Section 103(b): Obviously Unnecessary?

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I. INTRODUCTION

The Patent Act requires that a claimed invention be "nonobvious."[2] Many patent lawyers consider nonobviousness the most important of the basic patent requirements of novelty, utility, and nonobviousness.[3] The nonobviousness requirement exists to ensure that a development is a significant enough technical advance to merit the award of a patent.[4] The theory behind this requirement is that while an invention may be novel or useful, it only rises to the level of a true invention if it is more than a mere trivial change to the prior art.[5] Several years ago, 35 U.S.C. § 103(b), essentially a special obviousness section for certain biotechnologies was added to the Patent Act.[6] In a number of recent decisions, the Federal Circuit's

1. Suffolk University Law School, Class of 2005.
2. 35 U.S.C. § 103 (2004). "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 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." *Id.*
3. ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY 643 (3rd Ed. 2002) [hereinafter PATENT LAW AND POLICY].
4. *Id.* at 644.
5. *Id*.
6. 35 U.S.C. § 103(b) (defining biotechnology as the process of genetically altering organism, cell fusion procedures, or as the method of using product

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definition of obviousness has tilted the scales greatly in favor of biotech patent applicants by adapting patent law to the advances in this technology-driven area of law.[7]

This note examines whether special standards for evaluating the nonobviousness of biotech patents are necessary for individual technologies in light of recent patent case law. A background of biotechnology is provided to help the reader understand how patents exploit the technology. The history of the nonobviousness requirement for patents is examined, focusing on developments within the last decade. Finally, the issue of patenting DNA inventions and the obviousness requirement are analyzed together. This analysis concludes that creating special standards for specific types of technology is neither reasonable nor necessary in patent law.

II. THE LEGAL DOCTRINE OF OBVIOUSNESS

A. Obviousness Generally

The Patent Act's nonobviousness requirement states that an inventor cannot receive a patent for an invention if the subject matter, as a whole, would have been obvious at the time of the invention to a person having ordinary skill in the art to which said subject matter pertains.[8] The defining Supreme Court case, *Graham v. John Deere Co.,*[9] further developed the statutory rule by establishing a four-part test for obviousness.[10] The test requires the courts to 1) determine the scope and content of the prior art, 2) ascertain the differences between the claimed invention and the prior art, 3) resolve the level of ordinary skill in the pertinent art, and 4) consider secondary factors of nonobviousness, including commercial success and long-felt need in the art.[11] According to 35 U.S.C. §103(a), when the Patent and

produced by process). The act was created for two reasons, (1) to clarify Federal Circuit decisions that seemed to conflict on the issue, and (2) to negate the harsh effect that a Federal Circuit decision had on obtaining patent protection for biotechnology processes. *Id*.

7. Anita Varma & David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 55 (1996) (discussing the definition of the legal test of what constitutes a proper prima facie case of legal obviousness) [hereinafter DNA is Different]. The cases identified specifically show applicants attempting to gain patent protection for a DNA sequence for which the associated protein is either partially or fully known in the field. *Id.*

8. 35 U.S.C. § 103(a) (2004).

9. 383 U.S. 1 (1966).

10. *Id.* at 17.

11. *Id.*; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983)

Trademark Office (PTO) declares something as obvious, it is saying that even if the invention were novel,[12] the invention would have been obvious to a person of ordinary skill in the art to which the subject matter pertains at the time the invention was made.[13] Section 103[14] restricts patentability beyond novelty and utility, and excludes inventions that would have been obvious to someone skilled in the art.[15] This section asks the ultimate question of patentability: "whether an invention is a big enough technical advance to merit the award of a patent."[16]

A patent application is presumed patentable if it is properly filed with the PTO.[17] If the patent application is rejected due to obviousness, it must be accompanied by a detailed prima facie case of obviousness by the PTO.[18] Thus, the burden falls on the patent examiner to show obviousness and ultimately unpatentability.[19] Patent claims are properly rejected under § 103[20] when the modification of a single reference or the combination of two or more prior art references would have been obvious to one of ordinary skill in the art, leading to the invention of the claimed subject matter.[21]

(stating secondary factors are often most probative evidence in record).

12. 35 U.S.C. § 102 (2004). "An inventor does not become entitled to a patent merely by exercising his creative faculties in the production of an art [i.e. process] or instrument. The consideration for the grant of his exclusive privilege is the benefit which he confers upon the public by placing in their hands a means through the use of which their wants may be supplied. If the same means has already been made available to them by the inventive genius of a prior inventor, or if though they receive it first from him it is incapable of useful application, no benefit results to them from his inventive act and there is no consideration for his patent. When this want of consideration becomes apparent before a patent has been granted it will be refused; when afterward the patent is defeated." PATENT LAW AND POLICY, *supra* note 3 (quoting William Robinson, THE LAW OF PATENTS FOR USEFUL INVENTIONS §22, at 305 (1890)).

13. *See* Varma, *supra* note 7, at 65.

14. 35 U.S.C. § 103 (2004).

15. PATENT LAW AND POLICY, *supra* note 3.

16. *Id*.

17. In re Warner, 379 F.2d 1011, 1016 (Cust. & Pat. App. 1967).

18. In re Rouffett, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (holding to prevent use of hindsight examiner must prove the inventor's motivation to combine prior art to create claimed subject matter). Prima facie obviousness is a procedural tool that is used by the PTO during prosecution. *See* Varma, *supra* note 7, at 66.

19. *See* In re Warner, 379 F.2d 1011, 1016 (Cust. & Pat. App. 1967) (stating 35 U.S.C. § 102 places burden on Patent Office to produce factual basis for rejection of an application).

20. 35 U.S.C. § 103.

21. Bell, 991 F.2d at 783 (explaining obviousness cannot be established without some suggestion to combine prior art references). A prima facie case is made when the teachings from the prior art actually suggest the claimed invention to a person of ordinary skill in the art. *Id*. This suggestion must also be accompanied by a reasonable expectation of success by one of ordinary skill in the art to pass the

A prima facie case of obviousness exists when three basic criteria are met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success; and third the prior reference (or combined references) must teach or suggest all of the claim limitations.[22]

The suggestions or teachings to make the claimed invention and the reasonable expectation of success must both be found in the prior art.[23] The aid of hindsight is not allowed when evaluating the obviousness of an applicant's disclosure.[24] Courts have routinely applied the doctrine of structural similarity, as an alternative to the suggestion test, in chemical inventions.[25] The Federal Circuit, in the holding of *In re Dillon,*[26] restated that structural similarity between the claimed invention and prior art, proved by combining references or otherwise, where the prior art provides suggestion or motivation to make the claimed chemical compositions, creates a prima facie case of obviousness.[27] The burden then falls on the applicant to rebut that prima facie case after structural similarity has been shown.[28] Structural similarity simply means that if the structure of a compound found in the prior art is found to have analogous functional groups or structural formulae to the claimed invention, then as a matter of law

suggestion test. Varma, *supra* note 7, at 67.

22. In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991) (stating uncertainty of particular subject matter rebuts, rather than supports, obviousness). The claimed invention at issue was a chimeric gene expressing an insecticidally active protein expressed in cyanobacteria. *Id*. The court determined that not only was the claimed subject matter not suggested in the prior art, there was no reasonable expectation of success. *Id*. The fact that it was known that the Bacillus insect toxin gene could be expressed in other Bacillus species and E.coli did not make the cyanobacteria expression system obvious, even though all of the host organisms were prokaryotes. *Id. See also* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 682 PLI/Pat 285, 312 (2001).

23. *Id. See* Rochelle K. Seide et al., *Drafting Claims for Biotechnology Inventions*, 682 PLI/Pat 285, 308 (2001); Leora Ben-Ami et al., *Biotech Patent Law Developments*, 573 PLI/PAT 555, 562 (1999). This is commonly referred to in the field as the "suggestion test."

24. *See* Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 873 (Fed. Cir. 1985) (stating *Graham* factors are needed by courts to refrain from using hindsight).

25. Anita Varma & David Abraham, *DNA is Different: Legal Obviousness and the Balance Between Biotech Investors and the Market*, 9 HARV. J.L. & TECH. 53, 68 (1996).

26. 919 F.2d 688 (Fed. Cir. 1990) (reaffirming structural similarity creates a prima facie case of obviousness).

27. *Id.* at 692.

28. *Id. But see* In re Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963) (holding structural similarity, without more, does not give rise to prima facie obviousness).

the compounds are structurally similar.[29] Under *Dillon,*[30] both the starting and resulting materials in an analogous process are relevant, but not dispositive, in determining the obviousness of the process.[31]

B. Section 103(b) Obviousness

Courts and practitioners have recognized for several years that the nonobviousness requirement for chemical and biological inventions presents special issues that are difficult to address by simple application of § 103(a).[32] In the 1980s and early 1990s, a set of specialized cases emerged that addressed the unique issues arising from the rapidly developing field of biotechnology.[33]

In 1995, Congress passed the Biotechnological Process Patents Act (BPPA), which amended § 103 to provide new standards of patentability for certain areas of biotechnology-related inventions.[34] Congress removed any remaining ambiguity surrounding patent protection for biotechnology process claims.[35] The stimulus for the BPPA stemmed from a special problem related to biotechnology processes and the inventions of biotechnology products.[36] Prior to the enactment of the BPPA, the courts were relying heavily on chemical process patent cases in their analysis of biotechnology

29. *See* Cary W. Brooks, Comment, In re Dillon en banc, 32 IDEA 299 (1992).
30. 919 F.2d 688.
31. *Id.* at 695.
32. 35 U.S.C. § 103(a).
33. PATENT LAW AND POLICY, *supra* note 3, at 807. *See Generally* Deuel 51 F.3d 1552; Bell, 991 F.2d 781; In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986).
34. *See* BPPA § 1, 109 Stat. 351, codified at 35 U.S.C. § 103(b). The Act provides that a biotechnological process "using or resulting in" a novel composition of matter is nonobvious if the process and the novel composition of matter are contained in the same applications, or separate applications having the same effective filing date, and the process and composition are owned by or assigned to the same person at the time of invention. *Id.*
35. James W. Collett, *In re Durden Comes Full Circle: The Effect of the Biotechnology Process Patent Act and Recent Federal Circuit Cases on Biotechnology Process Patents*, Sheldon & Mak (1998), *at* http://www.usip.com/articles/Collett.pdf (last visited March 3, 2005).
36. *Id.* The economic value of biotechnology process claims arise from a problem unique to the biotechnology field. *Id*. Proteins, the product of most biotechnological processes, are usually known and naturally occurring, rendering the product claims unpatentable during prosecution. *Id*. As a result, process claims can protect the biotechnology product in addition to the process where the product is not patentable because it is naturally occurring or obvious. *Id.* The PTO routinely rejected claims to processes for making a patented material transformed to produce an unpatentable product under *In re* Durden. *See* 763 F.2d 1406 (Fed. Cir. 1985).

process patents.[37]

In the case of *In re Durden*[38] the Federal Circuit addressed the issue of whether the process for making a patentable compound was patentable itself.[39] The Federal Circuit, in *Durden*, affirmed that "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."[40] Almost two-thirds of PTO process claims were rejected based on the decision of *Durden*.[41]

The PTO regularly applied *Durden*[42] for the contention that the use of a nonobvious starting material in an otherwise obvious process does not necessarily result in a patentable, nonobvious process.[43] Overcoming this type of PTO rejection required a showing of "unexpected results," which generally translated into additional scientific experimentation and longer negotiations with the PTO.[44] The costs associated with further experimentation were prohibitive to applicants operating on limited budgets, such as universities and smaller firms.[45] Stretching small budgets was only one of the hurdles that smaller applicants had to overcome; the uncertainty was generally regarded as detrimental to the domestic biotechnology industry.[46]

As a result of this amendment, the rules of § 103[47] are now formally different for the biotechnology field than for all other fields of invention.[48] The BPPA gave inventors of biotechnology processes the option to make a "timely election" if certain specific conditions were met.[49] This election exempts the biotechnology process from the traditional § 103[50] obviousness inquiry.[51]

37. James W. Collett, *In re Durden Comes Full Circle: The Effect of the Biotechnology Process Patent Act and Recent Federal Circuit Cases on Biotechnology Process Patents*, Sheldon & Mak (1998), *at* http://www.usip.com/articles/Collett.pdf (last visited March 3, 2005).
38. 763 F.2d 1406.
39. *Id*.
40. *Id.* at 1410-1411.
41. *Id.*
42. *Id*. at 1406.
43. Collett, *supra* note 37.
44. Lisa J. Raines, *Protecting Biotechnology's Pioneers*, ISSUES IN SCI. & TECH. 33, 35 (Winter 1991-92).
45. *Id*.
46. *Id.*
47. 35 U.S.C. § 103.
48. PATENT LAW AND POLICY 807, *supra* note 3.
49. Stephen B. Maebius, *The New Era of Process Patentability*, Foley & Lardner (1996), *at* http://www2.ari.net/foley/processpat.html (last visited March 3, 2005).
50. An election to continue under 35 U.S.C. § 103(b) is made by filing a petition under 37 CFR 1.182. *Id*. The petition establishes that all of the requirements listed

II. GENERAL INTRODUCTION TO BIOTECHNOLOGY

A large number of biotechnology patents claim inventions related to cellular biochemistry.[52] Cellular biochemistry is comprised of three main disciplines: deoxyribonucleic acid (DNA),[53] protein,[54] and cell biology.[55] DNA is nucleic acid that codes for the production of a cell's proteins.[56] Proteins have a direct influence over a cell's biochemistry.[57] Examples of a protein's influence include the catalytic activity of enzymes and antibody responses.[58] DNA is therefore an important tool for biotechnologists because of its ability, when engineered, to induce a cell's existing mechanisms and produce a specific protein of choice. This tool is also a challenge for the PTO because although the end products are usually new and novel, the process used to make them is relatively standardized.

A gene is the segment of DNA involved in producing a polypeptide chain;[59] it includes regions before and after the coding region,[60] as well as the region of DNA on a chromosome whose sequence encodes a specific protein.[61] A codon, a triplet of three

in 35 U.S.C. § 103(b) have been met. *Id.* An election is considered timely if it is made no later than the date of payment of the issue fee or the filing of an appeal brief in an application for a composition of matter claim that has not been rejected under 35 U.S.C. § 102 or 35 U.S.C. § 103. *Id.*

51. 35 U.S.C. § 103.

52. Collett, *supra* note 37.

53. Seide, *supra* note 23.

54. DNA is made up of four repeating units called nucleotides. Nucleotides consist of a five-carbon sugar, a phosphate, and a base that is adenine (A), guanine (G), thymine (T), or cytosine (C). BENJAMIN LEWIN, GENES VI 49-115 (6th ed. 1998); DONALD VOET & JUDITH G. Voet, BIOCHEMISTRY 848-870 (2nd ed. 1995). G bonds with C, and A with T, to form complementary base pairs. *Id*. The complementary strands of DNA are arranged such that the bases of one strand form a weak bond with the bases of the opposite strand. *Id*.

55. KENNETH MILLER & JOSEPH LEVINE, BIOLOGY 74-75 (1991). Proteins are complex polymers of amino acids that build and repair cells. *Id.*

56. GEOFFREY M. COOPER, THE CELL A MOLECULAR APPROACH 30 (1996). In vitro cell culture systems enable scientists to study cell growth and differentiation, perform genetic manipulations, and understand gene function and structures. *Id.*

57. Miller, *supra* note 54, at 137.

58. *Id*. at 148.

59. Miller, *supra* note 54, at 148.

60. Polypeptide chains are polymers composed of many amino acid residues that are linked to its neighbors in a head-to-tail fashion forming a chain. LEWIN, *supra* note 54.

61. *Id*. The region before the coding region is referred to as leader sequence. *Id*. Leader is the nontranslated sequence at the five-prime end of messenger RNA (mRNA) that precedes the initiation codon. *Id*. The area after the coding region is referred to as trailer sequence. *Id*. Trailer is a nontranslated sequence at the 3-prime end of an mRNA following a termination codon. LEWIN, *supra* note 53.

62. *Id*.

nucleic acids in the gene sequence, specifies amino acids.[62] The specific arrangement of this series of codons defines the amino acid sequence of the protein.[63]

The resulting genetic code generates sixty-four possible triplets, sixty-one of which code for amino acids.[64] There are twenty different amino acids found in human proteins.[65] As a result of the sixty-one codons coding for only twenty different amino acids there is "degeneracy" in the genetic code.[66] This means that an amino acid can be coded for by multiple codons.[67] For example, most amino acids are coded for by four distinct codons.[68] The degeneracy of the genetic code makes it difficult for a biotechnologist to determine the DNA sequence of a specific gene when the amino acid sequence is all that she is provided with.[69]

Protein synthesis is completed in two stages: transcription and translation.[70] Transcription generates a single-stranded ribonucleic acid (RNA) that is identical in sequence with one of the strands of the DNA.[71] Transcription generates several different types of RNA: the messenger RNA (mRNA), transfer RNA (tRNA), and ribosomal RNA (rRNA).[72] The nucleotide sequence of RNA is converted to the sequence of amino acids that make up a protein during translation.[73] The entire length of mRNA is not translated; each mRNA contains at least one coding region (exon) and multiple non-coding sequences (introns).[74] mRNA is generated by transcription in the nucleus and then moves to the cytoplasm, where translation occurs.[75] The nucleotide sequence in the mRNA is translated into the

63. *Id*. Amino acids are the monomeric units of proteins. *Id.* at 56.
64. *Id*.
65. LEWIN, *supra* note 54.
66. *Id.* at 214.
67. *Id.* at 213.
68. *Id*.
69. LEWIN, *supra* note 54. Valine, Serine, Proline, Threonine, Alanine, Arganine, and Glycine can each be coded for by four separate codons. *Id*. A more extreme example is Leucine, which can be coded for by six separate codons. *Id.*
70. *Id.*
71. *Id.* at 153.
72. LEWIN, *supra* note 54.
73. *Id.* mRNA is a type of RNA that carries genetic information from the DNA in the nucleus out to the ribosomes in the cytoplasm. *Id*. tRNA is a type of RNA that carries amino acids to the ribosomes where the amino acids are joined together to form polypeptides. *Id*. rRNA is a type of RNA that makes up the major part of the ribosomes. *Id.*
74. LEWIN, *supra* note 54, at 153.
75. *Id.*
76. *Id.*

corresponding amino acid sequence.[76] Adaptor molecules, which recognize the mRNA codon and an amino acid, are then used in the translation process.[77]

A ribosome is also required to complete the process.[78] The ribosome travels along the mRNA molecule and translates the nucleotide sequence into single amino acid codons.[79] The presence of one of the three stop codons causes the synthesized polypeptide chain to be released from the ribosome.[80]

Most recombinant DNA construction begins with the making of complementary DNA (cDNA), or the ordering of genomic libraries.[81] The desired sequence is then extracted from the library or cDNA by the use of probes.[82] Recombinant techniques are then used to produce human proteins in bacterial cell lines.[83] This process of creating recombinant DNA is done by transforming competent bacterial cells with a portion of DNA that codes for the desired protein.[84] A successful transformation is achieved in less than an hour, producing bacteria that will express the desired protein.[85] The bacteria is then spread on agar plates and incubated overnight, producing many colonies that ensure large quantities and a continuing supply of the protein.[86]

Most biotechnologists begin learning the skills needed to produce recombinant DNA as early as high school, though most commonly in college. The commercial availability of restriction enzymes and ligation kits has provided the biotechnologist with the tools need to recombine DNA and produce their gene of choice quickly and easily. The procedures used to complete this work are relatively simple and the level of skill required to engineer a gene is not as high as one might imagine.[87] Therefore, it is very common in the field of biotechnology for a scientist to create a new recombinant gene and subsequently look for patent protection on the gene or the process of

77. *Id.*
78. *Id*. at 155.
79. LEWIN, *supra* note 54, at 159.
80. *Id.* at 160.
81. *Id.*
82. COOPER, *supra* note 55. Genomic libraries are commercial sources of a large variety of existing cDNAs. *Id*.
83. *Id.*
84. *Id.*
85. *Id.* at 108.
86. Lewin, *supra* note 54, at 108.
87. *Id.*
88. *Bell*, 991 F.2d at 783 (explaining a known amino acid sequence does not enable one to predict DNA sequence). *Deuel*, 51 F.3d at 1556 (indicating that to one skilled in the art it would have been obvious to clone a gene for HBGF).

making it.

III. PATENTING DNA AND OBVIOUSNESS

Nearly simultaneously to the BPPA's enactment, the Federal Circuit rendered opinions in two cases, which seemed to make the new amendment almost instantaneously obsolete for the intended purpose of obtaining biotechnology process patent protection, but yet "opened the door to potential problems in patent litigation."[88] Before *In re Ochiai*[89] and *In re Deuel*[90], the PTO used per se rules of unpatentability against process claims.[91] These rules were based on decisions from the *In re Larsen*[92] and *In re Durden*[93] cases. The idea behind these rejections was that a process could be found obvious for the sole reason of individual steps being widely known in the prior art.[94]

One of the leading issues related to biotechnology inventions and patenting DNA sequence is the controversy regarding whether prior art that discloses general methods for obtaining a DNA molecule may be used as prior art against claims to specific nucleotide sequences that encode specific proteins.[95] Prior case law appears to have rejected that idea because a multitude of nucleotide sequences may be capable of coding for a specific protein.[96] As a result, a prima facie

89. Seide, *supra* note 23, at 292.
90. 71 F.3d 1565 (Fed. Cir. 1995) (holding "analogous" chemical process at issue was nonobvious because of novel starting and resulting compounds).
91. 51 F.3d 1552 (Fed. Cir. 1995) (asserting relationship between proteins and nucleic acids does not render DNA sequence obvious).
92. Jeremy Zhe Zhang, Note, *In re Ochiai, In re Brouwer and the Biotechnology Process Patent Act of 1995: The End of the Durden Legacy?*, 37 IDEA 405, 433-434 (1997).
93. 292 F.2d 531 (C.C.P.A. 1961) (holding once compounds were conceived, process of making them became obvious). The appellant had applied for a patent on novel organic compounds and the processes of making them. *Id*. The claims were rejected for obviousness by both the examiner and the Board. *Id*. The court agreed, holding that the invention resided solely in the existence of the compounds. *Id.*
94. 763 F.2d 1406 (holding obvious chemical process does not become nonobvious because product or starting material is novel). The inventors claimed novel compounds and a novel process for making the compounds. A prior art reference taught similar processes for making compounds homologous to the claimed compounds. The court reaffirmed the case-by-case approach and ruled the process was obvious in light of prior art references. *Id.* and Jeremy Zhe Zhang, Note, *In re Ochiai, In re Brouwer and the Biotechnology Process Patent Act of 1995: The End of the Durden Legacy?,* 37 IDEA 405, 414 (1997).
95. Zhang, *supra* note 93, at 409.
96. Seide, *supra* note 23, at 308.
97. *Bell*, 991 F.2d at 784 (determining that a claimed DNA sequence was not prima facie obvious). The court determined the DNA sequence was not obvious in

case of obviousness cannot be made between a specific DNA and the protein it encodes in the same way that a prima facie case can be made in a chemical invention for homologs, analogs, and isomers, as illustrated in *Deuel*.[97]

In 1995, the Federal Circuit held in *In re Ochiai*[98] that per se rules could not be used by the PTO to determine process claims under 35 U.S.C. §103.[99] Instead, the recitation of the starting material or end product, in addition to all other limitations of a process claim, must be given consideration.[100] The court in *In re Ochiai* relied heavily upon the patentability of the starting material.[101] As a result, *In re*

view of prior art references that described the full amino acid sequence of the polypeptides encoded by the claimed DNA, along with a reference describing a general method for cloning DNA. *Id.*

98. 51 F.3d at 1558. The doctrine of prima facie obviousness based on structural similarity was routinely used in chemical case law. *See* Varma, *supra* note 7, at 68-99. As a result, the structural similarity test was applied to the patentability of DNA. *Id*. DNA differs from traditional polymers in a number of ways, however. *Id*. Minor changes in the DNA sequence are capable of significantly changing the function of the DNA. *Id*. This is unlike the majority of chemical compounds where minor changes do not drastically alter the function of the compound. *Id*. The most significant difference between chemical compound patents and DNA sequence patents is that the relationship between the DNA and the protein it codes for creates value. *See* Varma, *supra* note 7, at 68-69. The DNA structure alone has very little importance to the biotechnologist. *Id*.

99. 71 F.3d 1565 (Fed. Cir. 1995). Ochiai's application was for a process of using an acyl side chain from a particular type of novel and nonobvious organic acid having a 2-aminothiazolyl group, and a type of known amine to make a novel and nonobvious cephem compound, a cephalosporin type antibiotic. *Id*. The examiner in the Patent Office rejected the claims for obviousness based on prior art references that disclosed preparing analogous types of cephem by analogous acylation reactions using the same amine and analogous types of organic acids. *Id*. The explanation for the rejection was that "the only difference between what is being claimed and the prior art is the selection of a slightly different acylation agent (i.e., acid) to result in a slightly different final product. *Id.* (quoting examiner's answer to Ochiai's appeal to Board).

100. *Id.* at 1572 (stating the obviousness test requirement is accomplished by factual determinations). The court stated that the obviousness test required a fact-specific inquiry into the prior art and the subject matter as a whole. Ochiai's process claim required use of a novel, non-obvious acid as one of the starting materials; therefore the selection of the particular acid is part of the process. *Id*. The court held that since "one cannot chose from the unknown" and "one having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem," the process was nonobvious. *Id.* Zhang, *supra* note 93, at 429-430.

101. *See* Graham v. Deere, 383 U.S. 1 (1966) (holding each invention as a whole must be considered).

102. *Id.* at 1569 (explaining one who had no knowledge of a new, novel acid could not find making cephem obvious). The process required in Ochiai's invention specifically requires use of new, nonobvious acid as one of the starting materials. *Id*. Court states that it would not have been obvious to those of ordinary skill in the art to choose the particular acid claimed as an acylating agent for the known amine

Ochiai created a presumption of nonobviousness for a process claim when the starting material is novel and nonobvious.[102]

That same year, the Federal Court had another opportunity, in *In re Deuel,*[103] to decide whether the relationship between DNA sequence and a disclosed amino acid sequence rendered the particular DNA sequence obvious.[104] This time the court stated "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question of whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNA."[105]

The Federal Circuit decided *In re Brouwer*,[106] around the same time, linking process patentability to novel and nonobvious final

simply because the particular acid was unknown except for Ochiai's disclosure in the patent application. *Id.*

103. *Id.* at 1569-1570 (explaining prior art must have suggested or motivated modifications to deem claimed invention obvious).

104. 51 F.3d 1552. The inventors had applied for a patent for DNA and cDNA molecules that encoding proteins which stimulated cell division. The patent examiner rejected the claims, finding they did not meet the nonobviousness requirement. *Id*. The PTO Board of Patent Appeals and Inferences affirmed the examiner's decision, causing the inventors to appeal to the Court of Appeals. *Id*. The appellate court judge held that: (1) the combination of prior art that taught the method of gene cloning, and the reference that disclosed partial amino acid sequence for the protein that stimulated cell division, did not render the claims prima facie obvious; (2) the method of preparing DNA generally does not define it with the level of precision necessary to render it obvious over the protein it encodes; and (3) patent claims that encompassed all DNA sequences which encode human and bovine proteins to stimulate cell division were not invalid due to obviousness. *Id.*

105. *See Deuel* 51 F.3d at 1554. The claimed invention was drawn to a DNA sequence that encoded for a growth factor protein. The prior art disclosed only nineteen amino acids, not the complete amino acid sequence. The teachings of the prior art reference were combined with known cloning techniques by the PTO to find the claimed DNA sequence obvious in light of the combined prior art teachings. *Id.*

106. *Id.* The issues in this case were reduced to two separate questions of sufficient information. Is knowledge of only nineteen amino acids from a 168 amino acid sequence protein enough to recover the entire protein? Is knowledge of a protein sufficient to provide one of ordinary skill in the art with the cDNA sequence that codes for the protein? The court ruled that the prior art did not teach or mention the specific claimed compound, but only taught a general method of isolating cDNA molecules. *Id.* at 1558.

107. 77 F.3d 422 (Fed. Cir. 1996). The claim at issue was a process of making a novel, nonobvious sulfoalkylated resin catalyst by reacting a crosslinked resin with an ester of an alkenesulfonic acid. The process claim used a generally known, organic chemistry, standard technique (Michael addition reaction). The prior art reference cited a generic Michael addition reaction, but not the particular process claimed by Brouwer. The examiner and Board rejected the claim for obviousness, reasoning one skilled in the art would have found it obvious to choose the starting products and use a Michael addition reaction. The court held the process was nonobvious. *Id.* at 423.

products.[107] In this case, the starting materials of the claimed process were not covered by patent, but the final product was considered novel and nonobvious.[108] The court emphasized: "Without first knowing Brouwer's claimed process steps or the composition resulting from those steps, there is simply no suggestion in the references cited by the examiner to practice the claimed process. It is therefore not prima facie obvious." [109] Thus, between the decisions rendered in *In re Ochiai*, *In re Brouwer*, and *In re Deuel*, there exists great opportunity to obtain a patent on a biotechnological process, or even a process outside of biotechnology.[110]

IV. IS § 103(B) NECESSARY AFTER OCHAI AND DEUEL?

Several scholars have written about the BPPA's restrictive provisions and limited applicability noting that the newly amended § 103(b) is undesirable for many reasons.[111] Other scholars have questioned the practicality as to which route should be taken by someone seeking to process a biotechnology process patent in light of §103(b), now that the court decisions of *Ochai* and *Deuel* obviate the need to make the § 103(b) election.[112] The risks associated with a § 103(b) election must be assessed in light of the court's view and PTO's use to date of the two Federal Circuit cases, *In re Ochiai* and *In re Brouwer*.

Congress wrote the new § 103(b) very narrowly, applying it only to biotechnology processes and requiring that the process and composition claims be filed in the same application or expire on the same date.[113] If the inventor opts for separate applications, both

108. *Id*. at 425; Maebius, *supra* note 49.
109. *See Brouwer*, 77 F.3d at 425.
110. *Brouwer*, 77 F.3d at 425.
111. Zhang, *supra* note 93, at 440.
112. *See* Doody & Bent, *In re Ochiai: The Federal Circuit Demolishes* Durden, 15 BIOTECHNOLOGY LAW REPORT 34 (1996); Charles Van Horn & Stacey Barlow, *Section 103(b) of the Patent Law: A Solution in Search of a Problem?*, 14(6) NATURE BIOTECHNOLOGY 773 (1996). Opponents question whether there was really a problem that required action on the part of Congress because capital for biotechnology Research & Development is far from scarce, *Durden* is not a basis for the automatic or categorical rejection of all process claims; and the biotechnology industry already is granted many process patents and this is an example of poor public policy for a single industry to receive specialized treatment without showing unique problems. Raines, *supra* note 44. Critics of the amendment also contend that giving special protection to biotechnological processes "would undermine the credibility of our patent system". *Id*.
113. Collett, *supra* note 37.
114. 706.02(n) Biotechnology Process Applications, *available at* http://www.uspto.gov/web/offices/pac/mpep/documents/0700_706_02_n.htm (last visited Mar. 3, 2005); 35 U.S.C. § 103(b).

applications must be owned or assigned to the same person at the time of invention in order for § 103(b) to apply.[114] Although it appeared that § 103(b) was exactly what the biotechnology industry needed, the statute, from the very beginning, was at risk of becoming obsolete.[115] Many critics compared it to the Semiconductor Chip Protection Act,[116] a statute that was tied specifically to a technology that quickly became outdated.[117]

One of the greatest risks of prosecuting a biotechnology process patent through the use of § 103(b) is the possible loss of a presumption of validity.[118] This risk exists because the PTO will not examine the biotechnology process based on prior art when a process patent is applied for under § 103(b).[119] As a result, if the composition of matter claim that formed the basis for allowing the process claim is later held invalid, the process will also no longer be considered nonobvious solely on the basis of § 103(b).[120] If the patent relied upon was invalid, the process would have to be judged on its own patentability, without any presumption that the claimed process had been examined in the PTO.[121] Consequently, defending a patent granted under § 103(b) could be much more difficult than if the patent was granted without the aid of special patent laws.[122]

As a consequence of the timing of the *In re Ochiai*[123] decision, the month after § 103(b)'s enactment, members of the patent community have viewed the statute as largely insignificant.[124] The Federal

115. 35 U.S.C. § 103.
116. PATENT LAW AND POLICY, *supra* note 3, at 860.
117. The Semiconductor Chip Protection Act of 1984 essentially protects the topology of mask works fixed in a chip. PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 937 (5th ed. 2002). The work must be original and not consist only of staple, commonplace or familiar designs in the semiconductor industry. *Id*. The work also may not be a variation on any of the designs listed above, combined in a way that considered as a whole, they are not original. *Id*.
118. PATENT LAW AND POLICY, *supra* note 3, at 861.
119. Collett, *supra* note 37.
120. *Id*.
121. *Id*.
122. *Id*.
123. Collett, *supra* note 37.
124. 71 F.3d 1565.
125. PATENT LAW AND POLICY, *supra* note 3, at 861. Many practitioners forgo the §103(b) election as a matter of strategy to allow their process claims to stand independently and not risk the possibility of invalidation as a result of a successful attack on the underlying product claims should subsequent litigation occur. Collett, *supra* note 37. Also, as a practical matter, even without 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 *Ochai* or *Brouwer*. *Id*. There would also still be an option to make a timely election under §103(b) if the process claims

Circuit reiterated in *Ochiai* the importance of the long-used test in the *Graham*[125] case: to determine the obviousness or nonobviousness of an invention one must consider the invention as a whole against the prior art and the claims at issue through the eyes of someone of ordinary skill in the art.[126] Both Federal Circuit court decisions reaffirmed that the only proper test for obviousness is the one announced by the Supreme Court in Graham.[127] The PTO even published a notice stating that the use of § 103(b) should be rare.[128] Under this guidance, a PTO examiner should view a nonobvious product as one indication of a patentable process.[129] Recent history has shown that the applicant's need to use § 103 has been extremely rare; in fact it has never been mentioned in any judicial or administrative decisions.[130]

VI. CONCLUSION

Eight years after the enactment of the BPPA and § 103(b) became a reality, biotechnology process patent cases are still litigated under the original § 103 standards, now § 103(a). Thus far, there are no cases decided based upon § 103(b).

Ultimately, it does not appear necessary to have a special nonobviousness standard for specific types of technology, such as biotechnology. Almost a decade after § 103(b)'s enactment, it has failed to be used as a tool in biotechnological patent process litigation. This observation leads one to conclude that specialized standards are unnecessary. As technology progresses and new inventions create greater uncertainty in the world around us, it would be useful to have patent law remain homogeneous so that one knows what to expect at the PTO.

were rejected during prosecution. *Id*.
126. 383 U.S. 1.
127. *Ochiai*, 71 F.3d at 1572.
128. *Id.*
129. 706.02(n) Biotechnology Process Applications (the PTO's notice is available on the Internet at www.uspto.gov).
130. *Id*.
131. PATENT LAW AND POLICY, *supra* note 3, at 861.