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October 2004

## The Biotechnology Process Patent Act of 1995: Providing Unresolved and Unrecognized Dilemmas in U.S. Patent Law

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### Recommended Citation

Becca Alley, *The Biotechnology Process Patent Act of 1995: Providing Unresolved and Unrecognized Dilemmas in U.S. Patent Law*, 12 J. INTELL. PROP. L. 229 (2004).

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## NOTES

# THE BIOTECHNOLOGY PROCESS PATENT ACT OF 1995: PROVIDING UNRESOLVED AND UNRECOGNIZED DILEMMAS IN U.S. PATENT LAW

### I. INTRODUCTION

While the term “biotechnology” was coined early in the twentieth century,<sup>1</sup> the use of biotechnology processes dates back almost as far as the beginning of humankind.<sup>2</sup> Over 10,000 years ago, our early ancestors utilized biotechnology as they began raising crops and domesticating animals,<sup>3</sup> and by 2000 B.C. the ancient Sumerians were using yeast in fermentation processes for brewing, baking, and cheese production.<sup>4</sup> Centuries later, in 1797, biotechnology penetrated the world of medicine and healthcare when Edward Jenner produced a small pox vaccine from cowpox.<sup>5</sup>

Not until the nineteenth century, however, did scientists begin to understand the chemical and biological bases for these developments.<sup>6</sup> Specifically, the nineteenth century marked several important scientific breakthroughs, including Louis Pasteur’s discovery of yeast in the fermentation process, Gregor Mendel and Charles Darwin’s work on heredity, and Schleiden and Schwann’s discovery of the cell, all of which helped open the door for modern biotechnology.<sup>7</sup> Today biotechnology is a booming industry, generating billions of dollars and producing innovations ranging from new antibiotics to cloned animals and genetically-modified food products.<sup>8</sup>

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<sup>1</sup> Francis C.R. Manning, *Biotechnology: A Scientific Perspective*, in *THE INTERNATIONAL POLITICS OF BIOTECHNOLOGY: INVESTIGATING GLOBAL FUTURES* 13, 13 (Alan Russell & John Vogler eds., 2000).

<sup>2</sup> LISA YOUNT, *BIOTECHNOLOGY AND GENETIC ENGINEERING* 3 (2000).

<sup>3</sup> *Id.* at 3.

<sup>4</sup> Manning, *supra* note 1, at 15.

<sup>5</sup> *Id.* at 15.

<sup>6</sup> YOUNT, *supra* note 2, at 3.

<sup>7</sup> *Id.* at 3-4.

<sup>8</sup> ALUIZIO BOREM ET AL., *UNDERSTANDING BIOTECHNOLOGY* 46-59 (2003); CHI-JEN LEE, *MANAGING BIOTECHNOLOGY IN DRUG DEVELOPMENT* 6-10 (1996).

The commercialization of biotechnology has led researchers and corporations to seek patent protection for their biotechnological innovations. As the courts and the Patent and Trademark Office increasingly have allowed patents for these inventions, the biotechnology industry has demanded enhanced patent protection. In 1995, this demand led Congress to pass the Biotechnology Process Patent Act,<sup>9</sup> a specialized piece of legislation providing an exemption from the nonobviousness requirement for biotechnology processes.

This Note first addresses the historical and scientific background of the Biotechnology Process Patent Act of 1995. Next, this Note considers the Act's practical effects on our nation's patent law, including problems that the Act currently creates. Finally, this Note proposes a possible solution to these problems in the form of corrective legislation.

## II. BACKGROUND

### A. THE LAW

The United States Constitution grants Congress the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>10</sup> The First Congress was quick to exercise this power, passing the Patent Act of 1790 in the early days of its first session.<sup>11</sup> Since that time, subsequent Congresses have contributed to the growth and development of the United States patent system through such means as the formation of the Patent and Trademark Office (PTO) and the creation of the Court of Appeals for the Federal Circuit.<sup>12</sup>

Today the PTO reviews patent applications to ensure that they meet the following five legal requirements: (1) patentable subject matter, (2) utility, (3) novelty, (4) nonobviousness, and (5) enablement.<sup>13</sup> While all five requirements are necessary for patentability, many judges and scholars regard nonobviousness as the key requirement, in part, because it is frequently the most challenging to prove.<sup>14</sup> Courts have considered nonobviousness in determining patentability since at least 1851;<sup>15</sup> however, Congress did not codify the nonobviousness

<sup>9</sup> Pub. L. No. 104-41 (codified at 35 U.S.C. §§ 103, 282 (2003)).

<sup>10</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>11</sup> Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.

<sup>12</sup> ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE*, 110 (Erwin Chemerinsky et al. eds., Aspen Publishers, Inc., 3d ed. 2003).

<sup>13</sup> *Id.* at 112.

<sup>14</sup> *Id.* at 112.

<sup>15</sup> *See* Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1851).

requirement until The Patent Act of 1952.<sup>16</sup> Since the 1952 Act, the statutory requirement for nonobviousness has required that an inventor may not obtain a patent on an invention where “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.”<sup>17</sup>

The *Graham* Court and courts since have repeatedly emphasized that nonobviousness is a question of law which requires highly factual inquiries on a case-by-case basis.<sup>18</sup> To determine the obviousness of a particular invention, a court must make three main factual inquiries, evaluating (1) “the scope and content of the prior art,” (2) “differences between the prior art and the claims at issue,” and (3) “the level of ordinary skill in the pertinent art.”<sup>19</sup> Other “secondary considerations,” including “commercial success, long felt but unsolved needs, [and the] failure of others,” may also be relevant.<sup>20</sup>

The range of patentable subject matter under the patent code is quite expansive, including “any . . . process, machine, manufacture, . . . composition of matter, or . . . improvement thereof.”<sup>21</sup> The courts have interpreted this broad language to have a wide scope, declaring in 1980 that live, human-made microorganisms may qualify as compositions of matter and thus may be patentable.<sup>22</sup> That Supreme Court decision in *Diamond v. Chakrabarty* was a significant advance for biotechnology product patents. Since at least 1974, however, lower courts had already been finding biotechnology processes patentable.<sup>23</sup>

1. *Nonobviousness and Biotechnology Process Patents: The Beginnings.* In 1974, the Court of Customs and Patent Appeals held that use of a novel starting material may establish the nonobviousness of a biotechnology process, even when the steps of that process are part of the prior art.<sup>24</sup> In *In re Mancy*, the patent applicant applied a known method of aerobic cultivation to a new strain of *Streptomyces*

<sup>16</sup> 35 U.S.C. §§ 1-376 (1952) (current version at 35 U.S.C. §§ 1-376 (2003)); *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

<sup>17</sup> 35 U.S.C. § 103(a) (2003).

<sup>18</sup> *Graham*, 383 U.S. at 17.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> 35 U.S.C. § 101 (2003).

<sup>22</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

<sup>23</sup> See, e.g., *In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974) (allowing patent protection for a biotechnological process). The first biotechnology process patent may actually have been awarded to Louis Pasteur in 1893 for a microbial fermentation process. Manning, *supra* note 1, at 15.

<sup>24</sup> *In re Mancy*, 499 F.2d 1289.

to produce the antibiotic daunorubicin.<sup>25</sup> The court reasoned that the statutory standard for nonobviousness necessitates a consideration of the process “invention as a whole,” which includes the application of the known cultivation method to the previously unknown *Streptomyces bifurcus* microorganism.<sup>26</sup> The court explicitly rejected the Patent Board’s argument that one skilled in the art would find it obvious to cultivate the novel strain to produce daunorubicin, stating that “one cannot choose from the unknown.”<sup>27</sup>

The *Mancy* court also distinguished between a method of *using* a novel product, as involved here, and a method of *making* a novel product, as involved in previous cases in which the court rejected process patents on nonobviousness grounds.<sup>28</sup> The court emphasized that section 103 of the Patent Code requires an evaluation of the process “invention as a whole,” which includes the starting materials as well as the methods applied to them.<sup>29</sup> Based on this premise, the court suggested that the use of a novel starting material establishes the nonobviousness of the process as a whole while a novel resultant product does not speak to the obviousness or nonobviousness of the process.<sup>30</sup>

2. *Chemical Process Patents and In re Durden: The Trouble Begins.* In 1985, the Court of Appeals for the Federal Circuit decided *In re Durden*, holding that a chemical process, otherwise obvious, is not patentable simply because either or both the specific starting material and the product obtained are novel and nonobvious.<sup>31</sup> In *Durden*, Judge Rich, who had written the *Mancy* opinion just eleven years earlier,<sup>32</sup> stated that the novelty of the starting material as well as the novelty of the resultant product makes the process *novel* but not necessarily *nonobvious*.<sup>33</sup> In the course of the opinion, Judge Rich distinguished *Durden* from several previous chemical process cases but failed to mention the *Mancy* decision even once.<sup>34</sup> This suggests that he may have considered *Mancy* inapplicable because it concerned a biotechnology process.

Judge Rich also stressed that the court was not setting forth a per se rule of obviousness, declaring that courts must decide each obviousness case “on the

<sup>25</sup> *Id.*

<sup>26</sup> *Id.* at 1292.

<sup>27</sup> *Id.* at 1293.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 1292.

<sup>30</sup> *See id.* at 1293 (noting that the novelty of the starting material may lend nonobviousness to a method of use while the novelty of the product may not lend such nonobviousness to a process of making).

<sup>31</sup> *In re Durden*, 763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).

<sup>32</sup> Donald G. Daus, *New U.S. Legislation: Biotechnology Process Patents—A Legislative Change and Administrative Expansion*, 12 INTELL. PROP. J. 333, 338 (1997).

<sup>33</sup> *In re Durden*, 763 F.2d at 1410.

<sup>34</sup> *Id.*

basis of its own particular fact situation.”<sup>35</sup> Somewhat prophetically, Judge Rich warned against extracting a general rule from *Durden*, noting that “today’s rule would likely be regretted in tomorrow’s case.”<sup>36</sup> Despite this warning, over the next ten years, the PTO repeatedly relied on *Durden* to deny process claims, including biotechnology and software patents outside the realm of traditional chemical patents.<sup>37</sup>

3. *The Court’s Attempt at a Remedy: Drawing a Distinction Between Using and Making.* In 1990, five years after *Durden*, the Court of Appeals for the Federal Circuit was again confronted with a chemical process patent rejected on nonobviousness grounds.<sup>38</sup> This time around Judge Rich, again writing for the court, held that the chemical process was not obvious and the applicant was therefore entitled to his method claims.<sup>39</sup> Rather than overturning *Durden*, however, Judge Rich attempted to distinguish the case. Specifically, he drew a line between methods of *making* novel compounds, as involved in *Durden*, and methods of *using* those compounds, as involved in *Pleuddemann*.<sup>40</sup> Judge Rich seemed to suggest that the latter are nonobvious on the basis of the novelty of the compounds while the former are not.<sup>41</sup> At the same time, however, Judge Rich acknowledged that *Durden* actually involved both a method of making a novel and nonobvious product *and* a method of using a novel and unobvious starting material, admitting that “there were unobvious starting materials used and unobvious products obtained.”<sup>42</sup>

Not surprisingly, the *Pleuddemann* court’s artificial distinction between using and making only added to the confusion within the PTO and the larger legal community.<sup>43</sup> While patent attorneys could reasonably try to phrase process claims as “processes of using” rather than “processes of making,” many commentators lamented the difficulty of predicting when patent examiners would accept those claims and when they would instead reject the claim as a *Durden*-type

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 1411.

<sup>37</sup> *E.g., Ex parte C*, No. 92-0393, 1992 WL 515817, 27 U.S.P.Q.2d (BNA) 1492 (Bd. Pat. App. & Interf. Sept. 28, 1992) (citing *In re Durden* to deny a biotechnology process claim on obviousness grounds).

<sup>38</sup> *In re Pleuddemann*, 910 F.2d 823, 15 U.S.P.Q.2d (BNA) 1738 (Fed. Cir. 1990).

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 826.

<sup>41</sup> *See id.* at 828 (stating that the obviousness of the appellant’s method claims “depends on the obviousness of using appellant’s new compounds”).

<sup>42</sup> *Id.* at 827.

<sup>43</sup> *See* Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 57 (1991) (“Without a cogent explanation of the standard to apply, there is no reason to believe that the PTO is now more capable of distinguishing a Mancy situation from a *Durden* situation than it did in the past.”).

“process of making” claim in disguise.<sup>44</sup> Some legal commentators further worried that this increased uncertainty in the patent law would have a detrimental effect on the biotechnology industry. This concern spread to biotechnology companies who then lobbied Congress for greater patent protection.<sup>45</sup>

4. *Congress Tries to Step In: Failed Legislative Remedies from 1990 to 1995.* In the 101st Congress, Representative Boucher and Senator DeConcini introduced the Biotechnology Patent Protection Act of 1990 to the House and Senate, respectively.<sup>46</sup> These companion bills were intended to resolve the “Durden dilemma” by providing a nonobviousness exemption for process patents in general.<sup>47</sup> Specifically, the legislation would have added a new paragraph to section 103 of Title 35, stating that “a process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under Section 102 and otherwise nonobvious under Section 103.”<sup>48</sup>

After introducing these bills, the congressmen solicited the opinion of the Department of Commerce, which agreed on the need for legislation but objected to the proposed bill on several grounds, including the extension of enforcement rights “of a patent claiming biotechnological material used in the manufacture of a recombinant product.”<sup>49</sup> In response to these concerns, Representative Boucher introduced a second bill, House Bill 5664, which provided a nonobviousness exemption to process patents,<sup>50</sup> but the 101st Congress took no further action on this legislation.<sup>51</sup>

In the 102d Congress, Representative Boucher and Senator DeConcini introduced the Biotechnology Patent Protection Act of 1991, again through companion bills in the House and Senate,<sup>52</sup> with identical language to House Bill 5664 from the previous Congress.<sup>53</sup> The Senate passed the bill with an amendment that limited the scope of the legislation from processes in general to biotechnology processes only.<sup>54</sup> In the House, Representatives considered the bill in the Committee on the Judiciary, where opponents of the bill suggested that the

<sup>44</sup> See, e.g., David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 DENV. U. L. REV. 173, 178-80 (1991) (explaining the difficulty in predicting how the Patent Office and Federal Circuit would treat process claims after *Pleuddemann*).

<sup>45</sup> Timothy P. Linkkila & Timothy E. Tracy, *Biotechnology Process Patents: Is Special Legislation Needed?*, 5 RISK 177 (1994).

<sup>46</sup> H.R. 3957, 101st Cong. (1990); S. 2326, 101st Cong. (1990).

<sup>47</sup> 136 CONG. REC. 5,182 (1990); 136 CONG. REC. 1482 (1990).

<sup>48</sup> 136 CONG. REC. 5,182 (1990).

<sup>49</sup> S. REP. NO. 102-260, at 2 (1992).

<sup>50</sup> H.R. 5664, 101st Cong. (1991).

<sup>51</sup> S. REP. NO. 102-260, at 2 (1992).

<sup>52</sup> H.R. 1417, 102d Cong. (1991); S. 654, 102d Cong. (1991).

<sup>53</sup> S. REP. NO. 102-260, at 3 (1992).

<sup>54</sup> H.R. REP. NO. 102-1085, at 109 (1992).

legislation was “unnecessary” and, rather than alleviating the current uncertainty in the law, would actually “create new uncertainty.”<sup>55</sup> Opponents also worried that the bill was “overly broad” and would apply to inventions outside the field of biotechnology, including inventions “in the areas of electronics, computer technology, chemicals, mechanical engineering and machinery.”<sup>56</sup> The Committee reported that it did not have time in the remaining days of the 102d Congress to adequately consider amended Senate Bill 654, which may have addressed the Committee’s concerns, and the issue was therefore left for the next Congress.<sup>57</sup>

In the first session of the 103d Congress, the Senate passed the Biotechnology Patent Protection Act of 1993, which, like the amended Senate Bill 654, was limited exclusively to biotechnology processes.<sup>58</sup> The House, however, in the second session of the same Congress, considered a separate bill, House Bill 4307, which was not restricted to biotechnology processes but was “a middle ground approach which is neither industry-specific [n]or totally generic.”<sup>59</sup> Opponents of this generalized approach again defeated the legislation, and the 103d Congress ended without the passage of either version of the bill.<sup>60</sup>

5. *The Biotechnology Process Patent Act of 1995.* On November 1, 1995, the 104th Congress passed the Biotechnology Process Patent Act of 1995,<sup>61</sup> and President William J. Clinton promptly signed the bill into law.<sup>62</sup> Most notably, the Act amended Title 35 of the Patent Code, designating the former section 103 language, which sets forth the nonobviousness requirement for patents, as subsection (a) and adding a new subsection (b) which provides an exemption from the nonobviousness requirement for biotechnology processes using or resulting in novel and nonobvious compositions of matter.<sup>63</sup>

In order for this exemption to apply, the patent applicant must both expressly assert the exemption and claim the process and composition of matter in the same application or in separate applications having the same effective filing date.<sup>64</sup> Additionally, the process patent must include claims to the composition of matter and be set to expire on the same date as the composition of matter patent.<sup>65</sup>

<sup>55</sup> *Id.* at 109.

<sup>56</sup> *Id.* at 109.

<sup>57</sup> *Id.*

<sup>58</sup> 139 CONG. REC. S8815-06, 15792 (1993).

<sup>59</sup> 140 CONG. REC. 24911 (1994).

<sup>60</sup> 141 CONG. REC. 21543 (1995).

<sup>61</sup> Pub. L. No. 104-41 (codified at 35 U.S.C. §§ 103, 282 (2003)).

<sup>62</sup> 1995 U.S.C.C.A.N. 404-1 (1995).

<sup>63</sup> 35 U.S.C. § 103.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*



Finally, the claimed process must fall within the statutory definition of "biotechnology process," as provided in section 103(b).<sup>66</sup>

The legislative history indicates that Congress's main purposes in enacting this legislation were to "resolve the delays and inconsistent determinations faced by biotechnological process patent applicants under present PTO practices" and to close a loophole in the Process Patent Amendments Act of 1988, thereby providing American inventors with greater protection from competitors abroad.<sup>67</sup> In regards to the first purpose, the House Judiciary Committee noted that the bill and its predecessors were developed in response to "two conflicting and irreconcilable decisions" by the Court of Appeals for the Federal Circuit: *Durden* and *Pleuddemann*.<sup>68</sup> The Committee lamented the PTO's reliance on *Durden* in rejecting biotechnology process claims on nonobviousness grounds as well as the confusion caused by the using-making distinction described in *Pleuddemann*.<sup>69</sup> Both the House and the Senate anticipated that the Biotechnology Process Patent Act of 1995 would relieve confusion within the PTO and provide certainty for patent applicants.<sup>70</sup>

The legislative history also reveals, to some extent, Congress's intent in limiting the nonobviousness exemption to biotechnology processes rather than setting forth a broad exemption that would apply to process patents in general.<sup>71</sup> Specifically, members of both the House and the Senate recognized the failure of previous legislation that would have established a broad nonobviousness exemption for process patents.<sup>72</sup> Presumably, the drafters of the Biotechnology Process Patent Act limited its scope to biotechnology processes in order to pass the legislation, a goal they finally achieved at last in 1995, a full ten years after the *Durden* decision and five years after *Pleuddemann*.<sup>73</sup>

<sup>66</sup> *Id.*

<sup>67</sup> H.R. REP. NO. 104-178, at 1-2 (1995), *reprinted in* 1995 U.S.C.C.A.N. 395, 395-396; *see also* 141 CONG. REC. 28072 (1995) (statement of Sen. Hatch) (stating that the purpose of the legislation is to "resolve delays and inconsistent determinations faced by biotechnology patentees under present PTO practices").

<sup>68</sup> H.R. REP. NO. 104-178, at 3.

<sup>69</sup> *Id.*

<sup>70</sup> H.R. REP. NO. 104-178, at 5; 141 CONG. REC. 21543 (1995) (statement of Sen. Hatch).

<sup>71</sup> H.R. REP. NO. 104-178, at 4-5; 141 CONG. REC. 21543 (1995) (statement of Sen. Hatch).

<sup>72</sup> *See* H.R. REP. NO. 104-178, at 4-5 ("Although industry specific legislation, particularly in the context of patent law, is generally not favored, . . . predecessor bills, such as H.R. 4307, made their enactment unlikely."); 141 CONG. REC. 21543 (1995) (statement of Sen. Hatch) ("The House version of the bill introduced last year was drafted to address issues broader than biotechnology industry, due to then Chairman Hughes' insistence that the measure not be industry specific, an approach which was not acceptable to the Senate.").

<sup>73</sup> Biotechnology Process Patent Act of 1995, Pub. L. No. 104-41 (codified at 35 U.S.C. §§ 103, 282). Though limiting the scope of the legislation may have compromised Congress's goal of

6. *The Federal Circuit's Follow-up: In re Ochiai, In re Brouwer, and Torpharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.* Just one month after President Clinton signed the Biotechnology Process Patent Act of 1995 into law, the Federal Circuit decided *In re Ochiai*, holding that a chemical process was not obvious when the process utilized a novel and nonobvious starting material to create a novel and nonobvious product.<sup>74</sup> Although the facts of the case reveal that both the starting material and the resulting product were novel and nonobvious, the court emphasized the relevance of the starting material in its nonobviousness determination. Specifically, the court cited *Mancy* with approval, concurring with the *Mancy* court's reasoning that "one cannot choose from the unknown," to support the conclusion that a novel, nonobvious starting material establishes the nonobviousness of the process.<sup>75</sup>

In its analysis, the court failed to recognize a distinction between the law on biotechnology processes and that on chemical processes. In particular, the court noted that *Mancy* involved "a highly analogous set of facts"<sup>76</sup> without distinguishing between the biotechnology and chemical subject matter of the two cases. Additionally, the court neglected to point out that the recently enacted Biotechnology Process Patent Act of 1995 would apply to the facts of the *Mancy* case but not to the facts of *Ochiai*.

Despite the fact that the *Ochiai* court arrived at the opposite result of *Durden* under facts "identical to those that occurred in the *Durden* decision,"<sup>77</sup> the *Ochiai* court avoided explicitly overruling *Durden* by directly contradicting itself and suggesting that the facts of *Durden* are actually in some way distinguishable from those of *Ochiai*.<sup>78</sup> Specifically, the court asserted that the patent examiner incorrectly applied the *Durden* case which is one "turning on specific facts,"<sup>79</sup>

eliminating inconsistent determinations in the Patent Office, the successful passage of this legislation did allow Congress to meet its second goal of closing a loophole in foreign trade policy. As one commentator noted, this loophole posed a unique problem for biotechnology companies; that is, "while claims to transformed host cells may be patentable and readily granted, they have only limited commercial value insofar as a third party is able to freely import the protein made offshore, free from the scope of the Omnibus Trade and Competitiveness Act of 1988 and free from exclusion via the International Trade Commission." Harold C. Wegner, *Biotechnology Process Patents: Judicial or Legislative Remedy*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 24, 25 (1991). By passing the Biotechnology Process Patent Act of 1995, Congress could close this loophole, thus satisfying the monetary motivation which drove biotechnology companies to seek legislation in the first place.

<sup>74</sup> *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995).

<sup>75</sup> *Id.* at 1570.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 1568.

<sup>78</sup> *See id.* at 1570.

<sup>79</sup> *Id.*

thereby implying some significant peculiarity in the facts of *Ochiai* which makes the *Durden* decision inapplicable.

Three months later, the Federal Circuit decided *In re Brouwer*, holding that a chemical process is not obvious where the resulting product is new and nonobvious.<sup>80</sup> Like the *Ochiai* court, the *Brouwer* court noted that nonobviousness is a highly fact-specific inquiry.<sup>81</sup> Unlike the *Ochiai* court, however, the *Brouwer* court could not rely on the *Mancy* court's argument that "one cannot choose from the unknown" to back up its holding because, under the facts of *Brouwer*, only the resulting product, and not the starting material, was novel and nonobvious.<sup>82</sup> Again, the court avoided explicitly overruling *Durden*, instead rejecting it as inapplicable.<sup>83</sup>

More recently, in July 2003, the Federal Circuit held in *Torpharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.* that the owner of a chemical process patent was not estopped from arguing that the patent was nonobvious.<sup>84</sup> The court came to this conclusion even though the patent owner had originally defended against the patent examiner's nonobviousness objection by relying on the novelty of the product, which was later discovered not to be novel.<sup>85</sup> The court gave three reasons for its holding: (1) the plaintiff in this case actually had made two separate arguments for the nonobviousness of the process, and the other argument may still have been valid, (2) the appellee's argument of the form "If p, then q. Not p. Therefore, not q." is a logical fallacy, and (3) a patent examiner's reasons may be challenged so that, even if he only found the process nonobvious based on the novelty of the product, a process patent may still be valid on other grounds if the novelty of the product fails.<sup>86</sup> While the patent examiner's finding of nonobviousness on the basis of the novel resultant product was not in question, as the product was not truly novel, the *Torpharm* court suggested that, contrary to *Brouwer*, novelty of the product may not always be adequate to support a finding of nonobviousness of the process.<sup>87</sup> Specifically, the court asserted that "a process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious."<sup>88</sup> In other words, the *Torpharm* court suggested, as the *Mancy* court did twenty-nine years earlier, that a new and nonobvious product is not determinative, and may

<sup>80</sup> *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996).

<sup>81</sup> *Id.* at 425.

<sup>82</sup> *See id.* at 424 (noting that the claimed process results in a new, nonobvious product).

<sup>83</sup> *Id.* at 425-26.

<sup>84</sup> 336 F.3d 1322, 67 U.S.P.Q.2d (BNA) 1511 (Fed. Cir. 2003).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 1329.

<sup>87</sup> *Id.* at 1327.

<sup>88</sup> *Id.*

not even be relevant, to an assessment of the obviousness of a chemical or biotechnology process.<sup>89</sup>

## B. THE SCIENCE

Biotechnology in the scientific world is broadly defined as “the manipulation of organisms or their components to perform practical tasks or provide useful products.”<sup>90</sup> The science of biotechnology includes a vast array of practices from fermentation to antibiotic production to sewage treatment to genetic engineering and gene therapy.<sup>91</sup> “Biotechnology” as defined by section 103(b) of the Patent Code, however, is somewhat different.<sup>92</sup> Specifically, section 103(b) defines a “biotechnology process” as follows:

- (A) A process of genetically altering or otherwise inducing a single- or multi-celled organism to—
  - (i) express an 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).<sup>93</sup>

In other words, the statutory definition of a biotechnology process purports to include only two general types of procedures, genetic alteration and production of cell lines, which the statute further restricts in scope.

1. *Genetic Alteration.* Genetic alteration, in general, is the manipulation of genetic material, or deoxyribonucleic acid (DNA).<sup>94</sup> All living cells possess DNA,

<sup>89</sup> *Id.*; *In re Manay*, 499 F.2d at 1293.

<sup>90</sup> NEIL A. CAMPBELL ET AL., *BIOLOGY* 364 (5th ed. 1999). *See also* BOREM ET AL., *supra* note 8, at 2 (defining biotechnology as “any technology associated with the manipulation of biological systems”).

<sup>91</sup> OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY 72 (A.D. Smith et al. eds., 2000).

<sup>92</sup> *See* 35 U.S.C. § 103(b) (defining a biotechnology process).

<sup>93</sup> *Id.*

<sup>94</sup> Colin R. Harwood & Anil Wipat, *Genome Management and Analysis: Prokaryotes*, in *BASIC BIOTECHNOLOGY* 65 (Colin Ratledge & Bjørn Kristiansen eds., 2d ed. 2001).

which are complex molecules which code for the production of proteins.<sup>95</sup> These proteins, in turn, drive all of the basic functions of life.<sup>96</sup> Specifically, each DNA molecule is composed of two polynucleotides associated to form a double helix.<sup>97</sup> On the inside of this helix is a series of nucleic acid base pairs.<sup>98</sup> There are only four nucleic acid bases which always pair the same way: adenine with thymine and guanine with cytosine.<sup>99</sup> The sequence of these base pairs carries the organism's genetic information, providing instructions for the production of proteins (via ribonucleic acid (RNA)).<sup>100</sup> In particular, series of three bases, called codons, encode for twenty specific amino acids which join together in certain combinations to compose specific proteins.<sup>101</sup> These proteins play a central role in regulating the cell's functions and in determining the physiological characteristics of the organism as a whole.<sup>102</sup>

The statute describes genetic alteration as those procedures which stimulate a living thing to (1) express an exogenous nucleotide sequence, (2) change the expression of an endogenous nucleotide sequence, or (3) express a physiological trait not naturally associated with the organism.<sup>103</sup> "Expression" of a nucleotide sequence refers to the process of protein synthesis from the genetic code.<sup>104</sup> Expression of an exogenous nucleotide sequence thus involves an organism responding, via protein synthesis, to genetic information originating outside the organism. This new genetic information may be incorporated into an organism's pre-existing DNA through a number of recombinant DNA techniques.<sup>105</sup> For example, in gene splicing, scientists use proteins called restriction enzymes to cut DNA molecules at specific locations and then insert foreign DNA, from the same or different species, at these locations.<sup>106</sup> Similarly, altering the expression of an endogenous nucleotide sequence refers to a process of inducing an organism to express its original genetic material differently by starting, ceasing, or otherwise adjusting the production of certain proteins.

<sup>95</sup> BOREM ET AL., *supra* note 8, at 3.

<sup>96</sup> *Id.*

<sup>97</sup> H. ROBERT HORTON ET AL., *PRINCIPLES OF BIOCHEMISTRY* 12 (3d ed. 2002).

<sup>98</sup> MICHAEL T. MADIGAN ET AL., *BIOLOGY OF MICROORGANISMS* 171 (10th ed. 2003).

<sup>99</sup> *Id.*

<sup>100</sup> HORTON ET AL., *supra* note 97, at 12; MADIGAN ET AL., *supra* note 98, at 171.

<sup>101</sup> MADIGAN ET AL., *supra* note 98, at 194.

<sup>102</sup> *See* CAMPBELL ET AL., *supra* note 90, at 68 (describing the many functions of proteins).

<sup>103</sup> 35 U.S.C. § 103(b).

<sup>104</sup> David B. Archer et al., *Genetic Engineering: Yeasts and Filamentous Fungi*, in *BASIC BIOTECHNOLOGY* 96 (Colin Ratledge & Bjørn Kristiansen eds., 2001).

<sup>105</sup> *See* YOUNT, *supra* note 2, at 6-8 (describing the development of recombinant DNA procedures); Harwood & Wipat, *supra* note 94, at 66-81 (detailing genetic engineering techniques).

<sup>106</sup> YOUNT, *supra* note 2, at 7.

The third type of genetic alteration within the statutory definition involves the expression of a new physiological characteristic.<sup>107</sup> This category is significantly more expansive than the previous two, apparently covering processes which do not involve the manipulation of DNA and thus are not processes of genetic alteration in the scientific sense. Specifically, a new physiological characteristic broadly refers to any change in the normal functioning of a living organism.<sup>108</sup> The exact scope of this clause is somewhat vague and depends upon the definition of the word “express,” which in the context of the statute may be interpreted either as a genetics term of art or in its generic sense.

As mentioned earlier, expression in the field of genetics refers to the process of synthesizing proteins from the genetic code.<sup>109</sup> Applying this definition would limit the scope of clause (iii) to those physiological changes which result from altered protein synthesis due to adjustments in the genetic code. This interpretation, however, would render clause (iii) superfluous given that the previous two clauses already cover such genetic alterations. That is, at a basic level, clause (i) covers processes incorporating outside genetic information while clause (ii) covers all other genetic alterations, specifically those involving changes to the organism’s original DNA. Additionally, the statute refers to “a process of genetically altering *or otherwise inducing*” new physiological characteristics.<sup>110</sup> Since, “otherwise inducing” cannot apply to either of the previous clauses (because changes in nucleotide sequences are, by definition, processes of genetic alteration<sup>111</sup>), these words too would be rendered superfluous if not applied to clause (iii).

The difficulties surrounding the term of art definition suggest that “express” should be interpreted in its generic sense to denote an outward manifestation.<sup>112</sup> Under this extremely broad—but perhaps necessary—interpretation, any procedure which stimulates an organism to manifest an unnatural physiological characteristic (i.e., to change its normal functioning) is a biotechnology process under the statute. This definition could include procedures, such as injecting an organism with an inorganic chemical compound, which are beyond the bounds of genetic alteration in the scientific world.

<sup>107</sup> 35 U.S.C. § 103(b).

<sup>108</sup> WEBSTER’S II: NEW RIVERSIDE UNIVERSITY DICTIONARY 887 (Anne H. Soukhanov et al. eds., 1984).

<sup>109</sup> Archer et al., *supra* note 104, at 96.

<sup>110</sup> 35 U.S.C. § 103(b) (emphasis added).

<sup>111</sup> See CAMPBELL ET AL., *supra* note 90, at 6-7 (noting that genetic information is encoded in the nucleotide sequences of DNA).

<sup>112</sup> See WEBSTER’S II: NEW RIVERSIDE UNIVERSITY DICTIONARY, *supra* note 108, at 455 (defining “express” and “expression”).

2. *The Production of Cell Lines.* The second statutory category of biotechnology process involves the production of cell lines. Cell lines are populations of cells cultured in vitro (i.e., outside a living organism) that are descended from a single primary culture.<sup>113</sup> These cells have common characteristics,<sup>114</sup> and for this reason, researchers frequently utilize cell lines to produce specific proteins.<sup>115</sup> The statute expressly mentions monoclonal antibodies, which are immune proteins secreted by a clone of cells,<sup>116</sup> as an example of such a protein. Because these proteins specifically bind to particular antigens (i.e., foreign agents, such as bacterial and viral molecules, which elicit an immune response),<sup>117</sup> monoclonal antibodies are particularly useful in laboratory research, clinical diagnosis, and the treatment of disease.<sup>118</sup> The statute limits the production of cell lines, however, to those which result from cell fusion procedures, leaving out other production methods.<sup>119</sup>

Additionally, the statute fails to incorporate numerous procedures involving isolated cells and cell products, which scientists generally categorize as biotechnology processes. That is, part (A) of the statutory definition applies only to “single and multi-celled organisms” while part (B), which applies to isolated cells, is limited to the production of cell lines through cell fusion procedures.<sup>120</sup> This indicates that all other processes involving isolated cells or cell products are excluded under the statute (with the exception of those defined by part (C), described below). In other words, the statutory definition leaves out various biotechnological procedures, such as isolation of enzymes from animal and plant sources,<sup>121</sup> incorporation of amino acids in food products and pharmaceuticals,<sup>122</sup> and even certain developments in stem cell research.<sup>123</sup>

<sup>113</sup> OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY, *supra* note 91, at 101.

<sup>114</sup> *Id.*

<sup>115</sup> N. Vriezen et al., *Mammalian Cell Culture*, in BASIC BIOTECHNOLOGY 449, 450 (Colin Ratledge & Bjørn Kristiansen eds., 2d ed. 2001).

<sup>116</sup> CAMPBELL ET AL., *supra* note 90, at G- 15.

<sup>117</sup> *Id.* at 844.

<sup>118</sup> *Id.* at 853.

<sup>119</sup> See Vriezen et al., *supra* note 115, at 450 (noting infection with a virus and transfection with an oncogene or mutagenesis as alternative methods for producing a continuous cell line for purposes of protein production).

<sup>120</sup> 35 U.S.C. § 103(b).

<sup>121</sup> See David A. Lowe, *Production of Enzymes*, in BASIC BIOTECHNOLOGY 393-95 (Colin Ratledge & Bjørn Kristiansen eds., 2d ed. 2001) (noting isolation of enzymes from animal and plant products as a good source of some enzymes).

<sup>122</sup> See L. Eggeling et al., *Amino Acids*, in BASIC BIOTECHNOLOGY 282 (Colin Ratledge & Bjørn Kristiansen eds., 2d ed. 2001) (describing commercial uses of amino acids).

<sup>123</sup> See, e.g., Antonio Regalado, *Stem Cells Without Cloning*, WALL ST. J., Feb. 1, 2002, at B1 (noting fertilization and parthenogenesis (i.e., electrical or chemical stimulation) as alternative procedures to cloning in stem cell production).

The statutory definition includes one further category of “biotechnology process” in part (C), providing that a method of using a product created by a process in part (A) or (B) is also a “biotechnology process.”<sup>124</sup> This provision expands “biotechnology processes” to include all uses of products from any of the above-mentioned procedures, encompassing even some processes which scientists typically would not consider biotechnology. For example, a simple combination of two drugs<sup>125</sup> could constitute a biotechnology process under this definition. Furthermore, part (C) creates an artificial distinction between methods of using a biological material produced by a part (A) or (B) procedure and those which are not. For example, *any* use of a hormone produced through a recombinant DNA technique within part (A) is a “biotechnology process” under part (C), while the use of the same hormone produced through chemical synthesis<sup>126</sup> only qualifies as a biotechnology process if it meets the requirements of part (A) or (B).

### III. ANALYSIS

Despite Congress’s intent in passing the Biotechnology Process Patent Act of 1995 to relieve inconsistent determinations within the Patent Office,<sup>127</sup> the Act actually creates even greater inconsistencies in our nation’s patent law than previously existed. First, the Act unjustifiably singles out biotechnology processes as exempt from the standard nonobviousness requirement in certain situations. Second, the Act extends this exemption beyond process claims utilizing novel and nonobvious starting materials to those merely producing novel and nonobvious resultant products. The Biotechnology Process Patent Act of 1995 is therefore simultaneously too restrictive in the scope of subject matter covered and too broad in the application of its exemption from the nonobviousness requirement.

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<sup>124</sup> 35 U.S.C. § 103(b).

<sup>125</sup> See Amy Tsao, *Superpills with a One-Two Punch*, Businessweek Online, Oct. 9, 2003, at [http://www.businessweek.com/technology/content/oct2003/tc2003109\\_1337.htm](http://www.businessweek.com/technology/content/oct2003/tc2003109_1337.htm) (commenting on the new trend of pharmaceutical companies to produce combination pills composed of two or more commonly-used component drugs).

<sup>126</sup> See George B. Kresse, *Recombinant Proteins of High Value*, in BASIC BIOTECHNOLOGY 436 (Colin Ratledge & Bjørn Kristiansen eds., 2d ed. 2001) (noting chemical synthesis of proteins as a feasible alternative to gene technology).

<sup>127</sup> H.R. REP. NO. 104-178, at 1-2 (2000), *reprinted in* 1995 U.S.C.C.A.N. 395, 395-396; 141 CONG. REC. 28072 (1995) (statement of Sen. Hatch) (noting that the purpose of the legislation is to “resolve delays and inconsistent determinations faced by biotechnology patentees under present PTO practices”).



## A. THE SCOPE OF SUBJECT MATTER

The Biotechnology Process Patent Act of 1995 is too restrictive in the scope of subject matter covered and should at least apply to chemical process claims as well as biotechnology process claims, if not to process claims generally. While the statutorily-provided exemption from the nonobviousness requirement for certain biotechnology processes is most likely constitutional,<sup>128</sup> the exemption is a poor policy which creates inconsistency and inequality in our patent system. By providing this exception for biotechnology processes, Congress implies that this rule is not available for other types of process claims,<sup>129</sup> perhaps foreclosing an otherwise reasonable judicial interpretation to the contrary. This is especially problematic for chemical process claims, which are similar and even overlap with biotechnology process claims,<sup>130</sup> yet are subjected to a different nonobviousness analysis under the statute.<sup>131</sup>

Because of the significance courts have attached to the nonobviousness requirement for over a century,<sup>132</sup> a statutory exemption from this key requirement raises a question of constitutionality. The Biotechnology Process Patent Act of 1995 is probably authorized, however, under the United States Constitution.<sup>133</sup> That is, while the nonobviousness requirement plays an important role in determining the patentability of inventions,<sup>134</sup> nonobviousness does not seem to be constitutionally mandated.<sup>135</sup> It is therefore within the power

<sup>128</sup> Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119, 1185.

<sup>129</sup> See H.R. REP. NO. 104-178, at 4-5 (2000) (noting the Act's application to biotechnology processes only); 141 CONG. REC. 28074 (1995) (statement of Sen. Hatch) (commenting on the failure of previous legislation which applied to processes generally).

<sup>130</sup> See 7 PHYSICS AND CHEMISTRY BASIS OF BIOTECHNOLOGY 4 (Marcel de Cuyper & Jeff W. M. Bulte eds., 2001) (identifying the importance of applying physical and chemical principles to biotechnology); FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 19 (2002) (pointing out that biotechnology draws from many areas of science).

<sup>131</sup> See 2 JOHN GLADSTONE MILLS III ET AL., PATENT LAW FUNDAMENTALS § 10.36 (2d ed. 2003) (declaring that as a result of the Biotechnology Process Patent Act of 1995 "a legal (as opposed to a *factual*) distinction now exists between the patentability of biotechnological and non-biotechnological processes") (emphasis in original).

<sup>132</sup> See *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851) (requiring nonobviousness for patentability); *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (noting the codification of the nonobviousness requirement in the Patent Act of 1952).

<sup>133</sup> Heald & Sherry, *supra* note 128, at 1185.

<sup>134</sup> See MERGYES ET AL., *supra* note 12, at 112 (identifying nonobviousness as the ultimate requirement for patentability).

<sup>135</sup> See Heald & Sherry, *supra* note 128, at 1184 (reasoning that, while the Constitution requires more than novelty, Congress has "substantial discretion in determining how high a degree of

of Congress to provide an exemption from the nonobviousness requirement for biotechnology processes.<sup>136</sup>

Although providing an exemption from the nonobviousness requirement for certain biotechnology processes may be constitutional, it is an imprudent policy which creates inconsistency in our patent system. The United States Supreme Court has repeatedly emphasized the importance of the nonobviousness requirement as a limit on patent monopolies.<sup>137</sup> Congress should not permit an exemption to this fundamental requirement without a solid justification for doing so. In regard to the Biotechnology Process Patent Act of 1995, there is no good reason, in law or in science, to provide an exemption from the nonobviousness requirement for certain, statutorily defined biotechnology processes.

1. *Lack of a Scientific Justification.* Though the current law provides a special exemption from the nonobviousness requirement for biotechnology processes, there is no scientific basis for Congress to distinguish between biotechnology and other types of process claims. The disparity is particularly blatant in the context of chemical processes, which are similar to, and often overlap with, biotechnology processes<sup>138</sup> yet are not entitled to the same nonobviousness analysis under the statute. Additionally, through its statutory definition of “biotechnology processes,” the Act creates an unfounded division within the field of biotechnology itself by including certain types of biotechnology processes while excluding others.

A significant problem with the Biotechnology Process Patent Act of 1995 is that it creates an artificial distinction between biotechnology and chemical processes. While scientists and laypersons alike often refer to biotechnology as one field of science among many others, no field of science is truly independent.<sup>139</sup> Neurologists study biological systems, biologists utilize chemistry techniques, and chemists draw on the principles of physics.<sup>140</sup> Similarly, scientists working in the field of biotechnology constantly rely on the principles and methodology of other scientific disciplines, including chemistry.<sup>141</sup> At a very basic level, every living being is made up of cells, which in turn are made up of

innovation it will require”).

<sup>136</sup> *Id.* at 1185.

<sup>137</sup> 2 DONALD CHISUM, CHISUM ON PATENTS § 5.01 (2002).

<sup>138</sup> See 7 PHYSICS AND CHEMISTRY BASIS OF BIOTECHNOLOGY, *supra* note 130, at 4 (highlighting the importance of applying physical and chemical principles to biotechnology); see also FUKUYAMA, *supra* note 130, at 19 (noting that biotechnology incorporates techniques from many other areas of science).

<sup>139</sup> CAMPBELL ET AL., *supra* note 90, at 22.

<sup>140</sup> *Id.* at 22; MARIE T. BANICH, COGNITIVE NEUROSCIENCE AND NEUROPSYCHOLOGY 4-5 (2d ed. 2004).

<sup>141</sup> Manning, *supra* note 1, at 14; CAMPBELL ET AL., *supra* note 90, at 364.

molecules, which are the base units of all chemical compounds.<sup>142</sup> In a way, then, all biotechnology processes are actually chemical processes; they are just limited to those chemical processes that involve the manipulation of biochemical products (such as proteins and nucleic acid base pairs) or chemical processes within biological systems. Furthermore, chemical and biotechnology products and processes often serve similar functions; for example, pharmaceutical companies use both chemical and biotechnology processes in the production of new drugs.<sup>143</sup> Accordingly, distinguishing between such closely related subject matter by applying a different nonobviousness analysis to biotechnology and chemical process patents makes little sense from a scientific standpoint.

The Act is even more illogical in its definition of "biotechnology processes" in that the statutory definition creates an artificial distinction within the field of biotechnology itself. Specifically, the statute excludes some processes generally considered biotechnology, including methods for producing a cell line other than cell fusion (part (B))<sup>144</sup> and various methods involving isolated cells or cell products.<sup>145</sup> At the same time, the inclusion of any process inducing an organism to exhibit an unnatural physiological characteristic<sup>146</sup> (part (A), clause (iii)) and any method of using a biotechnologically-produced product<sup>147</sup> (part (C)) brings in processes from outside the realm of biotechnology.

The Act may further create an unreasonable distinction between biotechnology and other processes generally. The nonobviousness requirement serves the general purpose of preventing patent monopolies on inventions which fail to advance the state of the useful arts.<sup>148</sup> Therefore, in passing industry-specific legislation which provides a different nonobviousness analysis for certain types of process claims, Congress should have a reasonable justification for circumventing the traditional nonobviousness requirement. Congress, in passing

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<sup>142</sup> CAMPBELL ET AL., *supra* note 90, at 22.

<sup>143</sup> LEE, *supra* note 8, at 79.

<sup>144</sup> See Vriezen et al., *supra* note 115, at 450 (identifying infection with a virus and transfection with an oncogene or mutagenesis as two alternative methods to cell fusion for producing a continuous cell line).

<sup>145</sup> See, e.g., Eggeling et al., *supra* note 122, at 282 (discussing the incorporation of amino acids in some food products and pharmaceuticals); Lowe, *supra* note 121, at 393-95 (describing isolation of enzymes from animal and plant products); Regalado, *supra* note 123, at B1 (noting fertilization and parthenogenesis (i.e., electrical or chemical stimulation) as alternative procedures to cloning in stem cell production).

<sup>146</sup> See WEBSTER'S II: NEW RIVERSIDE UNIVERSITY DICTIONARY, *supra* note 108, at 887 (suggesting that a new physiological characteristic broadly refers to any change in the normal functioning of a living organism).

<sup>147</sup> See, e.g., Tsao, *supra* note 125 (commenting on the new trend of pharmaceutical companies to produce combination pills composed of two or more commonly used component drugs).

<sup>148</sup> CHISUM, *supra* note 137, § 5.01.

the Biotechnology Process Patent Act of 1995, has provided no such justification. The legislative history does reveal objections to extending the nonobviousness exemption to software, electronic, and machinery claims.<sup>149</sup> Even if the unique nature of software claims<sup>150</sup> might entitle them to a separate nonobviousness analysis, however, such an argument would support special treatment for software patents rather than for biotechnology patents.<sup>151</sup> Generally, in the absence of any compelling justification, Congress should not supply special exceptions, such as the 1995 Act's exemption from the nonobviousness requirement for biotechnology processes, in patent law.

2. *Lack of a Legal Justification.* Though Congress addresses its reasons for passing the Act,<sup>152</sup> these stated reasons fall short of providing a sound justification for the creation of a nonobviousness exemption specifically limited to biotechnology processes. In particular, in discussing the legislation, no member of Congress offered a single policy reason for singling out biotechnology process claims from other types of process claims. In fact, earlier versions of the bill, including the original 1990 Act, would have established a broad nonobviousness exemption for process patents,<sup>153</sup> suggesting that the bill drafters recognized this as a more favorable approach. Later, in considering the 1995 Act, members of both Houses pointed to the failure of this previous broad legislation as a reason for limiting the scope of the 1995 Act to biotechnology processes.<sup>154</sup> This, coupled with an indication of strong pressure from pharmaceutical and biotechnology companies,<sup>155</sup> suggests that Congress limited the scope of the 1995 Act to biotechnology processes simply to satisfy the demands of special interest groups rather than to achieve any beneficial patent policy.

In passing the Biotechnology Process Patent Act of 1995, Congress not only failed to provide a policy basis for singling out biotechnology process claims but

<sup>149</sup> H.R. REP. NO. 102-1085, at 109 (1992).

<sup>150</sup> See, e.g., *State St. Bank & Trust v. Signature Fin. Servs.*, 149 F.3d 1368, 47 U.S.P.Q.2d (BNA) 1596 (Fed. Cir. 1998) (suggesting that a software system might be patentable as a machine rather than a process).

<sup>151</sup> But see Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DEENV. U. L. REV. 127, 129 (1991) (suggesting an analogy between biotechnology and software processes by characterizing DNA as "a read-only memory for programming biological systems").

<sup>152</sup> H.R. REP. NO. 104-178, at 1-2 (1995), reprinted in 1995 U.S.C.C.A.N. 395, 395-396; 141 CONG. REC. 28072 (1995) (statement of Sen. Hatch).

<sup>153</sup> H.R. 1417, 102d Cong. (1991); S. 654, 102d Cong. (1991); 74 H.R. 3957, 101st Cong. (1990); S. 2326, 101st Cong. (1990).

<sup>154</sup> See *supra* notes 72-73 and accompanying text.

<sup>155</sup> See Burk, *supra* note 43, at 71 (noting extensive lobbying efforts by Genentech, Amgen, and other biotechnology companies which "spawned successive drafts of the proposed legislation, each of which did new violence to the current state of the patent law").

also actually undermined one of the purposes it set out to achieve. Specifically, the legislative history indicates that one of Congress's main purposes in enacting this legislation was to resolve inconsistencies in the patent law created by "two conflicting and irreconcilable decisions" in the Federal Circuit: *In re Durden* and *In re Pleuddemann*.<sup>156</sup> The Biotechnology Process Patent Act of 1995, however, applies only to biotechnology processes and would therefore have no effect on chemical process cases like *Durden* and *Pleuddemann*. In fact, the Act actually seems to create a new inconsistency by drawing a distinction between the law on chemical process patents and the law on biotechnology process patents.

The new section 103(b) of the Patent Code singles out biotechnology process claims—as defined in the statute—and provides an exemption from the nonobviousness requirement for claims which use or result in novel and nonobvious compositions of matter.<sup>157</sup> In specifically naming and defining "biotechnology processes," the Act clearly indicates that other types of process claims, such as those for chemical processes, are not covered under the Act. Additionally, the legislature's strict focus on biotechnology processes and objections to legislation that was broader in scope<sup>158</sup> suggests that the 1995 Act may actually foreclose the Federal Circuit's subsequent attempts, starting with *In re Ochiai*,<sup>159</sup> to establish a similar rule for chemical process claims.

Just one month after Congress passed the Biotechnology Process Patent Act of 1995, the Federal Circuit itself attempted to alleviate the confusion following its *Durden* decision in the case of *In re Ochiai*.<sup>160</sup> The *Ochiai* court effectively overruled *Durden*,<sup>161</sup> holding that a chemical process is not obvious where the process utilizes a novel and nonobvious starting material to create a novel and nonobvious product.<sup>162</sup> The Federal Circuit then expanded its ruling just three months later in the case of *In re Brouwer*, this time holding that a chemical process is not obvious where the resultant product—rather than the starting material—is new and nonobvious.<sup>163</sup> The combined result of *Ochiai* and *Brouwer* is to provide a rule for chemical processes similar to the rule that the Biotechnology Process Patent Act of 1995 provides for biotechnology processes.

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<sup>156</sup> H.R. REP. NO. 104-178, at 3.

<sup>157</sup> 35 U.S.C. § 103 (2003).

<sup>158</sup> See H.R. REP. NO. 102-1085, at 109 (1992) (recognizing concerns that House Bill 1417 would apply to inventions outside the field of biotechnology, including inventions "in the areas of electronics, computer technology, chemicals, mechanical engineering and machinery").

<sup>159</sup> *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).

<sup>160</sup> *Id.*

<sup>161</sup> *But see id.* at 1570 (avoiding outright rejection of *Durden* as a case "turning on specific facts").

<sup>162</sup> *Id.* at 1565.

<sup>163</sup> *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996).

Although the rules are similar in effect, there are two noteworthy differences between the statutory law of the Biotechnology Process Patent Act of 1995 and the judicial rule of the two Federal Circuit decisions. First, while the statute is expressly limited to biotechnology processes,<sup>164</sup> the rule established in the two Federal Circuit decisions is not expressly limited to chemical processes.<sup>165</sup> Second, while the statute presents an exemption not otherwise provided,<sup>166</sup> the court is simply interpreting the process invention “as a whole”<sup>167</sup> to include the starting material<sup>168</sup> and resulting product.<sup>169</sup> Because the court has not expressly limited its rulings to chemical processes and because the rule is based on a straightforward interpretation of the Patent Code (which applies to patents generally), the judicial rule may reasonably apply to other types of process claims.

Though the *Ochiai* court intended to finally resolve the confusion following the *Durden* decision, and provided what otherwise may have been the clearest and most accurate interpretation of the statutory law on process patents to date, the court’s holding may actually violate the Biotechnology Process Patent Act of 1995. That is, persuasive evidence demonstrates that the Federal Circuit’s holdings in *Ochiai* and *Brouwer* contradict both the language and history of the 1995 Act. First, the Act itself provides a nonobviousness exemption not otherwise provided, which it explicitly limits to biotechnology processes.<sup>170</sup> The fact that Congress believed an exemption was needed at all suggests that the starting material and resulting product are not naturally part of the invention “as a whole.”<sup>171</sup> If they were, a novel and nonobvious starting material or resulting product would already be adequate to establish the nonobviousness of any process. A broader statute applying to all process claims could be viewed as a simple codification of this interpretation; however, by limiting the statute to biotechnology processes, Congress has provided a special exemption for biotechnology process claims that is distinguishable from the law governing other types of process claims.

Second, the legislative history of the Biotechnology Process Patent Act of 1995 reveals (1) the failure of several previous bills applying to process claims generally and (2) Congress’s awareness of these failures and objections to a

<sup>164</sup> 35 U.S.C. § 103(b) (2003).

<sup>165</sup> *In re Ochiai*, 71 F.3d 1565; *In re Brouwer*, 77 F.3d 422.

<sup>166</sup> See 35 U.S.C. § 103(b) (“Notwithstanding [the nonobviousness requirement of] subsection (a) . . . a biotechnological process using or resulting in a composition of matter that is novel . . . and nonobvious . . . shall be considered nonobvious . . .”)

<sup>167</sup> 35 U.S.C. § 103(a).

<sup>168</sup> *In re Ochiai*, 71 F.3d 1565.

<sup>169</sup> *In re Brouwer*, 77 F.3d 422.

<sup>170</sup> 35 U.S.C. § 103.

<sup>171</sup> *Id.*

broader bill.<sup>172</sup> In other words, not only does the Act explicitly apply only to biotechnology processes, but also the legislative history indicates that Congress purposely drafted this limitation in order to exclude other types of process claims, including those for chemical and software patents. While there is no policy basis for drawing such a distinction between biotechnology and other types of process claims, the legislative intent is clear. Congress did not want the rule that novel and nonobvious starting materials or resulting products establish the nonobviousness of a process to apply to chemical, software, or other non-biotechnology process claims.

Ironically then, the 1995 Act, while purporting to alleviate inconsistencies in the patent system,<sup>173</sup> not only creates a new inconsistency (in distinguishing between biotechnology and other types of process claims) but also may preclude the court from alleviating the inconsistency judicially. Thus, the Federal Circuit's decisions in *Ochiai* and *Brouwer*, holding that chemical processes are nonobvious where the starting material or resulting product is novel and nonobvious, may in fact violate the Biotechnology Process Patent Act of 1995.<sup>174</sup> Until the courts or Patent Office recognize this contradiction, however, patent applicants will retain the benefit of these judicial decisions. As it stands now, the Federal Circuit clearly has not noticed this possible dilemma,<sup>175</sup> and the Patent and Trademark Office seems ignorant of it as well, applying both the statutory and judicial rules to patent applications.<sup>176</sup>

## B. APPLICATION OF THE EXEMPTION

Even as the Act is too narrow in the scope of subject matter covered, the Biotechnology Process Patent Act of 1995 is concurrently too broad in the application of its exemption. Specifically, the statute should provide that processes with novel and nonobvious starting materials, but not those with merely novel and nonobvious resulting products, are nonobvious themselves. In this sense, the 1995 Act went too far in its attempt to overrule *Durden*, a case involving both novel and

<sup>172</sup> See *supra* note 72 and accompanying text.

<sup>173</sup> H.R. REP. NO. 104-178, at 1-2 (1995), reprinted in 1995 U.S.C.C.A.N. 395, 395-396; 141 CONG. REC. 28072 (1995) (statement of Sen. Hatch).

<sup>174</sup> See *In re Brouwer*, 77 F.3d 422; *In re Ochiai*, 71 F.3d 1565.

<sup>175</sup> See *In re Brouwer*, 77 F.3d 422 (finding a chemical process nonobvious where a resultant product is novel and nonobvious); *In re Ochiai*, 71 F.3d 1565 (finding a chemical process nonobvious where a starting material is novel and nonobvious).

<sup>176</sup> See PTO Notice, *Guidance on Treatment of Product and Process Claims in Light of In re Ochiai, In re Brouwer, and 35 U.S.C. § 103(b)*, 1184 OFF. GAZ. PAT. OFF. 86 (Mar. 26, 1996) [hereinafter PTO Notice] (directing patent examiners to apply the *Ochiai* and *Brouwer* decisions to process claims).

nonobvious starting materials as well as novel and nonobvious resulting products.<sup>177</sup> In order to overrule *Durden*, Congress could simply have articulated a rule that proper analysis of process inventions “as a whole”<sup>178</sup> includes a consideration of the starting materials but not the resulting products.<sup>179</sup>

Congress may have avoided establishing that rule because of the confusion resulting from the using–making distinction of *Pleuddemann*.<sup>180</sup> The *Pleuddemann* decision likely caused this confusion, however, because the court failed to articulate the rule clearly<sup>181</sup> and because the court used *Durden*, a case involving both a method of using a novel material and a method of making a novel product, as its primary example of a “method-of-making” case.<sup>182</sup> While critics of the using–making distinction correctly point out that all processes are, at some level, processes of using some materials to make other materials,<sup>183</sup> the distinction becomes rational when the focus is on the starting materials versus the resultant products. Thus, in assessing process claims, patent examiners—and judges—should consider the starting materials used in the process but not the resultant products made by the process as part of the process invention “as a whole.”<sup>184</sup> That analysis finds support in both previous and subsequent case law<sup>185</sup> as well as in plain logic.

Though the *Pleuddemann* decision may be too convoluted to provide a useful analysis,<sup>186</sup> Judge Rich (the author of both the *Durden* and *Pleuddemann* opinions) set forth a clear distinction between novel, nonobvious starting materials and novel, nonobvious resulting products in the earlier case of *In re Mancy*.<sup>187</sup> The *Mancy* court emphasized that the statutory standard for nonobviousness demands a consideration of the process “invention as a whole.”<sup>188</sup> The court then suggested

<sup>177</sup> See *In re Durden*, 763 F.2d 1406, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985) (affirming the rejection of a patent application on nonobviousness grounds).

<sup>178</sup> 35 U.S.C. § 103(a).

<sup>179</sup> See *In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974) (adopting such an interpretation).

<sup>180</sup> See *In re Pleuddemann*, 910 F.2d 823, 15 U.S.P.Q.2d (BNA) 1738 (Fed. Cir. 1990) (attempting to distinguish between methods of making novel products, which may be obvious, and methods of using such products, which are nonobvious).

<sup>181</sup> See *id.* at 827 (“[T]he compounds and their use are but different aspects of, or ways of looking at, the same invention and consequently that invention is capable of being claimed both as new compounds or as a new method or process. . .”).

<sup>182</sup> *Id.*

<sup>183</sup> E.g., Leon Radomsky, *Can Process Claims that Include Id and Unobvious Product Limitations Still Be Obvious After In re Ochiai?*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 567, 588-89 (1997).

<sup>184</sup> 35 U.S.C. § 103(a).

<sup>185</sup> E.g., *In re Mancy*, 499 F.2d 1289; *In re Ochiai*, 71 F.3d 1565.

<sup>186</sup> Burk, *supra* note 43, at 56-57.

<sup>187</sup> *In re Mancy*, 499 F.2d 1289.

<sup>188</sup> *Id.* at 1292.



that a starting material is part of the invention as whole.<sup>189</sup> In particular, the court reasoned that one skilled in the art would not find it obvious to utilize a novel starting material because, as the court succinctly notes, “one cannot choose from the unknown.”<sup>190</sup> In contrast, the court implied that a novel resulting product does not speak to the obviousness or nonobviousness of the process.<sup>191</sup> In other words, the resulting product, unlike the starting material, is not logically part of the process invention as a whole.

Despite the fact that the *Mancy* decision was issued almost thirty years ago, courts continue to approve of its holding and its distinction between novel starting materials and novel resulting products. As recently as December 1995, the Federal Circuit cited *Mancy* with approval.<sup>192</sup> Specifically, the *Ochiai* court concurred with the *Mancy* court’s reasoning that “one cannot choose from the unknown” and similarly concluded that a novel, nonobvious starting material establishes the nonobviousness of the process.<sup>193</sup> Though shortly thereafter the Federal Circuit held that a novel, nonobvious resultant product is also adequate to establish the nonobviousness of a process,<sup>194</sup> the court has since backed away from this rule.<sup>195</sup> In July 2003, the Federal Circuit suggested in dicta that a new and nonobvious resultant product may not be relevant to an assessment of the obviousness of a process claim.<sup>196</sup> This supports the view that the starting materials, but not the resulting products, are part of the process invention as a whole and are thus relevant to a determination of the nonobviousness of a process claim.

#### IV. CONCLUSION

Despite these problems with the Biotechnology Process Patent Act of 1995, the revised statute has had surprisingly little practical effect. This may be due in part to one peculiar feature of the nonobviousness exemption: in order for the Patent Office to apply the exemption, a patent applicant must expressly claim it.<sup>197</sup> Patent

<sup>189</sup> *Id.* at 1293.

<sup>190</sup> *Id.* at 1293.

<sup>191</sup> *See id.* at 1293 (noting that the novelty of the starting material may lend nonobviousness to a method-of-use while the novelty of the product may not lend such nonobviousness to a process of making).

<sup>192</sup> *In re Ochiai*, 71 F.3d at 1570.

<sup>193</sup> *Id.* at 1570.

<sup>194</sup> *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996).

<sup>195</sup> *See Torpharm, Inc.*, 336 F.3d at 1327 (suggesting that novelty of a resulting product may not be adequate to support a finding of nonobviousness of a process).

<sup>196</sup> *Id.* at 1327 (“A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious.”).

<sup>197</sup> 35 U.S.C. § 103 (2003); *see also* PTO Notice, *supra* note 176 (emphasizing that § 103(b) applies only where the patent applicant makes a “timely election” (by petition under 37 CFR § 1.182) to

applicants may be reluctant to assert the exemption because the presumption of validity of a claim obtained pursuant to section 103(b) rests on the novelty and nonobviousness of the underlying composition of matter.<sup>198</sup> Applicants may be unwilling to risk losing the benefits of the presumption of validity, particularly where there are alternative arguments for nonobviousness.

A second, and perhaps more fundamental, reason for the Act's lack of influence may stem from the fact that the courts and the Patent Office consider the Federal Circuit's decisions in *Ochiai* and *Brouwer* applicable to biotechnology process claims.<sup>199</sup> That is, applying these two cases may achieve a similar result for process claims generally as applying the statute would achieve for biotechnology process claims. Thus, patent applicants and examiners may simply be relying on this judicial rule rather than on the more complex, limited statutory rule.<sup>200</sup> This is problematic because statutory law trumps case law and the Act seems to foreclose the *Ochiai* court's rulings in regards to chemical processes. Thus, while the Patent Office may be applying the law as it should be by relying on the *Ochiai* rule for chemical process claims,<sup>201</sup> that application does not accurately reflect the law as it truly stands.

Before Congress passed the Biotechnology Process Patent Act of 1995, the Federal Circuit or Supreme Court could have resolved the inconsistencies resulting from the *Durden* and *Pleuddemann* decisions by holding that the use of a novel and nonobvious starting material establishes the nonobviousness of a process. In fact, the Federal Circuit held exactly that in *Ochiai*.<sup>202</sup> Because the limited scope of the 1995 Act suggests that such a judicial interpretation is not available, however, the Federal Circuit's decision (or any court decision for that matter) is not adequate to resolve this new discrepancy between the law for biotechnology process patents and the law for all other types of process patents. Additionally, since the revised statute is most likely constitutional,<sup>203</sup> the Supreme Court is unlikely to step in and

proceed under this section).

<sup>198</sup> See STEPHEN A. BECKER, 1 PATENT APPLICATIONS HANDBOOK § 2:25 (2003) (noting the amendment to 35 U.S.C. § 282 as a major caveat to the Biotechnology Process Patent Act of 1995).

<sup>199</sup> See, e.g., *Ex parte Lee*, 1995 WL 1696759 (Bd. Pat. App. & Interf.) (remanding a *Durden*-type rejection of a biotechnology process claim for further consideration in light of *In re Ochiai*); *Ex parte Reider*, 1995 WL 1692980 (Bd. Pat. App. & Interf.) (reversing a patent examiner's rejection of a biotechnology process claim based on the *Ochiai* and *Brouwer* decisions).

<sup>200</sup> See BECKER, *supra* note 198, § 2:25 ("As a result of the Federal Circuit decisions, it is unclear whether [the Act] will provide applicants with any benefit . . .").

<sup>201</sup> See PTO Notice, *supra* note 176 (proclaiming that, in light of *Ochiai* and *Brouwer*, Patent Office personnel must consider all claim limitations, including "language in a process claim which recites making or using a nonobvious product," to analyze process claims); UNITED STATES PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2116.01 (8th ed. 2003) (suggesting that the *Ochiai* and *Brouwer* decisions apply to process claims generally).

<sup>202</sup> *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).

<sup>203</sup> Heald & Sherry, *supra* note 128, at 1185.

invalidate the Act. This leaves Congress to remedy the predicament it has created. Considering that the legislature previously rejected bills which were broader in scope<sup>204</sup> and that even the courts and the Patent Office appear oblivious to the dilemma,<sup>205</sup> Congress seems unlikely that will choose to pass corrective legislation any time soon.

Nonetheless, if Congress considers remedial legislation, that legislation should address several issues. First, the legislation should apply to all types of process claims, not just to those that meet a statutory definition of "biotechnology." Though this kind of broad legislation failed to pass earlier sessions of Congress, it is necessary to correct the current discrepancy in the law for biotechnology processes (as defined by statute) as compared to all other types of process claims. Second, the legislation should provide interpretative guidance rather than an exemption not otherwise provided. In other words, a corrective bill should include language indicating that consideration of the process invention "as a whole" includes the starting material and, for this reason, a novel and nonobvious starting material establishes the nonobviousness of a process. Finally, new legislation should indicate that resultant products, in contrast to starting materials, are not part of the process invention as a whole and thus their novelty and nonobviousness are irrelevant to the nonobviousness of a process. Though Congress failed to make this distinction in the Biotechnology Process Patent Act of 1995, the courts have suggested such a distinction is appropriate.<sup>206</sup> Oddly, a bill similar to the 1990 Act,<sup>207</sup> the first predecessor to the 1995 Act, would satisfy all of these conditions.

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<sup>204</sup> See H.R. REP. NO. 102-1085, at 109 (1992) (noting the failure of House Bill 1417); 141 CONG. REC. 21543 (statement of Sen. Hatch) (1995) (noting the failure of House Bill 4307).

<sup>205</sup> The Federal Circuit's decisions in *In re Ochiai* and *In re Brouwer* jointly establish a rule for chemical process claims which may be foreclosed by the Biotechnology Process Patent Act of 1995. See *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996) (holding that a novel and nonobvious resulting product establishes the nonobviousness of a chemical process); *In re Ochiai*, 71 F.3d 1565 (holding that a novel and nonobvious starting material establishes the nonobviousness of a chemical process). See also PTO Notice, *supra* note 176 ("In view of the Federal Circuit's decisions in *Ochiai* and *Brouwer*, an applicant's need to rely upon § 103(b) should be rare.").

<sup>206</sup> *In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974); *In re Ochiai*, 71 F.3d 1565; *Torpharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.*, 336 F.3d 1322 (Fed. Cir. 2003). *But see In re Brouwer*, 77 F.3d 422 (holding that a novel and nonobvious resultant product establishes the nonobviousness of a process).

<sup>207</sup> See 136 CONG. REC. 5182 (1990) (statement of Sen. DeConcini) (noting that the 1990 Act would have stating that a process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise nonobvious under section 103).