

**IN RE DURDEN COMES FULL CIRCLE: THE EFFECT OF THE BIOTECHNOLOGY
PROCESS PATENT ACT AND RECENT FEDERAL CIRCUIT CASES ON
BIOTECHNOLOGY PROCESS PATENTS**

by
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The 1995 Biotechnology Patent Processes Act created amendments to the nonobviousness requirement set forth in 35 U.S.C. § 103² that were directed specifically to obtaining patent protection for biotechnology processes. The purpose of the act was twofold, (1) to clarify Federal Circuit decisions which appeared to be in conflict on the issue, and (2) to negate the harsh effect one Federal Circuit decision had on obtaining patent protection for biotechnology processes.

The courts have heavily on cases relating to chemical process patents in their analysis of biotechnology process patents. However, the application of chemical process patent case law by the United States Patent and Trademark Office's (hereinafter PTO) in its examination of biotechnology process patent applications has posed unique problems for the nascent biotechnology industry. Additionally, the Federal Circuit had failed to address the Patent and Trademark Office's expansive interpretation of certain Federal Circuit cases as applied to biotechnology processes. The goal of Congress in implementing the 1995 Biotechnology Process Patent Act was to negate the difficulty in obtaining patent protection for biotechnology process patent protection while not interfering with the welfare of other industries. However, almost concurrently with enactment of the Biotechnology Process Patent Act, the Federal Circuit rendered opinions which seem to make the amendments to section 103 obsolete for the purpose of obtaining patent protection for biotechnology processes, but yet open the door to potential problems in patent litigation.

Patent protection for biotechnology products and processes

Issues of patentability for biotechnology inventions relate to the individual claims describing the aspects of the invention and the process for obtaining it. These claims may be in the format of product claims, process claims, or product-by-process claims.³ Product claims may be directed to novel protein products, to known protein products which have been purified, or to the DNA sequence of a gene that encodes a particular protein. Process claims may, for example, be directed at the preparation or use of recombinant DNA, the use of bacteria or cultured cells transformed with vectors containing DNA encoding a desired protein product, methods of use for proteins, and methods for production or use of monoclonal antibodies.

¹ Copyright © 1998 Sheldon & Mak, Inc. Special thanks to Jeffrey G. Sheldon for comments regarding this article. James W. Collett is an associate at Sheldon & Mak.

² All Sections (§) refer to Title 35 of The United States Code.

³ See How to Write a Patent Application, 1997, § 14.5.3 p.14-29, Jeffrey G. Sheldon.

The commercial value of biotechnology process claims arises from a unique problem not encountered in the chemical arts. Proteins which are the product of biotechnological processes are often known and naturally occurring and, because of this, product claims can be subject to rejection during prosecution.⁴ Thus process claims can protect the biotechnology product as well as the process where the product is not patentable because it is naturally occurring or obvious under section 103. A process patent is of particular importance where the inventor has not obtained a patent on the resulting product of the process because a foreign competitor will then be prevented from importing the product into the United States.⁵ However under In re Durden, 763 F.2d 1406 (1985), the PTO routinely rejected claims to process for cultivating a patented transformed host cell to produce an unpatentable product.

Analysis of biotechnology claims by the Patent and Trademark Office

Prior to the Biotechnology Process Patent Act, the PTO made it very difficult to obtain biotechnology process claims to genetically engineered starting materials. The PTO regularly applied In re Durden, 763 F.2d 1406 (1985), for the contention that the use of a nonobvious starting material in an old process does not necessarily result in a nonobvious process. In In re Durden, the Federal Circuit addressed the issue of whether the process for making a patentable compound was necessarily patentable itself. Durden was not the first case to address the issue of whether the process for making a patentable compound is *ipso facto* a patentable process but it is the most often cited case supporting the rejection of chemical and biotechnology process claims.

In In re Durden the Federal Circuit court affirmed, and noted the following:

[A]n otherwise old process becomes a *new* process when a previously unknown starting material, for example, is used in which it is then subjected to a conventional manipulation or reaction to produce a product which may also be *new*, albeit the *unexpected* result of what is done. But it does not necessarily mean that the whole process has become *unobvious* in the sense of § 103. In short, a *new* process may still be obvious when considered ‘as a whole’, notwithstanding the specific starting material or resulting product, or both, is not found in the prior art.⁶

⁴ See 35 U.S.C. § 101.

⁵ Under 35 U.S.C. 154 the patent owner is granted “the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process.”

⁶ 763 F.2d at 1410-1411, 226 USPQ at 362.

The primary impetus for Congress to implement the Biotechnology Process Patent Act was the difficulty of obtaining patent protection for biotechnology processes due to the PTO's interpretation of section 103. Unlike the statutory requirement of novelty under 35 U.S.C. § 102, an examiner may combine the teachings of references under section 103 in reaching a determination of obviousness. To be sure, where a section 102 rejection has been avoided, section 103 rejections are common for biotechnology claims.

The Biotechnology Process Act of 1995

The 1995 statute divided section 103 into three subsections. The former first paragraph became section 103(a), a new section 103(b) was added, and the former second paragraph became section 103(c). Section 103(b) now provides:

(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered novel if -

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same filing date; and

(B) the compositions of matter, and the process at the time it was invented were owned by the same person or subject to an obligation for assignment to the same person.

(2) A patent issued on a process under paragraph (1) -

(A) shall also contain the claims to the composition of matter used in or made by that process; or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means -

(A) a process to genetically alter or otherwise inducing a single-or multi-celled organism to -

(i) express and exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

- (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
- (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).⁷

The Federal Circuit's belated response to the PTO's overly broad reliance on *In re Durden*

Soon after the 1995 Act, the Federal Circuit issued two *per curiam* decisions that further put the Durden holding into question.⁸ These cases involved obviousness rejections for process claims to chemical synthesis which utilized new and unobvious starting material in conventional and obvious chemical reactions to synthesize new and unobvious compositions. In In re Ochiai, 71 F. 3d 1565 (1995), a Federal Circuit panel reversed a PTO rejection of process claims very similar to those invalidated under section 103 in In re Durden. The Federal Circuit panel reasoned that the Board of Patent Appeals and Interferences method of analysis was founded on legal error because it substituted the supposed *per se* rules of Durden for the particularized inquiry by section 103. The court further noted that the board indulged in a non sequitur when it grounded its conclusion of obviousness on the assertion that the starting materials were similar to the prior art because the starting material itself had been patented in a parent application and thus was nonobvious.⁹ The court evoked and added to the holding in In re Dillon by stating the following:

“[w]hen any applicant properly presents and argues suitable method claims, they should be examined in light of all . . . relevant factors, free from any presumed controlling effect of Durden’ or any other precedent.”¹⁰

Impact on PTO examination and biotechnology infringement

The current position of the PTO is that an applicant’s need to rely on the amended section 103(B) should be rare in view of the recent Federal Circuit decisions in Ochiai and Brouwer. A notice by the PTO following the Ochiai and Brouwer decisions suggest that a process claim will be given an initial presumption of unobviousness when the starting material or final product recited in the process is found patentable. The PTO noted that

⁷ 35 U.S.C. §103(b), as amended by Pub. L. No. 104-41, Sect. 1.

⁸ In re Ochiai, 71 F. 3d 1565, 1568, 37 USPQ 2d 1127 (Fed. Cir. 1995). In re Brouwer, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996).

⁹ 71 F. 3d at 1570-71, 37 USPQ at 1132.

¹⁰ 71 F. 3d at 1572, 37 USPQ 2d at 1133, *quoting In re Dillon*, 919 F.2d 688, 695, 16 USPQ 2d 1897, 1903 (Fed. Cir. 1990) (en banc), cert denied, 111 S. Ct. 1682 (1991).

the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under 35 U.S.C. 103. Rather, 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a *whole* and comparing it to the prior art.

The PTO has indicated that it will treat section 103(b) elections on a case-by-case basis by way of petition.¹¹ That petition must establish that all the requirements set forth in section 103(b) have been satisfied. An election will normally be considered timely if it is made no later than the earlier of either (1) the payment of the issue fee, or (2) the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under 35 U.S.C. 102 or 103. In an application where at least one composition of matter claim has not been rejected under 35 U.S.C § 102 or §103, a section 103(b) election may be made by submitting the petition and amendment requesting entry of process claims which correspond to the composition of matter claim.¹²

The important practical difference between an applicant relying section 103(a) in the absence of a timely election to proceed under section 103(b) is that the applicant would forgo his guarantee of nonobviousness under section 103(b). Thus, an applicant defending an obviousness attack in litigation would need to rely on the reasoning of Ochiai for an attack on validity. However, it is not clear that Durden has been overruled by Ochiai or Brouwer with respect process claims because neither case was an en banc decision, thus process claims could be subject to attack of obviousness based on Durden.¹³ Until the Federal Circuit panel addresses such cases the outcome of such a litigation has an element of uncertainty which could be effected by the members of the court and the skill of the advocates. If the Federal Circuit adheres to Ochiai, it appears that all (chemical) process claims, not merely biotechnological, will be liberated from an overly expansive application of the Durden analysis. It appears as though the Federal Circuit has left itself some maneuvering room for a case-by-case analysis of process claims.

It is not certain whether an applicant which relied on section 103(b) for a presumption of nonobviousness during prosecution of a process claim would be afforded the same degree of presumption of validity given to a claim which has been independently examined by the PTO. Once a challenger has mounted a prima facie case of obviousness of a process claim, the patent holder would need to rebut. While it is unlikely that judges would overtly and explicitly diminish the presumption of validity conferred by Congress, it is possible that the lack of independent review by the PTO could have an unstated effect on the court's deference in weighing the opposing parties arguments regarding obviousness and the presumption of validity that is reliant on a finding of nonobviousness.

¹¹ Petition under 37 C.F.R. 1.182.

¹² PTO notice, guidance on treatment of product and process claims in light of In re Ochiai and In re Brouwer and 35 U.S.C. 103 (B), 1184 O.G. 86 (1996).

¹³ See Biotechnology and the Federal Circuit, 1997 Supplement., § 6.11(d) p. 35, Kenneth J. Burchfiel.

Importantly, a process claim which relied on a presumption of nonobviousness under the amended section 103(b) may be challenged in court if the underlying composition of matter claim is latter held invalid. 35 U.S.C. § 282 does not require that the underlying claim need be invalidated for failure to satisfy section 103, but appears to remove the presumption of nonobviousness for the process claim under 103(b)(1) under any circumstance where the underlying composition of matter claim is invalidated.

For this reason most practitioners forgo the election as a strategic matter to allow their process claims to stand independently and not risk the possibility of invalidation in subsequent litigation as a result of a successful attack on the underlying product claims. As a practical matter, even in the absence of an election it is highly unlikely that the PTO will reject chemical and biotechnology process claims to a novel and unobvious product in light of Ochiai or Brouwer. A practitioner would still have the option to make a timely election under section 103(b) if his process claims were rejected until the patent had issued.

Conclusion

In view of the Federal Circuits nearly concurrent decision of In re Ochiai, one might wonder if the amendment to section 103 by Congress in 1995 was a motivating factor for the courts and the PTO to shift their analysis of process claims to conform with the fundamental analysis prescribed by section 103, as well as Graham v. Deer, and a narrowly interpreted In re Durden. Notwithstanding the good intentions of the legislation, a potential problem with enactment of the legislation is the breath of the amended section 103. The amended section 103 is more expansive than required to overrule the holding in In re Durden. Under the amended 103(b)(3)(C), a biotechnological process includes not only methods of producing patentable products but also methods of using a known product produced by a recombinant biotechnological process. Additionally, the effect of the 1995 Act is to confer absolute immunity to qualified biotechnological process claims from an obviousness defense in litigation. In view of the fact that an challenge of validity under section 103 is an important defense for an alleged infringer and a balancing factor to prevent overly broad patents, it is not clear what effect this element of the legislation will have on commercialization, litigation, and enforcement of biotechnology patents.