims for certain processes. The legislation is entitled the "Biotechnology Patent Protection Act of 1991," but covers all fields.... Section 103... would be amended to provide that if a product claim in a patent application is patentable, then the process of making or using the product is also patentable.

Hearings were held on the Boucher-DeConcini legislation in both houses... in 1991, and hearings were held on a predecessor bill in the House in 1990. The Senate Judiciary Committee filed its report in March 1992. Proponents urge that the legislation is needed to remedy problems caused by the manner in which the... PTO... is applying... *In re Durden*.

In September 1992, the Senate passed an amended version²⁵ of the Biotechnology Patent Protection Act of 1991, but the House did not pass an equivalent bill.²⁶ Reintroduced as the Biotechnology Patent Protection Act of 1993, S.298 passed by voice vote on July 15, 1993.²⁷

²² See, e.g., 139 Cong. Rec. S8815-06 (daily ed. July 15, 1993). See also, e.g., Michael W. Blommer, *Washington Letter*, AIPLA Bull., Apr.-June 1993, at 429.

²³ Special protection for a particular industry is not unheard of; see *supra* note 8.

Also, in the 19th Century, land grants were provided to railroads for construction of infrastructure. Such grants have been called patents; see *U.S. v. Northern Pac. Ry.* and *Northern Pac. Ry. v. U.S.*, 311 U.S. 317 (1940).

²⁴ *Intellectual Property Laws and Bills of the 102d Congress, A Legislative Overview*, 39 Fed. B. News & J. 260 (1992).

²⁵ As amended, new Title II of the bill also added an amendment to 35 U.S.C. § 271 to forbid, e.g., importation of a product made by using a biotechnological material, hence filling the gap left by the *Amgen* case discussed *supra* at note 12.

²⁶ *Senate Passes Biotechnology Bill*, J. Proprietary Rts., Nov., 1992, at 22.

²⁷ 139 Cong. Rec. S8815-06 (daily ed. July 15, 1993).

Title I of S.298 primarily provides that:²⁸

[35 U.S.C. § 103] is amended...

(3) by adding at the end thereof the following new subsections:

(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if...

(2) the claimed process is a biotechnological process as as defined in subsection (d)...

(d) For purposes of this section, the term "biotechnological process" means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.

Opposition to the Proposal

At several hearings, opposition to the proposed amendment to § 103 has been voiced by the American Intellectual Property Law Association (AIPLA), Intellectual Property Owners (IPO), the National Association of Manufacturers (NAM) and others, including members of the biotechnology industry itself.²⁹

Such opponents question whether there is a problem warranting any action. First, they point out that capital for biotechnology R&D is far from scarce. For example, it seems that 85 biotechnology companies raised \$3.7 billion in stock offerings in 1991 alone.³⁰ In the same vein, it has been reported that:³¹

²⁸ S.298, § 101, 103d Cong., 1st Sess. (1993). *See supra* note 26 regarding Title II.

²⁹ *But see*, 139 Cong. Rec. S8817-06 (daily ed. July 15, 1993) (statement of Senator Kennedy):

The act is supported by the academic research community as well as the pharmaceutical and biotechnology industries. It enjoys wide bipartisan support. The Bush administration supported the bill, and President Clinton has indicated his support as well.

³⁰ *See, e.g.*, B. J. Spalding, *37 Biotech Firms Raise \$1.3 Billion*, 10 *Biotechnology* 481 (1992).

³¹ Craig W. Johnson, *Recent Developments in Venture Capital Financing for Biotechnology Companies*, C886 ALI-ABA 1, 5 (Biotechnology: Business, Law and

Driven largely by Amgen's tremendous success with EPO, the public stock market for biotech companies caught fire in 1991 and 1992, providing much needed liquidity... This liquidity in turn encouraged limited partners to invest more money.... \$2.6 billion was committed to venture capital funds in 1992, up from \$1 billion in 1991. A significant part of this new money was targeted for biotech investments.

Second, critics maintain that, while pending bills are designed to protect domestic companies from unfair foreign competition, there is no evidence of need.³² They point out, too, that a change in § 103 would benefit domestic and foreign firms equally and that foreign corporations receive more domestic patents than U.S. companies do.³³

Those who oppose amendments to § 103 also point out that, while *Durden* may have caused problems,³⁴

Pleuddemann and *Dillon* have established that *Durden* is not a basis for the automatic or categorical rejection of all process claims, especially those incorporating the use of patentable starting materials, including biotechnological materials.

Others contend that proper application of *Durden* by the PTO would not warrant legislative intervention.³⁵ Also, the PTO seems

Regulation 1993).

In the same ALI-ABA volume, Bruce Alan Mann, *Creative Techniques for Financing Biotechnology*, 25, at 28, also relates:

According to Ernst & Young's Eighth Annual Report on the Biotechnology Industry (1993), during 1992 the net burn rate of public biotechnology companies exceeded \$2.1 billion. Because the public market for traditional equity or debt offerings by even the most highly regarded biotechnology companies has been subject to frequent... extended periods in which financing is virtually impossible, creative financing has become a necessity. As the... Report (p. 50) observed: "Of all the challenges facing biotech CEOs, financing is the most constant.... But necessity has long been the mother of invention in biotech financing. This industry's creativity in financing is second only to its innovation in technology."

³² See, e.g., *Biotechnology Patent Protection Act of 1991: Hearings on H.R. 1417 Before the House. on Intellectual Property of the House Judiciary Comm.*, 102d Cong., 1st. Sess. (1991), at 118-120 (statement of Donald S. Chisum) (hereafter H.R. 1417 Hearings).

³³ *Id.* at 121.

³⁴ Blommer, *supra* note 23, at 430.

willing to cooperate, having already expressed official approval of pending amendments.³⁶ Thus, one might expect corrective action.

Moreover, opponents contend that the biotechnology industry already receives many process patents and that it is poor public policy for a single industry to receive special treatment without showing unique problems.³⁷ They believe that giving special protection to biotechnological processes would "undermine the credibility of our patent system."³⁸ AIPLA, for example, foresees no end to special interests thereafter insisting on having their day on Capitol Hill.³⁹

Even if there is a problem in the biotechnology industry, opponents also believe that still more serious legal problems could be created by amending § 103. They argue that making certain classes of claims per se nonobvious could result in many process patents on otherwise unpatentable inventions⁴⁰ and add uncertainty to patent enforcement.⁴¹ In their view, the scope of existing patents could be eroded, and, without careful examination, new process patents could remove technology from the public domain.⁴² Thus, they predict a flood of litigation to resolve ambiguities should the amendments be enacted.

Looking beyond U.S. borders, opponents are concerned that changes would threaten global efforts to harmonize patent laws and reduce international trade restrictions.⁴³ Indeed, they fear violating both the North American Free Trade Agreement and the agreement on

³⁵ Telephone interview with Mr. E. Anthony Figg, Chair, ABA-Intellectual Property Biotechnology Committee (Nov. 8, 1993).

³⁶ S. Rep. No. 82, at 3 (1993). *See also, supra* note 30.

³⁷ 110 Daily Exec. Rep. (BNA) d18 (1993).

³⁸ H.R. 1417 Hearings, at 430 (statement of Donald S. Chisum).

³⁹ *Id.*

⁴⁰ H.R. 1417 Hearings, at 102 (statement of Donald S. Chisum).

⁴¹ *Biotechnology Patent Protection Act of 1990: Hearings on H.R. 3957 and H.R. 5664 Before the House, on Intellectual Property of the House Judiciary Comm.*, 101st Cong., 1st Sess. (1990).

⁴² H.R. 1417 Hearings, at 172 (statement of John J. Kelly) and at 103 (statement of Donald S. Chisum).

⁴³ H.R. 1417 Hearings, at 121 (statement of Donald S. Chisum).

Trade Related Intellectual Property (part of the General Agreement on Tariffs and Trade). Articles 1709.7 and 27.1 of those respective agreements each provide that patents must be available if an

invention (is) new, result(s) from an inventive step and (is) capable of industrial application... patent rights shall be *available without discrimination as to the field of technology*. [Emphasis added.]

This raises the possibility that, if biotechnology processes get special protection, the U.S. would facially breach those agreements.⁴⁴ Indeed, AIPLA is concerned that the bill, if passed, could reduce expected benefits of these agreements to a “few crumbs” because other countries could respond with legislation making it more difficult for U.S. inventors to receive protection abroad.⁴⁵

Further Thoughts on Special Protection

A few who seek special protection make arguments that are overblown. They suggest that biotechnology was invented in the U.S., but biotechnology has long been used, e.g. to brew beer, ferment wine and make bread. Indeed, Mendel’s famous pea experiments in the early 19th Century can be viewed as the beginnings of modern biotechnology.⁴⁶

Some proponents of pending bills also appear to believe that biotechnology inventions can be protected only by patents.⁴⁷ Yet, for many processes, trade secrets may be preferable. Process patent infringement is often impossible to detect, making enforcement

⁴⁴ Blommer, *supra* note 23 and Michael W. Blommer, *Washington Letter*, AIPLA Bull., Jan.–Feb 1994, at 188.

⁴⁵ Blommer, *supra* note 23, at 432. However proponents maintain that the bill violates neither article because all biotechnology processes are treated equally. *Id.* and Blommer (1994) *supra* note 43.

⁴⁶ See also, Cook-Deegan, *supra* note 1, e.g., at 110.

⁴⁷ One commentator suggests that trade secret protection suffers because, to attract the most skilled scientists, biotechnology companies need to allow their scientists to publish. She also argues that small biotechnology companies require legally recognized property such as patents to raise capital. See Sheryl Rubenstein Silverstein, 66 S. Cal. L. Rev. 937 (1993). Still, it is difficult to see how these points effectively counter the inability to police patents that cover many processes.

difficult at best. That aside, a process finally used commercially may not be the same as one that led to an earlier patent but may be unpatentable over it. Also, institutions with limited resources may find that pursuing more than one patent on essentially the same process is not cost justified.

If the PTO itself is unable to solve problems involving the obviousness of process claims, the Federal Circuit should be allowed further opportunity to deal with them before Congress steps in. Indeed, although the Senate has acted, the House appears to be giving the Court such an opportunity⁴⁸ before voting.⁴⁹

Major pharmaceutical companies do not see a serious problem with the present law. They regard emerging biotechnology as primarily a potent tool for developing drugs.⁵⁰ Their current goal is to discover the active site(s) on biotechnology-produced proteins and to use rational drug design⁵¹ to develop small molecules that mimic the activity of these proteins at less cost. Although rational drug design has been somewhat elusive, as technology progresses, drugs and other biologically active products may commonly be developed this way.

⁴⁸ *Ex parte Ochiai*, 24 U.S.P.Q.2d 1265 (BPAI 1992) is now on appeal. It involves claims directed to a process of making an AB product. The process of introducing A into AB or reacting A with B are standard processes used by practitioners in the prior art for reacting similar A moieties with the same B moiety.

In upholding a rejection of process claims, the Board noted at 1268, that:

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

⁴⁹ H.R. Rep. No. 433, 103d Cong., 2d Sess. (1994).

⁵⁰ Interview with Mr. Charles Caruso, Director of International Patents, Merck & Co., Inc., in Concord, NH (Nov. 8, 1993).

⁵¹ Rational drug design is a process that uses protein structures to determine the active sites for a given protein and uses this data in computer simulation to design organic molecules that "fit" the active sites. It is hoped that by designing compounds in this manner the amount of bench research required to produce an array of similar compounds will be greatly reduced.

End products that do not occur naturally⁵² also offer important intellectual property advantages.⁵³ They are apt to be patentable, and, because such products are marketed, it is relatively easy to determine whether patents are being infringed. Moreover, patents on such products are infringed in any country where they are obtained — regardless of how or where they are made. R&D that focuses on such products generally renders process protection of little importance.

This brings up Title II of the pending bills, a recent addition that has received less attention. It provides that, e.g., use or sale of unpatentable end products made by a patented “biotechnological material” constitutes infringement regardless of where the patented starting material is used. Superficially, this change appears trivial insofar as § 271(g) already provides that sale of an unpatented product made by a patented process, even if done abroad, constitutes infringement.

Yet, Title II is said to suffer the same faults as its companion.⁵⁴ For example, because it lacks safeguards that appear in § 271(g), Title II covers any product made by (or by using) a patented living organism. Thus, unauthorized sale of bread made with a genetically modified yeast or milk from a transgenic cow could constitute patent infringement. One prominent patent attorney has asked on behalf of IPO and NAM:⁵⁵

Does the Congress want bread, milk and all other manner of everyday commodities to come within the patent laws simply because a patented biotechnical material was involved in their production?

⁵² E.g., purified DNA encoding a specific amino acid sequence, a host cell transformed with DNA encoding a specific amino acid sequence or a protein in purified and isolated form.

⁵³ Another advantage is that biotechnology-based therapeutics are very expensive to develop and market compared to synthesized molecules, such as Proscar®.

⁵⁴ Statement of Robert A. Armitage (prepared for June, 1993 hearings concerning H.R.760, the equivalent of S.298) — copy provided by IPO.

⁵⁵ *Id.* at 14.

Summary and Conclusion

The health of a thus-far thriving domestic biotechnology industry is clearly important to the economic well being of the U.S. However, perceived inadequacies in the patent law are said to present obstacles to optimum growth and to encourage free riding by firms abroad. This had led to proposed federal legislation. From our examination of the bills and arguments on both sides, we agree with opponents that there are serious flaws in pending proposals.

One proposal would change the law of nonobviousness to reduce uncertainty, but it could easily create more uncertainty than it resolves. If such a change is warranted in view of basic objectives of the patent system, it is difficult to justify its limitation to biotechnology alone. Attempting to do so may run afoul of new treaty obligations and generally interfere with global efforts to reduce trade barriers and harmonize intellectual property law.

This seems likewise true of a second proposal to reduce free riding by foreign firms. That proposal expands the set of acts that constitute patent infringement and is superficially similar a 1988 amendment, but close consideration reveals a serious lack of safeguards. It is not tailored finely enough and is apt to have serious and unintended domestic consequences.

Thus, we conclude that, at least without substantial revision, the pending Biotechnology Patent Protection Act of 1993 will provide abundant opportunities, even for its proponents within the biotechnology industry, to win a small battle and lose a big war.

