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Steve

Calendar No. 421

102D CONGRESS *2d Session* | SENATE | REPORT 102-260

BIOTECHNOLOGY PATENT PROTECTION ACT OF 1991

MARCH 11 (legislative day, JANUARY 30), 1992.—Ordered to be printed

Mr. BIDEN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 654]

The Committee on the Judiciary, to which was referred the bill (S. 654) relating to an amendment to title 35, United States Code, to provide conditions for the patentability of certain patents for processes, and for other purposes, having considered the same, reports favorably thereon with an amendment to S. 654 in the nature of a substitute and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. CONDITIONS FOR PATENTABILITY; NON-OBVIOUS SUBJECT MATTER.

Section 103 of title 35, United States Code, is amended—

(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and

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

59-010

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"(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—

"(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section; and

"(2)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

"(B) claims to the process and to the machine, manufacture, or composition of matter, are entitled to the same effective filing date, and appear in the same patent or in different patents which are owned by the same person and are set to expire on the same date.".

SEC. 2. PRESUMPTION OF VALIDITY.

The first unnumbered paragraph of section 282 of title 35, United States Code, is amended by inserting after the second sentence "A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.".

SEC. 3. EFFECTIVE DATE.

The amendments made by this Act shall apply to all United States patents granted 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.

I. PURPOSE

The purpose of S. 654 is to amend our Patent Code to afford needed additional protection for process inventions, primarily in the field of biotechnology. S. 654 will eliminate barriers to process patenting thereby increasing innovation and thus stimulating the development of new products and processes.

II. LEGISLATIVE HISTORY

In the 101st Congress, Senator DeConcini and Representative Boucher each introduced the Biotechnology Patent Protection Act of 1990. Representative Boucher introduced H.R. 3957, on February 6, 1990. S. 2326 was then introduced by Senator DeConcini on March 22, 1990. The bills differed only in their effective date.

After introducing these bills, Representative Boucher and Senator DeConcini as well as Representative Kastenmeier, then Chairman of the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, solicited the views of the Department of Commerce. In a July 1990 response letter, the Department expressed agreement with the need for the legislation but voiced objections to the provisions amending section 337 of the 1930 Tariff Act, as well as to title 35 of the United States Code, which would extend enforcement of the rights of a patent claiming biotechnological material used in the manufacture of a recombinant product.

In consideration of the views of the Department of Commerce, Representative Boucher introduced a second bill, H.R. 5664, in the 101st Congress. There was no further action on these bills in the 101st Congress.

In the 102d Congress, Senator DeConcini introduced S. 654, the Biotechnology Patent Protection Act of 1991 on March 13, 1991,

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with Senators Hatch, Kohl, Lautenberg, Specter, and Grassley. Companion legislation, H.R. 1417, was introduced in the House of Representatives by Representative Boucher on the same day. As introduced in the 102d Congress, S. 654 and H.R. 1417 had identical language to H.R. 5664 from the 101st Congress.

In conjunction with the introduction of S. 654, Senator DeConcini also wrote to the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Harry F. Manbeck, Jr., requesting the administration's position on the legislation as well as its views on alternative language proposed by DeConcini. Senator DeConcini expressed concern in the letter that the positive effects of S. 654 would be unnecessarily circumscribed by limiting the legislation to overrule *In re Durden*[1] in cases only where a single patent issues. The result, he contended, may be that examiners in the Patent and Trademark Office could frustrate the intent of the new law by making a restriction requirement.

Senator DeConcini suggested in the correspondence that a possible solution to this problem would be to amend the legislation so that its benefits would also be provided in cases where the product and process become separated by virtue of such a restriction requirement. Thus, recognizing the need to address the potential ramifications of the language of S. 654 as introduced, DeConcini enclosed in his letter to Manbeck the text of a suggested amendment to S. 654.[2]

On June 10, 1991 Wendell L. Willkie II, the General Counsel of the Department of Commerce, responded to the DeConcini letter, outlining the Administration's position on S. 654 and their comments on the suggestive alternative language in the DeConcini correspondence. Willkie stated that the Administration had concluded that common inventorship was not essential as long as there was common ownership of the product and process inventions. However, Willkie asserted that the Administration continued to believe that "different patents issued on the product and on the process of making or using that product must be set to expire on the same date unless a process of making or using a product is an invention separately patentable from the product." In response the Administration stated its support for S. 654 and suggested its own alternative language.

On June 12, 1991 the Subcommittee on Patents, Copyrights and Trademarks held a public hearing on S. 654. On July 25, 1991, the subcommittee reported S. 654 to the full Committee with an amendment in the nature of a substitute that incorporated the suggested language in the Willkie letter. S. 654 as amended favorably passed the Judiciary Committee unanimously on November 21, 1991.

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[1] 763 F.2d 1406 (Fed. Cir. 1985).

[2] The DeConcini proposed amendment contained the following language and would amend sec. 103 of title 35.

> A process of making or using a machine, manufacture, or composition of matter is not unpatentable under this section if the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section, provided, claims to the process and claims to the machine, manufacture, or composition of matter are entitled to the same effective filing date and appear either (a) in the same patent, or (b) in different patents which (1) are owned by the same person, (2) name the same inventor, and (3) are set to expire on the same date.

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III. Discussion

A. BACKGROUND

"Biotechnology" is a broad term coined to encompass man-made processes which manipulate biological components. The Office of Technology Assessment defines biotechnology as "any technique that uses living organisms (or substances from those organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." [3]

Biotechnology is a multidisciplinary science, combining biology and chemistry, material science and physics, computer science and medicine. It is used in diverse industries from pharmaceuticals, agriculture, and veterinary medicine to environmental cleanup and new energy resources. Widely known products made with the use of biotechnology include home pregnancy tests, diagnostic tests for human immunodeficiency virus (HIV), insulin, and sweeteners such as aspartame (the sweetener marketed as Nutrasweet) and the enzyme used to turn glucose into highly sweet fructose.

While the term "biotechnology" is relatively new, man has used processes involving biological organisms for centuries. Yeast is a fungus, familiarly used for fermentation to produce alcoholic beverages and leaven dough. The best beef and pork in the world are the result of selective cross-breeding, more recently with artificial insemination. Penicillin and other naturally occurring antibiotics are commercially produced with micro-organisms and the 1992 Winter Olympic Games produced snow by using organisms that promote ice crystallization.

Today's biotechnology is far more complex than that of yesteryear. In the 1950's Watson and Crick discovered the DNA double helix, a complex molecule made of billions of single atoms, which functions as a genetic template. The basis of much of the biotechnology industry today is the elucidation of relatively minute sections of DNA.

Until the advent of the computer chip and advanced electronics, efforts to determine the makeup and function of these minute sections was essentially trial and error. However, biotechnology has made it possible to create and test molecules of choice with relative precision. And the capability to create these organic molecules has created dramatic breakthroughs in the ability to make human life better.

All living things are composed of cells, from tiny, one-celled bacteria to giant multicellular whales. Each cell contains a complete genetic "blueprint" of the organism encoded in an enormously long molecule called deoxyribonucleic acid (DNA). DNA guides the construction and functions of the organism by directing cellular synthesis of proteins.

Sections of DNA called genes contain chemical instructions that guide the cell's machinery in constructing proteins. Proteins give living things their unique characteristics. Some proteins give structure to living organisms. Others mediate the chemical reactions

[3] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Ownership of Human Tissues and Cells-Special Report." OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987).

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that are necessary for organisms to function. Proteins are sequences of amino acids whose major role is to act as catalysts for chemical reactions in the body. When acting as a biocatalyst, proteins are known as enzymes.

Some people are born with problems with their DNA in certain genes. These genetic defects scramble the coded instructions in the gene, causing the cell to produce a defective protein or no protein at all. This has serious consequences to the health of the individual; if the function of the defective or missing protein is important, the person may die without it. In other cases, normally functioning genes may develop problems due to infection, age, or other factors. These genes may develop abnormal characteristics, leading in some cases to cancer or arthritis.

Because proteins can regulate chemical reactions, determining which specific protein performs which function is vitally important in fighting disease. For example, by preventing a given chemical reaction from occurring by removing or tying up the reaction-specific catalyst, it may be possible to stop the growth of diseased cells. Or, by enabling a given reaction to occur by supplying a missing gene which codes for an enzyme in an organism's own system, an organism's own system can be forced to produce beneficial chemicals, such as insulin. It is this marvel of science that biotechnology has opened up.

Several technologies are available for performing these feats. Today's hot technologies include recombinant DNA and monoclonal antibodies. Recombinant DNA technology uses naturally occurring enzymes to clip out fragments of DNA and then insert the fragment containing a specific gene into a different cell, altering that cell so that it carries a new genetic message. This technology has enabled scientists to successfully generate human insulin with E. coli, which are bacteria inhabiting the human digestive tract.

These micro-organisms then grow at a tremendous rate; some have a generation time of 30 minutes or less. The multiple copies of the microbe produce large amounts of the desired protein. Consequently, proteins that occur in minute quantities in nature can be produced in large quantities through recombinant technology. The proteins produced by the micro-organisms are also free of viral contamination that might contaminate the protein if extracted from human tissue or fluids.

This complex research is expensive and can take many years to yield practical results. It is estimated that it takes an average of 12 years to bring a drug from discovery through final FDA approval.[4] In 1988 the average cost of discovery and bringing a single drug to market exceeded $100 million,[5] and today exceeds $230 million.[6] In combination, private- and government-sponsored research exceeded

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[4] Thompson, "High Cost of Rare Diseases, When Patients Can't Afford to Buy Lifesaving Drugs", Washington Post Health, June 25, 1991.

[5] Lippard, "Molecular Basis of Drug Design," in Biotechnology and Materials Science-Chemistry for the Future 31 (1988).

[6] "Anticompetitive Abuses of the Orphan Drug Act: Invitation to High Prices: Hearing Before the Senate Judiciary Subcommittee on Antitrust, Monopolies and Business Rights," 102d Cong., 2d sess. (January 21, 1992). (statement of John P. McLaughlin, vice president and General Counsel of Genentech, Inc.) (citations omitted).

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$4 billion in 1988, and the industry is growing because of the enormous need for biotech products.[7]

Commercial successes in 1990 garnered the U.S. biotechnical industry sales of $2.9 billion, doubling the sales of 1989 and quadrupling the amount for 1988.[8] However the biotechnology industry faces formidable challenges in continuing this groundbreaking research. Japan has targeted pharmaceutical development as an industry of vital economic importance.[9] Europe invests heavily in biotech research and actually leads in the production of monoclonal antibodies.[10]

B. BIOTECHNOLOGY PATENTING

Because of intense competition, the biotechnology industry relies heavily on intellectual property law to fend off piracy of its inventions. However, patent protection for biotech products is sometimes difficult to obtain under current U.S. law and unavailable in many foreign countries. Without such protection it becomes difficult to recoup R&D costs which, in turn, stifles invention.[11]

Biotech products are often the recombinant versions of a naturally occurring substance usually found in an animal or plant. When the scientific literature or other available information reveals that the naturally occurring version of the protein has been purified to some extent, even if it has not been definitively characterized, a patent for the recombinant version may be denied for lack of novelty. In patent law terms, the product has already been discovered.[12] This may occur even when the amount of the natural product that has been isolated is insufficient for any practical use and the method employed cannot provide practical quantities of the material. Inventors of some recombinant versions of naturally occurring products have found it difficult to obtain adequate patent protection because of the mere existence of literature disclosing incomplete information about the natural protein.[13]

A second hurdle inventors must overcome is that a patent application for a recombinant product may be denied because it is deemed obvious, and thus unpatentable, despite its novelty. In many cases, although the protein has never before been isolated in a substantially pure form or the product is not well characterized prior to the recombinant synthesis, if its basic properties and some aspects of its structure are known, the Patent and Trademark

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[7] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: U.S. Investment in Biotechnology—Special Report." OTA-BA-401 (Washington, DC: U.S. Government Printing Office, July 1988).

[8] "Biotechnology Patent Protection Act of 1991: Hearing on S. 654 Before the Judiciary Subcommittee on Patents, Copyrights and Trademarks," 102d Cong., 1st sess. (1991) (statement of Henri Termeer, president and CEO of Genzyme Corporation on behalf of Industrial Biotechnology Association).

[9] The President's Council on Competitiveness. "Report on National Biotechnology Policy" at 5, Washington, DC (February 1991).

[10] Id.

[11] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989).

[12] See generally, Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A. Q.J. 294, 303-04 (1988-89); Andrews, "Unaddressed Question in the Amgen Case," New York Times, Mar. 9, 1991, sec. 1, at 30, col. 5.

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

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Office may assert that the use of recombinant technology to make a pure form of such a product is obvious. The ability to obtain a patent for a purified version of a protein to block the use of a process to make commercially viable quantities of a recombinant version of the protein has been criticized.[14]

The mere existence of a previously discovered protein should not, by itself, always preclude the issuance of a patent for a recombinantly created version of the same protein. The rationale under which a patent may be granted for a product existing in nature is that in its natural form, such a product is not available and useful to the public without further isolation and purification. The law as currently expressed provides that to be considered obvious:

> the differences between the subject matter sought to be patented *and the prior art* [must be] such that the *subject matter as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[15]

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and its predecessor, the U.S. Court of Customs and Patent Appeals (C.C.P.A.), have reiterated many times that an applicant's disclosure in a patent application cannot be treated as prior art in determining the obviousness of the claimed invention.[16] The court has also emphasized that the invention as a whole must be considered in assessing obviousness.[17] Finally, the court has cautioned that a patentability determination must be made as of the time the invention was made, and not as part of a hindsight reconstruction of the invention given the applicant's disclosure.[18]

Because questions of novelty and obviousness often preclude product patents, the biotechnology industry has become heavily dependent upon process patents. Yet, product patents are generally considered to provide better protection for drugs than process or use patents because the latter two types usually can be circumvented more easily. Additionally, it may be more difficult to detect the infringement of a process patent than the product patent because products are available to the public, but the processes used to make them are kept secret within the walls of a manufacturer.

The biggest problem facing the United States biotech industry is the lack of clarity in the rules for patentability of biotech processes. Sound investment decisions require a degree of economic certainty. The lack of legal certainty for biotechnology process patents, generated from case law, affects the probability of return on

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[14] See Merges & Nelson, "On the Complex Economics of Patent Scope," 90 Colum. L. Rev. 839, 903-04 (1990). See also *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 666 F.Supp. 1379 (N.D. Cal. 1987), modified on reconsideration, 678 F.Supp. 1429 (N.D. Cal. 1988); *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 707 F.Supp. 1547 (N.D. Cal. 1989); *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 724 F.Supp. 690 (N.D. Cal. 1989), aff'd in part rev'd in part, vacated in part, *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, Nos. 89-1541, -1542, -1543, -1646, 1647 (Fed. Cir., Mar. 11, 1991) (LEXIS, Genfed library, U.S. App. file 3925) (reserving for further analysis by the district court the issue whether a patent on a purified protein should serve to block a patent on a recombinant version of the same protein).

[15] 35 U.S.C. 103 (1988) (emphasis added).

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

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

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

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investment and has had a stifling effect on some venture capital investments.[19]

C. CASE LAW

In re Durden

A major defect in U.S. patent case law has led the Patent and Trademark Office to an inconsistent application of *In re Durden*,[20] a nonbiotech patent case, to important biotechnology-derived processes. As recognized by a Patent Office supervisor, the use of this case as a basis for rejecting process patent claims in biotechnology is on the rise.[21] This is so because many examiners have been routinely applying the *Durden* case to biotechnology.

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

The Federal Circuit thus held, on the facts before it, that a process using a patentable "starting compound" to make a patentable "final compound" was not patentable. The Federal Circuit indicated in its opinion, however, that the patentability of each process must be evaluated on a case-by-case basis. In following *Durden*, the Patent and Trademark Office believes that it cannot interpret section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

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

Durden precludes needed patent protection for biotechnology processes and has been roundly criticized by commentators and legal practitioners.[22] Since the *Durden* decision it has become in-

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[19] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989).

[20] 763 F. 2d 1406 (Fed. Cir. 1985).

[21] Wiseman, "Biotechnology Patent Practice—A Primer," 16 A.I.P.L.A. Q.J. 394, 411 (1988–89), see generally Litman, "Obvious Process Rejection Under 35 U.S.C. 103," 71 J. Pat. & Trademark Off. Soc'y (1989); Wegner, "Much Ado About Durden," 71 J. Pat. & Trademark Off. Soc'y 785 (1989).

[22] See Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A. Q.J. 294 (1988–89); Wegner, "Much Ado About Duren," 71 J. Pat. & Trademark Off. Soc'y, 785 (1989); Comment, "The Elimination of Process: Will the Biotechnology Patent Protection Act

Continued

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creasingly difficult to obtain process patent protection in the United States for genetic engineering inventions. Although some inventors overcome *Durden* rejections, the uncertainty in this area of the law has lead to inconsistent results by examiners.

The inconsistent application of *Durden* by the Patent and Trademark Office has led to severe delay or denial of issuance of process patent protection to deserving inventors. The Federal Circuit acknowledges that there have been conflicting views on this issue both in the Patent Office Board of Appeals and in the C.C.P.A.[23]

Moreover, case law exists in this area which conflicts with the *Durden* reasoning and which would be more appropriately applicable to biotechnology process patents.[24] The application of *Durden* by the Patent Office to biotechnology cases, which involve microorganisms, conflicts with *In re Mancy*.[25]

In *Mancy*, the court held that a standard method of culturing microorganisms to produce antibiotics could not be treated as prior art in determining the patentability of a similar method using a patentable microbe to produce an antibiotic therefrom. In other words, novelty and nonobviousness of the microbe imparted patentability to a method using it.

To the detriment of biotechnology process patent applicants, the Patent and Trademark Office has felt constrained to follow *Durden* rather than *Mancy*. Troubling is the fact that the reasoning in *Mancy* is the law for inventions in Europe and Japan, where the patenting of process inventions that use patentable starting materials has long been recognized.[26]

In re Pleuddemann

The Federal Circuit revisited the issue of the patentability of processes in *In re Pleuddemann*.[27] In that case the patentee had a patent to a starting material that he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method (process) of making the final product was admittedly already known. The Federal Circuit held that the method of using the patented starting material to produce the patentable final product was patentable in this particular case.

Although the Federal Circuit attempts to distinguish *Pleuddemann* from *Durden*, it is difficult, if not impossible, to reconcile these two cases. It is not clear why a *method of using a starting material* should be treated differently, for purposes of determining non-obviousness, from a *method of making the end product*. Yet, under *Pleuddemann*, the former is per se non-obvious, while the latter is not.

Revive Process Patents?," 24 John Marshall L. Rev. 263 (1990); McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664," 72 J. Pat. & Trademark Off. Soc'y 1188, (1990); Beier and Benson, "Biotechnology Patent Protection Act," 68 U. of Denver L. Rev. 173 (1991).

[23] *Durden*, 763 F. 2d at 1409.

[24] See, e.g., *In re Mancy*, 499 F.2d 1989 (C.C.P.A. 1974). See also *In re Kuehl*, 475 F.2d 658 (C.C.P.A. 1973).

[25] 499 F.2d 1289 (C.C.P.A. 1973).

[26] "Biotechnology Patent Protection Act of 1991: Hearing on S. 654 Before the Judiciary Subcommittee on Patents, Copyrights and Trademarks," 102d Cong., 1st sess. (1991) (statement of Henri Termeer, president and CEO of Genzyme Corp. on behalf of Industrial Biotechnology Association).

[27] 910 F.2d 823, 15 U.S.P.Q. 2d 1738 (Fed. Cir. 1990).

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

A prudent attorney certainly would seek to use *Pleuddemann* to the client's advantage by rephrasing "a recombinant DNA process of making protein *X*" into a *Pleuddemann*-style process-of-using claim, such as, "contacting DNA with cellular enzymes or with a transcription/translation apparatus." However, it is not clear that such a semantic change would always be successful. For example, an examiner could assert that such a claim was really a process-of-making claim in disguise.

Alternatively, some have argued that given the right case on appeal, the Federal Circuit might, at some future date, reverse *Durden* by applying a *Pleuddemann*-type analysis finding that *making* is also not obvious because the *Durden*-type rejection presumes the new starting material or novel product to be prior art. While this possibility is consistent with the analysis in *Pleuddemann,* there clearly is no certainty that such a future decision will ever occur, particularly as the court has rejected this approach over the past 20 years.

Some had hoped the November 9, 1990, rehearing of *In re Dillon*[28] would provide guidance regarding *Durden* and perhaps overrule it. In very clear dicta, the Federal Circuit summarized its attitude regarding *Durden* as follows:

> Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old *type of process,* such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of *Durden.*[29]

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

Durden-type rejections remain an even greater problem following *Pleuddemann* because the Federal Circuit explicitly avoided ques-

[28] 919 F.2d 688 (Fed Cir. 1990) (en banc).
[29] Id. at 695 (emphasis in original).

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tioning *Durden* as good law, and distinguished *making* and *using* as two different types of process claims.[30] A patent applicant may ask what new route to protect a recombinant DNA process claim is available after *Pleuddemann?* The answer is not clear because *Pleuddemann* does not address that question. One could rephrase *making* claims as *using* claims and then wait years to see whether the Patent Office and the courts will accept this semantic manipulation as a means of avoiding a *Durden*-style obviousness rejection. The committee believes that congressional passage of clear statutory language that explicitly removes the *Durden*-style rejection is a more direct and unambiguous route to protect recombinant DNA method-of-making protein claims.

The Patent and Trademark Office, along with the Industrial Biotechnology Association and other witnesses, has opined that *Pleuddemann* has not clarified the law and leaves patent applicants unable to predict with reasonable certainty whether they can obtain process patents of this nature. Testifying before the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, Commissioner Manbeck stated that, "the distinction between *Pleuddemann,* on the one hand, and *Durden* and *Albertson* [31] on the other hand is esoteric, at best.[32] Appearing with Commissioner Manbeck, the Solicitor of the Patent and Trademark Office, Fred McKelvey, responded affirmatively to Representative Boucher's inquiry that the *"Pleuddemann* decision doesn't do anything to clear up the confusion that exists in the law currently." [33]

Manbeck further testified that the Patent Office will continue to have difficulty during the examination of patent applications relating to processes in resolving the seemingly unnecessary issue of whether a process is one for "making" or "using" a patentable product.

D. SENATE BILL 654

S. 654 amends section 103 of title 35, the Patent Code, to effectively avoid the Federal Circuit decision in *In Re Durden.* S. 654 resolves the *Durden* dilemma by providing that a process of making or using a product will not be considered obvious if the starting material or resulting product is novel and non-obvious. Additionally, S. 654 provides certainty and needed incentives for the biotechnology industry, incentives to grow and not to be deterred by our patent laws. It will allow the United States to continue to lead biotechnology research world-wide and will provide essential protection to an industry that generates billions of dollars for the U.S. economy.

By providing a mechanism to avoid *Durden,* S. 654 provides a solution to another deficiency in our law that has created an obstacle for the U.S. biotechnology industry. Under present U.S. patent law,

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[30] *Pleuddemann,* 910 F.2d at 827.
[31] 332 F.2d 379, 141 U.S.P.Q. 730 (C.C.P.A. 1964).
[32] "Biotechnology Patent Protection: Hearing on H.R. 3957 and H.R. 5664 Before the Subcomm. on Courts, Intellectual Property and the Administration of Justice of the House Comm. on the Judiciary," 101st Cong., 2d sess. 18 (1990) (statement of Harry F. Manbeck, Jr., Asst. Sec. and Commissioner of Patents and Trademarks, U.S. Dept. of Commerce).
[33] Id. at 27.

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the holder of a patent to a host cell would be able to preclude another from using the cell in the United States. However, without patent protection for the process of using that cell, the inventor has no effective remedy against someone who takes the patented host cell to another country, uses it to produce a protein, and imports that protein back into the United States.

The importance of process claim protection is illustrated by Amgen, Inc.'s inability to prevent importation of erythropoietin (EPO) into the United States from Japan by Chugai Pharmaceutical Co. This most controversial and public patent dispute in biotechnology [34] involved the innovative product, recombinant erythropoietin (rEPO), as litigated in *Amgen, Inc.* v. *Chuqai Pharmaceutical Co.*[35] Amgen's patent did not contain a claim to a process of making EPO using patented host cells. The International Trade Commission (ITC) refused to interpret the claims to the host cells alone as constituting a process claim under existing law. Consequently, Amgen was denied relief based upon its patented host cells since the ITC held that such claims to "host cells" per se were not process of making claims.

In this case, Amgen had conducted groundbreaking scientific research enabling it to produce commercially viable commodities of rEPO.[36] This major scientific and medical advance did not, however, give Amgen sufficient patent rights to prevent importation of competing products from Japan even though Amgen's competitors could not produce rEPO within the United States without infringing Amgen's patents.

If at the end of a long and uncertain period of discovery of innovated drug products and development of patented technology, a U.S. innovator must watch helplessly as infringing foreign imitators reap the harvest to which the innovator is entitled, there will be a substantial diminution or elimination of the economic incentives intended to encourage those efforts. Ultimately, the reforms of this legislation are likely to provide sufficient protection to overcome the lack of host cell protection experienced by American companies such as Amgen. However, by providing a mechanism to avoid *Durden*, this legislation provides only a partial solution to the deficiency in our law that created obstacles to U.S. biotechnology companies such as Amgen.

Amgen is not the only entity facing this problem today. There are other small biotechnology companies and universities that have obtained only host cell protection. Indeed, some of these entities may have given up rights to process claims in order to receive protection of the host cell. If the loophole in the patent laws is not closed, these companies and universities could also experience the problem faced by Amgen—competition from a foreign competitor who can do what no U.S. manufacturer may lawfully do. Thus, the

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[34] See, e.g., Andrews, "Mad Scientists", Bus. Month, May 1, 1990, at 54.

[35] 9 U.S.P.Q. 2d 1833 (D. Mass. 1989); 13 U.S.P.Q. 2d 1737 (D. Mass. 1989): 927 F.2d 1200 (Fed. Cir. 1991); 14 U.S.P.Q. 2d 1734 (Fed. Cir. 1990).

[36] Amgen is currently alone on the market with its version of EPO, EOPGEN, because of provisions of the Federal Food, Drug, and Cosmetic Act, § 527, 21 U.S.C. 360 (cc) (1988). Under this act, the sponsor of a new drug or biologic can, if certain market criteria are met, obtain market exclusivity for a period of 7 years. In this case, Amgen obtained market exclusivity because it established that rEPO was a safe and effective therapy for treatment of chronic renal failure, the relevant patient population of which is less than 200,000.

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committee is hopeful that this issue ultimately may be resolved by Congress in the near future.

Although not the primary purpose of the legislation, S. 654 also offers the ancillary benefit of reducing the increasingly high transaction costs associated with patent prosecutions and litigation by providing certainly in the law for both the Patent and Trademark Office and the process patent applicants.[37] The high costs of such litigation may seriously drain the research budgets of biotech companies.[38] Unfortunately, the chilling effect of a process rejection has fallen most heavily upon those who lack the resources to pursue process patents, small companies and universities. The most disturbing potential ramification of inadequate intellectual property protection is that some promising therapies will be pursued.

S. 654 is consistent with the structure of existing law and avoids the unnecessary creation of sui generis forms of intellectual property protection. Unlike the situation faced by Congress in the context of mask work protection, S. 654 does not fundamentally alter the requirements of patentability. Rather, S. 654 clearly modifies the test for obtaining a process patent for all forms of invention. Most importantly, S. 654 is the least drastic alternative to solve a limited problem.

In many respects this legislation is considered a continuation of the Congressional policy behind the Process Patent Amendments Act of 1988. Without appropriate process claims in their patents, biotechnology inventors cannot take advantage of the benefits of the Process Patent Amendments Act of 1988. As a consequence, the advantages of the Process Patent Amendments Act of 1988 are essentially nullified for the biotechnology industry. Finally, S. 654 will make our laws in greater harmony with those of our trading partners.

S. 654 has the support of the administration, the Industrial Biotechnology Association, the Pharmaceutical Manufacturers Association, the National Association of Manufacturers, the National Venture Capital Association, the Association of University Technology Managers, and the America Council on Education as well as numerous universities in their own capacity.

IV. Vote of the Committee

On July 25, 1991, the Subcommittee on Patents, Copyrights and Trademarks, a quorum being present, reported S. 654, with an amendment in the nature of a substitute, to the Committee on the Judiciary by voice vote.

On November 21, 1991, the Committee on the Judiciary, a quorum being present, favorably reported by unanimous consent S. 654 as reported by the subcommittee.

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[37] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report." OTA-BA-370 at 56-58 (Washington, D.C. : U.S. Government Printing Office, April 1989). U.S. Congress, Office of Technology Assessments.

[38] U.S Congress, Office of Technology Assessment, "Commercial Biotechnology: An International Analysis" 403 (1984).

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V. Section-by-Section Analysis

Section 1. Conditions for patentability; non-obvious subject matter

Section 1 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances, a process would not be considered obvious if it either makes or uses a machine, manufacture, or composition of matter that itself is novel and non-obvious. To obtain this determination, the product and process claims must be sought to be patented in the same application. Continuing applications would also be eligible where the specified conditions are met.

The amendment to section 103 would thus provide a mechanism for applicants to avoid a conclusion that a claim directed to a process of making or using a patentable product was obvious under this section, along the line of the decision in *In re Durden,* 763 F.2d 1406 (Fed. Cir. 1985). Process patents granted under 103(c) would not affect an existing process patent right.

With regard to patent terms, section 1 provides that process claims that are granted the benefits of the non-obviousness rule under subsection 103(c) must coterminate with the product claims on which they depend for patentability. The purpose of this provision is to prevent a patent applicant from obtaining an effective patent term in excess of 17 years (and any applicable patent term extension) on essentially a single invention.

The committee does not intend to deprive independently patentable inventions of the patent terms to which they are entitled under current law. Therefore, if an applicant elects to demonstrate the independent patentability of a process, notwithstanding a possible *Durden* rejection, rather than rely on the non-obviousness rule established in the legislation, he or she is entitled to the full 17-year term (and any applicable patent term extension) available under current law for both product and process inventions, without coterminations.

Thus, applicants have the option of either demonstrating the independent patentability of a process (as must be done under current law) or proceeding under the non-obviousness rule established by this legislation. Independent patentability may be demonstrated, for example, by showing the non-obviousness of the process.

Applicants who unsuccessfully attempt to demonstrate independent patentability do not forfeit their right to amend their application to one that relies upon the rule established by this legislation. However, an applicant who so amends his application is required to have his process claims coterminate with his product claims. In such cases, patent term extension will continue to be available to extend the term beyond the termination date otherwise established.

Section 1 would simplify and provide certainty in the determination of patentability of processes using or making novel and non-obvious products, for applicants who comply with its requirements. It would also make our patent law consistent with the patent granting process now practiced in the European and Japanese Patent Offices.

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Section 2. Presumption of validity

Since an applicant may rely on the non-obviousness rule established in this legislation to expedite issuance of his or her process claims rather than risk the costs and delays involved in overcoming a *Durden* rejection, section 2 provides that there is no presumption that process claims are invalid if the product claims, which form the basis for invoking the non-obviousness rule, are invalidated. Any litigation should provide the patentee with the opportunity to prove that the process claims are independently patentable.

Section 3. Effective date

The amendments made by this act are effective on the date of enactment. The amendments affect all patents granted on or after the date of enactment, all patent applications pending on the date of enactment, and all patent applications filed after the date of enactment. Patent applications include applications for reissuance of a patent.

VI. Cost Estimate

In accordance with paragraph 11(a), rule XXVI, of the Standing Rules of the Senate, the committee offers the Report of the Congressional Budget Office:

U.S. Congress,
Congressional Budget Office,
Washington, DC, November 25, 1991.

Hon. Joseph R. Biden, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 654, a bill to amend title 35, United States Code, with respect to patents on certain processes, as ordered reported by the Senate Committee on the Judiciary on November 21, 1991. CBO estimates that enactment of S. 654 would result in no significant costs to the federal government and in no costs to state and local governments. Enactment of S. 654 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

S. 654 would expand the definition of non-obvious for purposes of patentability. The bill also would prohibit the Patent and Trademark Office from holding patent claims invalid solely because the product or inputs themselves lack novelty or are obvious.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb, who can be reached at 226–2860.

Sincerely,

Robert D. Reischauer,
Director.

VII. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has concluded that no significant additional regulatory impact would be incurred in carrying

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out the provisions of this legislation. After due consideration, the committee concluded that the changes in existing law contained in the bill will not increase or diminish any present regulatory responsibilities of the U.S. Department of Commerce or any other department or agency affected by the legislation.

VIII. Changes in Existing Law

In compliance with paragraph 12 of Rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 654 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

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TITLE 35—PATENTS

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CHAPTER 10—PATENTABILITY OF INVENTIONS

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§ 103. Conditions for patentability; non-obvious subject matter

(a) 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.

(b) 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. (Added November 8, 1984, Public Law 98-622, sec. 103, 98 Stat. 3384.)

(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—

(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section; and

(2)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

(B) claims to the process and to the machine, manufacture, or composition of matter, are entitled to the same effective filing

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date, and appear in the same patent or in different patents which are owned by the same person and are set to expire on the same date.

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CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. *A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.* The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

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