

# Product-by-Process Patent Claim Construction: Resolving the Federal Circuit's Conflicting Precedent

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## INTRODUCTION

Imagine trying to patent a soufflé, using only the recipe to define what it is. If you have never seen a soufflé, you would not necessarily know how to identify it based on the recipe used to make it. You would only describe a soufflé in this manner if you lacked the words to describe the structural characteristics, such as size, density, and other appropriate measures. What happens if the recipe only describes soufflés that are four inches in diameter? Should you be able to assert that you have described every type of soufflé that can be made?

This is the problem that courts have struggled with for many years with regard to product-by-process claim construction. These claims use the process by which a product is created to define the invention, instead of just claiming the structural elements as a

typical product claim would.<sup>1</sup> The patent statutes do not specifically allow for product-by-process claims—they are a creation of the Patent Office and the courts.<sup>2</sup> Recently, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) again attempted to address the issue of product-by-process claim construction, but failed to give much clarity or correctness to the subject.<sup>3</sup> In fact, the two judges of the Federal Circuit that have advocated differing approaches to product-by-process claim construction have both called for an en banc decision to decide this controversial issue.<sup>4</sup> Much of the problem with these claims is the inherent ambiguity when claiming the invention of a product in process language. This Note will discuss the ways that courts have grappled with this problem and will suggest a path out of the current legal morass.

Product-by-process claims are an acceptable form of claiming an invention in U.S. patent law.<sup>5</sup> These claims are used to define an invention when the structural elements are more difficult to claim.<sup>6</sup> However, these claims are often avoided because the Federal Circuit has issued conflicting decisions in the *Scripps Clinic* and *Atlantic Thermoplastics* cases regarding the scope of these types of claims.<sup>7</sup> Separate panels of the Federal Circuit issued these two decisions sixteen months apart, and the en banc Federal Circuit reviewed neither case.<sup>8</sup> Some district courts have applied the first decision because the first decision of two conflicting decisions is binding precedent. Other courts have

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<sup>1</sup> U.S. Patent and Trademark Office, Manual of Patent Examining Procedure, § 2113 (8th ed., rev. 4 2005) [hereinafter MPEP].

<sup>2</sup> See 35 U.S.C. § 112 (2006).

<sup>3</sup> See *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006), *reh’g en banc denied*, 453 F.3d 1346 (Fed. Cir. 2006).

<sup>4</sup> *SmithKline*, 453 F.3d at 1347 (Newman, J., and Rader, J., dissenting separately from the denial of rehearing en banc).

<sup>5</sup> MPEP, *supra* note 1.

<sup>6</sup> 3 DONALD S. CHISUM, CHISUM ON PATENTS § 8.05 (2006).

<sup>7</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) (holding that product-by-process claims “are not limited to product prepared by the process set forth in the claims”); *Atl. Thermoplastics Co. v. Faytex Corp.* 970 F.2d 834, 846–47 (Fed. Cir. 1992) (holding that “process terms in product-by-process claims serve as limitations in determining infringement”), *reh’g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).

<sup>8</sup> *Atl. Thermoplastics*, 974 F.2d 1279 (Fed. Cir. 1992) (rehearing en banc denied).

found the rationale in the second case more compelling.<sup>9</sup> Quite obviously, this has created great uncertainty in the law, making the scope of product-by-process claims ill-defined.<sup>10</sup>

Claim construction has always been one of the most hotly contested areas of patent law because every patent infringement lawsuit requires figuring out what the invention actually is.<sup>11</sup> After the *Markman* decision, claim construction is a matter of law, normally determined during a hearing before a jury is empanelled.<sup>12</sup> The recent decision in *Phillips v. AWH* eliminated a primary focus on dictionary definitions to determine the scope of claims and reaffirmed the central role of the specification in helping courts determine the actual scope of patent protection.<sup>13</sup> But what these decisions have not done is create more certainty for claim construction at the District Court level. According to one study, claim construction is reversed on appeal 34.5% of the time.<sup>14</sup>

Despite the inherent ambiguities in product-by-process claims, certain industries have a special interest in claiming their inventions using product-by-process language. One industry where product inventions are often described in process language is the pharmaceutical industry.<sup>15</sup> By defining compounds by their

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<sup>9</sup> For cases that follow *Scripps*, see, for example, *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 372 F. Supp. 2d 430 (D.N.J. 2005); *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 218 F. Supp. 2d 594 (D. Del. 2002); *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000); *DeKalb Genetics Corp. v. Northrup King Co.*, No. 96 C 50169, 1997 U.S. Dist. LEXIS 14275 (N.D. Ill. Aug. 14, 1997) (marked not for publication). For cases that follow *Atlantic Thermoplastics*, see, for example, *Kennametal, Inc. v. Cerametal S.A.R.L.*, No. 99-CV-74678-DT, 2001 U.S. Dist. LEXIS 25284 (E.D. Mich. May 10, 2001); *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7 (D. Mass. 1993); *Fairfax Dental Ltd. v. Sterling Optical Corp.*, 808 F. Supp. 326 (S.D.N.Y. 1992).

<sup>10</sup> CHISUM, *supra* note 6.

<sup>11</sup> *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967).

<sup>12</sup> *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

<sup>13</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

<sup>14</sup> Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005).

<sup>15</sup> Mark D. Passler, *Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. MIAMI L. REV. 233, 234 (1994).

method of manufacture or synthesis, the inventor is hedging his bet as to which claims would actually stand up during an infringement suit.<sup>16</sup> When there are hundreds of millions, if not billions, of dollars on the line when a drug loses patent protection, product-by-process claims can often become crucial.<sup>17</sup>

The controversy over product-by-process claiming also highlights unique issues of appellate procedure and faithfulness to precedent. The Federal Circuit is unique in that its appellate jurisdiction is not limited by geography, but by subject matter.<sup>18</sup> When Congress created the Federal Circuit in 1982, it wanted to create a court that would set national standards, especially in patent law.<sup>19</sup> Disagreement among the other circuits usually aids the evolution of national standards, as the Supreme Court benefits from the deliberation and analysis of the several courts in ultimately reaching its decision.<sup>20</sup> But for the Federal Circuit, there should never be a situation akin to a circuit split.<sup>21</sup> Any conflicting precedent should be resolved by the en banc court.<sup>22</sup> However, when the *Atlantic Thermoplastics* case was appealed for en banc review, the full court refused to hear the case, with the dissenters possessing a completely different interpretation of the scope of the controlling precedent of the *Scripps* case.<sup>23</sup> So not only did two conflicting precedents arise out of the two decisions, but the court was also split on the procedural aspect of how conflicting precedents should be resolved.<sup>24</sup> The recent decision in

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<sup>16</sup> See *In re Hughes*, 496 F.2d 1216, 1219 (C.C.P.A. 1974).

<sup>17</sup> Passler, *supra* note 15, at 234.

<sup>18</sup> 28 U.S.C.S. § 1295(a)(1) (2006).

<sup>19</sup> S. REP. NO. 97-275, at 1 (1981), as reprinted in 1982 U.S.C.C.A.N. 11, 11.

<sup>20</sup> See, e.g., *Judicial and Admin. Review of Immigration Decisions: Testimony before the S. Comm. on the Judiciary*, 109th Cong. (2006) (testimony of Prof. David A. Martin), available at [http://judiciary.senate.gov/testimony.cfm?id=1845&wit\\_id=673](http://judiciary.senate.gov/testimony.cfm?id=1845&wit_id=673) (arguing against placing immigration appeals within the jurisdiction of the Federal Circuit).

<sup>21</sup> S. REP. NO. 97-275, at 3 (1981), as reprinted in 1982 U.S.C.C.A.N. 11, 13 (stating that the Federal Circuit's jurisdiction is defined in terms of subject matter, rather than geography).

<sup>22</sup> FED. CIR. R. 35(a).

<sup>23</sup> *Atl. Thermoplastics, Co.*, 974 F.2d 1279.

<sup>24</sup> *Id.*

*SmithKline Beecham v. Apotex* has done little to resolve the conflicts between the two decisions.<sup>25</sup>

Though there are situations where product-by-process claims are needed, this method of claiming is such an inferior way to claim an invention that every effort should be made to exclude the practice from use. For claims that already exist, there should be a renewed emphasis on whether or not the invention was distinctively described. These issues of law will have to be decided by the Federal Circuit en banc, the Supreme Court or by an act of Congress. Another contradictory panel decision would only serve to further muddy the waters in an already murky area of patent jurisprudence. This would restore much of the balance missing in today's product-by-process claim construction jurisprudence.

Part I of this Note will discuss the current state of product-by-process claim construction case law. Part II will examine why that precedent is hopelessly contradictory. Finally, Part III will argue for a newly restrictive regime where product-by-process claims are strongly disfavored, with an eye to foreign patent systems as a guide for the U.S. patent system.

## I. THE HISTORY OF PRODUCT-BY-PROCESS CLAIM CONSTRUCTION

### A. *Supreme Court Precedent*

There is a series of cases from the 1880s that do have some relevance for any discussion of product-by-process claims. However, since these decisions antedate so much of the modern techniques of patent drafting, much of their precedential weight is undercut.

In *Goodyear Dental Vulcanite Co. v. Davis*, the Supreme Court reviewed an infringement suit where the product claim had a reference to the process used to make it in the specification.<sup>26</sup> The

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<sup>25</sup> See *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006).

<sup>26</sup> *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 223 (1880).

patent concerned a set of dentures made out of vulcanized rubber<sup>27</sup> where the specification described the process used to make it.<sup>28</sup> The defendant made a set of dentures out of celluloid, which did not require vulcanization.<sup>29</sup> The court held: “[c]elluloid is not an equivalent for the material which the patent makes essential to the invention, and in the use of it for a dental plate, the process which is inseparable from the invention is not, and cannot be, employed.”<sup>30</sup> The court read the process limitations into the claim, even though the products were distinguishable.

Four years later, the Supreme Court reviewed another claim similar to modern product-by-process claims.<sup>31</sup> Here, the Supreme Court analyzed a patent for an artificially made dye that can also be found in nature.<sup>32</sup> The claim covered the dye itself and it referenced a particular method for making it.<sup>33</sup> The patentee sued another patent holder that had made the same dye, but instead used an entirely different process.<sup>34</sup> The Court held that:

[U]nless it is shown that the process of No. 4,321 [plaintiff’s patent] was followed to produce the defendant’s article, or unless it is shown that that article could not be produced by any other process, the defendant’s article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown.<sup>35</sup>

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<sup>27</sup> “Vulcanization, or curing of rubber, is a chemical process in which individual polymer molecules are linked to other polymer molecules by atomic bridges. The end result is that the springy rubber molecules become cross-linked to a greater or lesser extent. This makes the bulk material harder, much more durable and also more resistant to chemical attack. It also makes the surface of the material smoother and prevents it from sticking to metal or plastic chemical catalysts.” WIKIPEDIA, *Vulcanization*, <http://en.wikipedia.org/w/index.php?title=Vulcanization&oldid=75592500> (last visited Sept. 13, 2006).

<sup>28</sup> *Goodyear*, 102 U.S. at 222.

<sup>29</sup> *Id.* at 228–29.

<sup>30</sup> *Id.* at 230.

<sup>31</sup> *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884).

<sup>32</sup> *Id.* at 294–96.

<sup>33</sup> *Id.* at 296.

<sup>34</sup> *Id.* at 310.

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

The Court also went on to give an alternative holding.<sup>36</sup> There, the Court said that the dye itself was not patentable because the dye constituted prior art to the plaintiff's patent.<sup>37</sup> Thus, the Court held that the patent was for the novel process used to make the dye.<sup>38</sup>

Three years later, in the *Plummer* case, the Court looked again at a version of product-by-process claiming.<sup>39</sup> The patent at issue in this case was for “the new manufacture hereinabove described, consisting of iron ornamented in imitation of bronze by the application of oil and heat, substantially as described.”<sup>40</sup> But because of a process already known in the prior art, the Court held that the patent for the product was only novel because of the process used to make it.<sup>41</sup> Thus, the only way to construe the patent as not anticipated necessarily implied that there was no infringement.<sup>42</sup> The Court did not lay down a blanket rule that all product-by-process claims are novel; rather, the Court held that a process limitation had to be read into this claim to make it novel.

#### B. Patentability and the P.T.O.

Following United States Court of Customs and Patent Appeals (“C.C.P.A.,” a forerunner court to the Federal Circuit that had jurisdiction over appeals from the Patent Office) and Federal Circuit precedent, the United States Patent and Trademark Office (“P.T.O.”) follows the rule that “product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.”<sup>43</sup> The P.T.O. also cites *In re Thorpe* for the rule that:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product

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<sup>36</sup> *Id.* at 311–13.

<sup>37</sup> *Id.* at 311.

<sup>38</sup> *See id.* at 310–12.

<sup>39</sup> *Plummer v. Sargent*, 120 U.S. 442 (1887).

<sup>40</sup> *Id.* at 445 (quoting the text of the patent application).

<sup>41</sup> *Id.* at 449.

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

<sup>43</sup> MPEP, *supra* note 1, § 2113.

does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.<sup>44</sup>

This rule is consistent with the maxim that claims should be given their broadest possible interpretation when examining their patentability.<sup>45</sup> These rules balance two competing public policy goals of the P.T.O. On one hand, giving proposed claims their broadest possible interpretation “reduce[es] the possibility that claims, finally allowed, will be given broader scope than is justified . . . .”<sup>46</sup> On the other hand, it is not unfair to applicants, because “‘before a patent is granted the claims are readily amended as part of the examination process.’”<sup>47</sup>

Prior to this current rule, the C.C.P.A. had a long debate over whether or not product-by-process claiming could be used when the product could *only* be described in process language, the so-called “Rule of Necessity.”<sup>48</sup> This rule is now less strictly enforced, but much of the debate over the scope of the rule greatly informs the current problems the Federal Circuit faces in determining the scope of product-by-process claims.

The Rule of Necessity originated in a decision on patentability by the Commissioner of Patents in 1891.<sup>49</sup> In *Painter*, the product was defined “wholly by the process of making it.”<sup>50</sup> While acknowledging that as a general rule “a claim for an article of manufacture should not be defined by the process of producing that article,”<sup>51</sup> the Commissioner held:

When the case arises that an article of manufacture is a new thing, a useful thing, and embodies invention, and that article cannot be properly defined and discriminated from

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<sup>44</sup> *Id.* (citing *In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985)).

<sup>45</sup> *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

<sup>46</sup> *Id.* (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)).

<sup>47</sup> *Id.* (quoting *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1583 (Fed. Cir. 1987)).

<sup>48</sup> CHISUM, *supra* note 6, § 8.05[2][a].

<sup>49</sup> *Ex parte Painter*, 1891 C.D. 200, 57 O.G. 999 (Dec. Comm’r Pat. 1891).

<sup>50</sup> *Id.* at 200, 57 O.G. at 999.

<sup>51</sup> *Id.*, 57 O.G. at 999.

the prior art otherwise than by reference to the process of producing it, a case is presented which constitutes a proper exception to the rule.<sup>52</sup>

This was the rule cited by the Patent Office in one form or another prior to the adoption of the major revisions of U.S. patent law in 1952.<sup>53</sup>

Following the adoption of the 1952 Act,<sup>54</sup> the C.C.P.A. could not settle on one rule for the patentability of product-by-process claims for over twenty years.<sup>55</sup> In *In re Steppan*, the C.C.P.A. held that there was no statutory basis to sustain the Rule of Necessity.<sup>56</sup> One year later, the C.C.P.A. reaffirmed the Rule of Necessity, holding that “a claim for an article capable of such definition must define the article by its structure and not by the process of making it.”<sup>57</sup> Two years later, after deciding *Steppan*, the C.C.P.A. did not specifically reject the Rule of Necessity, but cited *Steppan* favorably in holding that the applicant met the requirement of 35 U.S.C. § 112 that the invention be distinctively claimed.<sup>58</sup> Finally, *Hughes* did not specifically reject the Rule of Necessity, but said that it was not founded on section 112.<sup>59</sup> Instead, it refused to reject the rule because it had such a sound policy justification.<sup>60</sup>

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<sup>52</sup> *Id.* at 201, 57 O.G. at 1000.

<sup>53</sup> See *In re Lifton*, 189 F.2d 261 (C.C.P.A. 1951); *In re Shortell*, 173 F.2d 993 (C.C.P.A. 1949); *In re Moeller*, 117 F.2d 565 (C.C.P.A. 1941); *In re McKee*, 95 F.2d 264 (C.C.P.A. 1938); *In re Dreyfus*, 75 F.2d 501 (C.C.P.A. 1935); *In re Grupe*, 48 F.2d 936 (C.C.P.A. 1931); *In re Butler*, 37 F.2d 623 (C.C.P.A. 1930); *In re Brown*, 29 F.2d 873 (D.C. Cir. 1928); *Ex parte Fesenmeier*, 1922 C.D. 18, 302 O.G. 199, (Dec. Comm’r Pat. 1922).

<sup>54</sup> Bryson Act, Pub. L. No. 82-593, 66 Stat. 792 (1952).

<sup>55</sup> *In re Hughes*, 496 F.2d 1216 (C.C.P.A. 1974); *In re Pilkington*, 411 F.2d 1345 (C.C.P.A. 1969); *In re Johnson*, 394 F.2d 591 (C.C.P.A. 1968); *In re Steppan*, 394 F.2d 1013 (C.C.P.A. 1967).

<sup>56</sup> *Steppan*, 394 F.2d at 1019.

<sup>57</sup> *Johnson*, 394 F.2d at 594.

<sup>58</sup> *Pilkington*, 411 F.2d at 1349–50.

<sup>59</sup> *Hughes*, 496 F.2d at 1218.

<sup>60</sup> *Id.*

### C. *The Scripps Decision*

The *Scripps* case concerned an infringement suit over a patent for a protein essential to blood clotting, Human Factor VIII:C.<sup>61</sup> The claim at issue in the case was: “[h]ighly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.”<sup>62</sup> At issue with regard to the product-by-process claims was the district court’s denial of summary judgment for infringement of these claims.<sup>63</sup> The court (with an opinion written by Judge Pauline Newman) then cited a number of C.C.P.A. decisions on patentability for the proposition that “[the rule that] product-by-process claims would not be infringed unless the same process were practiced . . . appears to diverge from our precedent.”<sup>64</sup> The court then held:

In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims.<sup>65</sup>

As a result, the court ruled that summary judgment was incorrect and remanded to the district court.<sup>66</sup>

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<sup>61</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1568 (Fed. Cir. 1991).

<sup>62</sup> *Id.* at 1570. Claim 1 was:

1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of
  - (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
  - (b) eluting the VIII:C,
  - (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
  - (d) eluting the adsorbed VIII:C, and
  - (e) recovering highly purified and concentrated VIII:C.

*Id.*

<sup>63</sup> *Id.* at 1583.

<sup>64</sup> *Id.* (citing *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985); *In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972); *In re Bridgeford*, 357 F.2d 679, 682 n.5 (C.C.P.A. 1966)).

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

<sup>66</sup> *Id.* at 1584.

*D. The Atlantic Thermoplastics Case*

Sixteen months after the *Scripps* decision, a different three-judge panel of the Federal Circuit handed down another decision that hinged on the construction of product-by-process claims.<sup>67</sup> In *Atlantic Thermoplastics v. Faytex*, the court examined the appeal of a trial verdict that held the Faytex Corporation liable for infringement of Atlantic Thermoplastics' patent for a shock-absorbing innersole.<sup>68</sup> The claim at issue was: "The molded innersole produced by the method of claim 1."<sup>69</sup> The district court held that because the process that Faytex used was different from the process included in Atlantic Thermoplastics' product-by-process claim, Faytex did not infringe the product-by-process claim.<sup>70</sup>

However, in deciding the infringement issue, this Federal Circuit panel refused to use the rule of *Scripps* and instead stated in a footnote, "[a] decision that fails to consider Supreme Court precedent does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent. For the reasons set forth below, we necessarily so conclude."<sup>71</sup> The court then evaluated a series of Supreme Court and C.C.P.A. decisions and concluded, "[I]n both

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<sup>67</sup> *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), *reh'g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).

<sup>68</sup> *Id.* at 835.

<sup>69</sup> *Id.* at 836. The method of Claim 1 was:

- (a) introducing an expandable, polyurethane into a mold; and
- (b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises:

- (i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and

- (ii) recovering a molded innersole with the insert material having a tacky surface forming a part of the exposed bottom surface of the recovered innersole. *Id.* at 835–36.

<sup>70</sup> *Id.* at 836.

<sup>71</sup> *Id.* at 838–39 n.2 (citations omitted).

patentability actions before the CCPA and infringement actions before the Supreme Court or the regional circuits, the courts regarded the process language in product-by-process claims as limiting the claim.”<sup>72</sup> But the court also noted that prior precedent with regard only to patentability set forth the rule that, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.”<sup>73</sup> Thus, the court held that process steps form claim limitations for the purposes of infringement, the court affirmed the ruling of the district court and found that Faytex did not infringe the product-by-process claim.<sup>74</sup>

The *Atlantic Thermoplastics* decision provoked an extraordinarily heated response when the Federal Circuit rejected a petition to rehear the case before the en banc court.<sup>75</sup> Judges Nies, Rich, Newman and Lourie all filed dissenting opinions against the denial of en banc review.<sup>76</sup> Judge Nies expressed no opinion on the merits of either side’s arguments, but did vote for the en banc court to hear the case.<sup>77</sup> Judge Rich blasted the panel both for being wrong in its claim interpretation, but worst of all totally ignoring the precedential rules of the court.<sup>78</sup> Judge Rich wrote that the footnote describing the panel’s reason why it chose not to follow the *Scripps* decision was “not only insulting to the *Scripps* panel (Chief Judge Markey, Judge Newman and a visiting judge), it is mutiny. It is heresy. It is illegal.”<sup>79</sup> Judge Rich also added a comment that has guided many lower courts that have evaluated

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<sup>72</sup> *Id.* at 845.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 847.

<sup>75</sup> *Atl. Thermoplastics*, 974 F.2d 1279.

<sup>76</sup> *Id.* Federal Circuit rules require that attorneys acting on behalf of their clients include one of two statements when asking for an en banc rehearing: “Based on my professional judgment, I believe the panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this court: (cite specific decisions). [or] Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance: (set forth each question in a separate sentence).” FED CIR. R. 35(b)(2).

<sup>77</sup> *Atl. Thermoplastics*, 974 F.2d at 1280 (Nies, J., dissenting on the denial of rehearing en banc).

<sup>78</sup> *Id.* at 1280–81 (Rich, J., dissenting on the denial of rehearing en banc).

<sup>79</sup> *Id.* at 1281.

product-by-process claims, stating that, “[f]ortunately, this court has another rule—as yet to be ignored by a panel, I believe—that where there are *conflicting* precedents, the *earlier* precedent controls. But the conflict should have been eliminated *in banc* to avoid confusion in the law.”<sup>80</sup> Judge Lourie (joined by Judges Rich and Newman) also questioned both the way that the panel addressed the precedential weight of the *Scripps* decision<sup>81</sup> and the breadth of its holding on process steps informing claim limitations.<sup>82</sup>

Judge Newman’s dissent (joined by Judges Rich and Lourie) is the most interesting here because she filed opinions in all of the three most recent cases on product-by-process claims.<sup>83</sup> She first identified the *Atlantic Thermoplastics* claim as *not* a true product-by-process claim.<sup>84</sup> She suggested a three-tiered classification scheme for claims that have process elements:

(1) [W]hen the product is new and unobvious, but is not capable of independent definition; (2) when the product is old or obvious, but the process is new; (3) when the product is new and unobvious, but has a process-based limitation (e.g. a “molded” product). Type (2) includes the *Atlantic* class of claim; such claims are examined as process claims, their validity depends on the novelty and unobviousness of the process, and they are infringed only when the process is used. Type (1) is the *Scripps* class of claim; such claims are examined as product claims, their validity depends on the novelty and unobviousness of the product, and they are infringed by the product however made. Indeed, claims of types (2) and (3) are not properly called “product-by-

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<sup>80</sup> *Id.*

<sup>81</sup> “[I]t is contrary to our case law and procedures for a panel to act contrary to a prior precedent of this court. If this panel thought *Scripps* was wrongly decided (and I do not), it was either bound to follow our precedents or to seek an *in banc* review.” *Id.* at 1298 (citation omitted) (Lourie, J., dissenting on the denial of rehearing en banc).

<sup>82</sup> *Id.* at 1298–99.

<sup>83</sup> See *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1321 (Fed. Cir. 2006) (Newman, J., dissenting); *Atl. Thermoplastics*, 974 F.2d at 1281 (Newman, J., dissenting on the denial of rehearing en banc); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1568 (Fed. Cir. 1991).

<sup>84</sup> *Atl. Thermoplastics*, 974 F.2d at 1282.

process” claims, if that term is used with precision.<sup>85</sup>  
(footnote omitted)

Judge Newman then specifically rebutted each of the cases that the panel cited as precedent to bolster this three-tier scheme.<sup>86</sup> In Judge Newman’s view, by classifying the claims in *Scripps* and *Atlantic Thermoplastics* as distinguishable, there was no need for the *Atlantic Thermoplastics* panel to determine that there was a conflict with Supreme Court precedent.<sup>87</sup>

#### *E. District Court Decisions after Scripps and Atlantic Thermoplastics*

District courts have not consistently followed either the *Scripps* decision or the *Atlantic Thermoplastics* decision.<sup>88</sup> These district court opinions exemplify how difficult it is to make any meaningful distinction between the two decisions.<sup>89</sup> This subsection examines how district courts have applied these conflicting rules.

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<sup>85</sup> *Id.* at 1284. See also Eric P. Mirabel, *Product-by-Process Claims: A Practical Perspective*, 68 J. PAT. & TRADEMARK OFF. SOC’Y 3 (1986).

<sup>86</sup> *Atl. Thermoplastics*, 974 F.2d at 1285–97.

<sup>87</sup> *Id.* at 1283.

<sup>88</sup> For cases that follow *Scripps*, see, for example, *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 372 F. Supp. 2d 430 (D.N.J. 2005); *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 218 F. Supp. 2d 594 (D. Del. 2002); *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16 (D. Mass. 2000); *DeKalb Genetics Corp. v. Northrup King Co.*, 1997 U.S. Dist. LEXIS 14275 (N.D. Ill. 1997) (marked not for publication). For cases that follow *Atlantic Thermoplastics*, see, for example, *Kennametal, Inc. v. Cerametal s.a.r.l.*, 2001 U.S. Dist. LEXIS 25284 (E.D. Mich. 2001); *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7 (D. Mass. 1993); *Fairfax Dental Ltd. v. Sterling Optical Corp.*, 808 F. Supp. 326 (S.D.N.Y. 1992).

<sup>89</sup> In fact, many courts have expressed frustration at the lack of guidance that the Federal Circuit has provided for this type of claim construction. See *Trs. of Columbia Univ.*, 126 F. Supp. 2d at 32 (“Plainly, the law on this issue is in a state of uncertainty. By denying the rehearing en banc, not only are lower courts left with little guidance, but so are the inventors and investors of the biotechnology and pharmaceutical industries who must make research and development decisions not knowing how much protection is available to a claim for a novel biological or chemical product.”); *DeKalb Genetics Corp.*, 1997 U.S. Dist. LEXIS 14275, at \*5–6 (“It cannot be questioned that there is a direct conflict between the rule enunciated in *Scripps* and the one set forth in *Atlantic Thermoplastics*.”); *Tropix*, 825 F. Supp. at 8 (“Unfortunately, the judges of the Federal Circuit Court are in open disagreement on the point, making such a prediction hazardous.”).

### 1. District Court Rulings That Follow *Scripps*

At least four district court rulings have sided with the *Scripps* court.<sup>90</sup> Most recently, in *Aventis Pharmaceuticals*, the court ruled on a defendants' summary judgment motion based on the invalidity of the product-by-process claims at issue in the suit.<sup>91</sup> The court opted to follow the *Scripps* decision because it was the earlier precedent.<sup>92</sup> That rationale was also compelling for the *Trustees of Columbia University* and *DeKalb Genetics* cases.<sup>93</sup> In *Mannington Mills*, the court found the *Scripps* decision more compelling in part because adding process clauses "imparts no patentability to the product resulting from the process."<sup>94</sup> In total, the primary justification for following the *Scripps* court was to follow precedent in the manner advocated by Judge Rich in his *Atlantic Thermoplastics* dissent.<sup>95</sup>

### 2. District Court Rulings That Follow *Atlantic Thermoplastics*

By contrast, other district courts have chosen to follow *Atlantic Thermoplastics*.<sup>96</sup> The *Tropix* court agreed with the rationale of *Atlantic Thermoplastics* more than any other district court.<sup>97</sup> The decision in *Tropix* was a memorandum of controlling law on the scope of product-by-process claims at issue in the suit.<sup>98</sup> The court recognized the confused state of the law and decided to "apply the

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<sup>90</sup> *Aventis Pharms.*, 372 F. Supp. 2d 430; *Mannington Mills*, 218 F. Supp. 2d 594; *Trs. of Columbia Univ.*, 126 F. Supp. 2d 16; *DeKalb Genetics Corp.*, 1997 U.S. Dist. LEXIS 14275.

<sup>91</sup> *Aventis Pharms.*, 372 F. Supp. 2d at 433.

<sup>92</sup> *Id.* at 437 n.4.

<sup>93</sup> *Trs. of Columbia Univ.*, 126 F. Supp. 2d at 32 ("Until the *Scripps* decision is rejected by a hearing en banc, it is the precedential decision."); *DeKalb Genetics Corp.*, 1997 U.S. Dist. LEXIS 14275, at \*6 ("Accordingly, applying the direct conflict rule, the court will apply *Scripps* in the present case.").

<sup>94</sup> *Mannington Mills*, 218 F. Supp. 2d at 599. Note, however, that this statement is not at odds with *Atlantic Thermoplastics*. There the court held that process terms are read into the claim only for purposes of determining *infringement*, not *patentability*.

<sup>95</sup> *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1281 (Fed. Cir. 1992).

<sup>96</sup> *Kennametal, Inc. v. Cerametal s.a.r.l.*, 2001 U.S. Dist. LEXIS 25284 (E.D. Mich. 2001); *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7 (D. Mass. 1993); *Fairfax Dental Ltd. v. Sterling Optical Corp.*, 808 F. Supp. 326 (S.D.N.Y. 1992).

<sup>97</sup> *Tropix*, 825 F. Supp. 7.

<sup>98</sup> *Id.*

rule which [appeared] to be most consonant with the main stream of existing authority and the purpose of the governing statute.”<sup>99</sup> After a thorough review of product-by-process claim jurisprudence,<sup>100</sup> the court held that Judge Newman’s belief in *Scripps* that there should be symmetry between claim construction for patentability and infringement “[did] not appear to be supported by any authority, given the different functions of each institution.”<sup>101</sup> The court finally concluded that it would follow *Atlantic Thermoplastics* because “even in the confused state of the record . . . a majority of the judges of the Federal Circuit would rule that *Atlantic* states the controlling law.”<sup>102</sup> Other courts have also ruled that *Atlantic Thermoplastics* is controlling precedent when a process step was added as a claim limitation during prosecution<sup>103</sup> and when interpreting a hypothetical product-by-process claim as a way to apply the Hypothetical Claim Test<sup>104</sup> of the Doctrine of Equivalents.<sup>105</sup>

#### F. *SmithKline Beecham v. Apotex*

In this recent case, SmithKline Beecham sued Apotex for infringing its patent for the drug Paxil (whose chemical name is paroxetine).<sup>106</sup> The district court granted summary judgment for

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<sup>99</sup> *Id.* at 8.

<sup>100</sup> *Id.* at 8–10.

<sup>101</sup> *Id.* at 10.

<sup>102</sup> *Id.*

<sup>103</sup> See *Kennametal, Inc. v. Cerametal s.a.r.l.*, 2001 U.S. Dist. LEXIS 25284, at \*33–34 (E.D. Mich. 2001) (bolstering support for using *Atlantic Thermoplastics* because of Supreme Court precedent based on prosecution history estoppel).

<sup>104</sup> “The Doctrine of Equivalents allows a patent owner to hold as infringement a product or process that does not correspond to the literal terms of a patent’s claim but performs substantially the same function in substantially the same way to obtain the same result as the claimed subject matter.” CHISUM, *supra* note 6, § 18.04. “It is well settled law that a patentee cannot assert a range of equivalents that encompasses the prior art. To test this limit, the notion of a hypothetical claim may be useful. A hypothetical claim may be constructed to literally cover the accused device. If such a claim would be unpatentable under 35 U.S.C. §§ 102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law.” *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1380 (Fed. Cir. 2001) (citations omitted). These patent doctrines will not be discussed further because they are well outside the scope of this Note.

<sup>105</sup> *Fairfax Dental Ltd. v. Sterling Optical Corp.*, 808 F. Supp. 326 (S.D.N.Y. 1992).

<sup>106</sup> *SmithKline Beecham v. Apotex*, 439 F.3d 1312, 1313 (Fed. Cir. 2006).

Apotex, holding that the patent at issue was anticipated by a previous patent held by SmithKline.<sup>107</sup> The patent at issue claimed the compound paroxetine, but did not define it in terms of its structural characteristics, instead claiming the compound as the end result of the process required to make the pill.<sup>108</sup> The prior art reference was an invalid patent<sup>109</sup> obtained by SmithKline that covered paroxetine as a compound without any reference to process steps.<sup>110</sup>

After surveying the controversy over the *Scripps* and *Atlantic Thermoplastics* decisions, the court stated: “Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process.”<sup>111</sup> After a survey of the relevant C.C.P.A. and Supreme Court decisions, the court held:

As this history of cases from the Supreme Court, our court, and our predecessor court make clear, anticipation by an earlier product patent cannot be avoided by claiming the

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<sup>107</sup> *Id.* at 1314–15.

<sup>108</sup> The two claims at issue in the litigation were: Claim 1. A pharmaceutical composition in tablet form containing paroxetine, produced on a commercial scale by a process which comprises the steps of:

- a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
- b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
- c) compressing the mixture into tablets.

Claim 2. A pharmaceutical composition in tablet form according to claim 1 containing an amount of paroxetine selected from 10 mg, 20 mg, 30 mg, 40 mg and 50 mg, wherein the amount of paroxetine is expressed as the free base, produced on a commercial scale by a process which comprises the steps of:

- a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
- b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
- c) compressing the mixture into tablets using a single punch or rotary tablet machine. *Id.* at 1314.

<sup>109</sup> The court noted that invalid patents still constitute prior art under 35 U.S.C. § 102(a) as of the date the patent is published. *Id.* at 1317 n.5.

<sup>110</sup> *Id.* at 1313.

<sup>111</sup> *Id.* at 1317.

same product more narrowly in a product-process claim. It makes no difference here whether the '944 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided. While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. We agree with the district court's conclusion that the '723 patent disclosure anticipated the identical product claimed by the '944 patent even though that product was produced by an allegedly novel process.<sup>112</sup>

The court then disregarded an argument that there was a substantive difference between the product in the patent at issue (a purified tablet form of paroxetine) and the prior art patent (paroxetine with an impurity) because it was insufficiently developed by the appellant's brief.<sup>113</sup> Therefore, the court affirmed the district court's grant of summary judgment.<sup>114</sup>

Outvoted as a member of the three-judge panel, Judge Newman filed a dissenting opinion.<sup>115</sup> On the whole, she echoed many of the same themes as her dissenting opinion in *Atlantic Thermoplastics*.<sup>116</sup> For one, she rejected the "one-type-fits-all pigeonholes for claims, even for claims containing process limitations."<sup>117</sup> Though she did not explicitly revive her tripartite scheme from *Atlantic Thermoplastics*, her dissent in *SmithKline* is logically consistent.<sup>118</sup> She believed that the product claimed by

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<sup>112</sup> *Id.* at 1318–19.

<sup>113</sup> *Id.* at 1320.

<sup>114</sup> *Id.* at 1321.

<sup>115</sup> *Id.* at 1321–25 (Newman, J., dissenting).

<sup>116</sup> *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1281 (Fed. Cir. 1992) (Newman, J., dissenting from the denial of rehearing en banc).

<sup>117</sup> *SmithKline Beecham*, 439 F.3d at 1322.

<sup>118</sup> *See Atl. Thermoplastics*, 974 F.2d at 1284. In this opinion, Judge Newman set out a tripartite scheme of claim construction: "(1) when the product is new and unobvious, but is not capable of independent definition; (2) when the product is old or obvious, but the process is new; (3) when the product is new and unobvious, but has a process-based limitation (e.g. a 'molded' product)." *Id.* Since Judge Newman thought that this form of

SmithKline was a novel one, namely a tablet form of paroxetine that reduces a particular type of impurity.<sup>119</sup> She also concluded that the issue was sufficiently preserved on appeal.<sup>120</sup> Therefore, she would have reversed the district court's grant of summary judgment and remanded the case because she determined that the process steps in the claim made the product itself novel and patentable.<sup>121</sup>

After the panel ruling, the entire Federal Circuit rejected a petition for a rehearing en banc, with three out of eleven active judges on the court voting instead to grant rehearing.<sup>122</sup> Both Judge Newman and Judge Rader filed dissents, with Judge Gajarsa signing onto both opinions.<sup>123</sup> Judge Newman stated:

*Scripps* accommodates the situation where the product is novel and complex and cannot be described other than by the way it was made, while *Atlantic Thermoplastics* deals with a product whose production requires use of a certain process, whether or not the product itself is novel.

In view of the apparent uncertainty within the patent community as to the distinction between such situations, it is time for this court to interpret the law with one voice.<sup>124</sup>

Judge Rader was less sanguine about whether a direct conflict existed in product-by-process claim construction jurisprudence:

This court's decision in *Smithkline Beecham Corp. v. Apotex Corp.* expands on the existing confusion by suggesting that the specific language of the claims is not relevant to anticipation. That additional confusion does a disservice to this court's jurisprudence. Without doubt, this

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paroxetine was a new and unobvious product, she classified it in the first group of product-by-process claims.

<sup>119</sup> *SmithKline Beecham*, 439 F.3d at 1322.

<sup>120</sup> *Id.* at 1325.

<sup>121</sup> *Id.* at 1324.

<sup>122</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, 453 F.3d 1346 (Fed. Cir. 2006).

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at 1347.

court's product-by-process law contains an apparent conflict.<sup>125</sup>

## II. THE DEFICIENCIES OF THE CURRENT LAW OF PRODUCT-BY-PROCESS CLAIM CONSTRUCTION

The morass that the Federal Circuit finds itself in with regard to claim construction of product-by-process claims begs for a better approach. This Part analyzes the problems with claim construction in the product-by-process context and critiques the approaches of the Federal Circuit.

### A. *Product-by-Process Claims Are Doubly Troublesome*

The Federal Circuit has in recent years debated the proper role of district court judges, juries and the standard of review in claim construction.<sup>126</sup> Much of this law is still subject to revision, leaving district courts unable to reduce the rate of reversal on claim construction.<sup>127</sup> The lack of agreement on the standard for claim construction is only amplified when courts have to examine a product-by-process claim.

When district courts construe a simple product or process claim, trial judges have to closely examine every clause of the claim to determine what the invention protected by the patent actually is.<sup>128</sup> The claims are also read in light of the specification

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<sup>125</sup> *Id.* at 1348 (citations omitted). Note that Judge Rader was the judge who wrote the opinion in *Atlantic Thermoplastics* that created the conflicting authority within the Federal Circuit. *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992) (Rader, J.). Judge Rader also voted against a rehearing en banc of that same case by the Federal Circuit. *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299 (Fed. Cir. 1992) (Rader, J., concurring in the denial of rehearing en banc).

<sup>126</sup> See *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1332 (2006); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

<sup>127</sup> Compare Moore, *supra* note 14, at 239, with Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1, 14 (2001) (Prof. Moore, now Judge Moore of the Federal Circuit, completed two studies of claim construction reversals. The first study found a 27% rate of verdicts reversed or vacated during the period 1996–2000, while the second study found a 29.7% rate of reversal/vacation for the period 1996–2003.).

<sup>128</sup> See *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970).

because the specification explains the invention in “plain” English, helping patent examiners, attorneys in an infringement action and courts interpret the claims.<sup>129</sup> This is a difficult process, so much so that a recent study found that the Federal Circuit, upon de novo review of all claim constructions at the trial court level, has held that 34.5% of all such claim constructions have been wrongly construed at the trial court level.<sup>130</sup> If one believes that process steps should not always be read into the claims, then one has to evaluate what the invention actually is from the process used to make it.<sup>131</sup> It only makes sense that if one wants to describe what something *is*, describing *how you made it* is an inferior way to do so. If one incorporates the process steps into the claim, little progress is made, because the first step in examining the claims will still always be what the product actually is.<sup>132</sup> For that, there is the same problem as when the process steps do not limit the claim. It only makes things simpler because one can now also examine part of the claim in the same way that courts examine process claims.

As discussed in Part II, the Courts have disagreed over both the scope and the standard of allowability for product-by-process claims.<sup>133</sup> The main reason why the courts cannot seem to agree on a single rule in each context is that sometimes the process steps seem more important for figuring out what the product is, and sometimes the process steps seem less important for making that determination. When courts regard the process steps as more important, they tend to come to the same conclusion as Judge Newman and find that there are good reasons for treating product-by-process claims differently based on the novelty of the product.<sup>134</sup> Alternatively, when process steps are less important, courts typically construe these patents narrowly by using the process steps as claim limitations and requiring the Rule of

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<sup>129</sup> See *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967).

<sup>130</sup> Moore, *supra* note 14, at 239.

<sup>131</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) (citing *In re Brown* for the proposition that “in product-by-process claims the patentability of the product must be established independent of the process”).

<sup>132</sup> See *SmithKline Beecham v. Apotex*, 439 F.3d 1312, 1317 (Fed. Cir. 2006).

<sup>133</sup> See *supra* Part II.

<sup>134</sup> See *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1284 (Fed. Cir. 1992).

Necessity.<sup>135</sup> Since courts have disagreed over the scope and the standard for allowability of product-by-process claims for at least the last 40 years,<sup>136</sup> it is clear that courts are ill-equipped to handle the product-by-process claims in every situation except when that is the only way the invention may be claimed.

*B. The Indistinctness of Claim Description in Product-by-Process Claims*

One consideration about all of these claims that is insufficiently addressed by all of the courts that have taken up the issue of product-by-process claims is the distinct claiming requirement. Any patent applicant must conclude his patent application “with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”<sup>137</sup> This requirement is located in the patent statute for two reasons: to provide notice to those who may practice similar inventions and to make the analysis easier for judges and patent examiners when determining the scope of the claims.<sup>138</sup> Claim distinctiveness is analyzed “always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.”<sup>139</sup> Recent decisions have tended to focus on the specific meaning of individual words in a claim.<sup>140</sup>

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<sup>135</sup> See *In re Hughes*, 496 F.2d 1216, 1219 (C.C.P.A. 1974) (“While we recognize that several structural or characterizing terms derive from processes or methods and that their use in a claim will not prevent it from being considered to be a true product claim, we do not believe that the emphasized language in claim 8 can be considered to be anything other than a description of the shake in terms of the process by which it was made.” (footnote omitted)).

<sup>136</sup> See, e.g., *Atl. Thermoplastics Co. v. Faytex Corp.* 970 F.2d 834 (Fed. Cir. 1992), *reh’g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992); *Scripps*, 927 F.2d 1565; *In re Hughes*, 496 F.2d 1216 (C.C.P.A. 1974); *In re Pilkington*, 411 F.2d 1345 (C.C.P.A. 1969); *In re Johnson*, 394 F.2d 591 (C.C.P.A. 1968); *In re Steppan*, 394 F.2d 1013 (C.C.P.A. 1967).

<sup>137</sup> 35 U.S.C. § 112 (2006).

<sup>138</sup> *CHISUM*, *supra* note 6, § 8.03.

<sup>139</sup> *In re Moore*, 439 F.2d 1232, 1235 (C.C.P.A. 1971) (footnote omitted).

<sup>140</sup> See, e.g., *Personalized Media Comm’ns, LLC v. U.S. Int’l Trade Comm’n*, 161 F.3d 696, 705 (Fed. Cir. 1998); *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1567 (Fed. Cir. 1992).

The notice requirement tells possible users of patented products or processes what they can and cannot do.<sup>141</sup> This is tremendously important for the efficiency of the patent marketplace.<sup>142</sup> The typical analogy for patent claims is that they are akin to a land deed that tells others the boundary of their land.<sup>143</sup> Taking the analogy further, imagine that instead of a fence, you had a fog-making machine that spit out condensation over a ten-foot wide boundary between properties. The two owners would either leave the boundary land unused or risk a lawsuit for trespass. Either result creates significant economic inefficiencies.<sup>144</sup>

Product-by-process claims make it extremely difficult to claim the invention with the certainty most patentees would expect. First of all, even the Federal Circuit cannot agree on a clear standard for what these claims actually mean.<sup>145</sup> This creates tremendous uncertainty for anyone who wants to innovate in a technological area where a product-by-process patent exists.<sup>146</sup> Second, as emphasized *supra* in Section A, when a product claim uses process language, all the linguistic tools that courts and patent examiners bring to bear are much more difficult to apply.<sup>147</sup>

One reason courts may have been unwilling to champion an approach that emphasized the lack of distinctiveness of product-by-process claims is that the claims themselves are not necessarily

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<sup>141</sup> See *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891) (“The object of the patent law in requiring the patentee to ‘particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery’ is not only to secure to him all to which he is entitled, but to apprise the public of what is still open to them.”).

<sup>142</sup> FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 1, at 29 (Oct. 2003) *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited Sept. 26, 2006) [hereinafter FTC REPORT].

<sup>143</sup> *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917).

<sup>144</sup> FTC REPORT, *supra* note 142, ch. 1, at 29.

<sup>145</sup> *SmithKline Beecham v. Apotex*, 439 F.3d 1312 (Fed. Cir. 2006); *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

<sup>146</sup> See *Festo v. Shoketsu Kinzoku Kogyo Kabushiki*, 535 U.S. 722, 732 (2002) (“If competitors cannot be certain about a patent’s extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures.”).

<sup>147</sup> See *supra* Part III.A.

ambiguous on their face.<sup>148</sup> However, this argument misses the point because defining a product through process claims requires a significant inferential step. The only direct analysis of a product-by-process patent claim would be evaluating the novelty of the process. As a result, there is a serious bootstrapping problem because the public then has to depend much more heavily on the specification to actually know what the product is, thus inverting the role of the two sections of a patent application.

### *C. Problems with the Product-Focused Approach*

Much of product-by-process claim construction precedent can be summarized as falling into two camps. One, exemplified by the *Scripps* approach, looks to the novelty of the product and does not read process limitations into the claim.<sup>149</sup> The other, exemplified by the *Atlantic Thermoplastics* decision, looks largely to the process limitations in the claim to define it.<sup>150</sup> This Section will examine the problems with the product-focused approach and why it fails to adequately address the problems with the distinctiveness of product-by-process claims.

The first and most glaring problem with focusing on the product to the exclusion of the process is that it ignores the plain meaning of the claim. Claims are used to define and limit the scope of patent protection.<sup>151</sup> It would seem that if one is going to use process terms in the claim itself, that should limit the scope of patent protection to the process used to make the patent.<sup>152</sup> Normally, for a product patent, the specification will discuss the method by which the product is made, otherwise known as the

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<sup>148</sup> See, e.g., *In re Hughes*, 496 F.2d 1216, 1218 (C.C.P.A. 1974) (“We cannot agree with the solicitor that defining a product in terms of process makes the language of the claims imprecise or indefinite. Their scope, if anything, is more definite in reciting a novel product made by a specific process, assuming, of course, that the process is clearly defined. It does not create a definiteness problem under § 112.”).

<sup>149</sup> *Scripps*, 927 F.2d at 1583.

<sup>150</sup> *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 846–47 (Fed. Cir. 1992).

<sup>151</sup> See, e.g., *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) (“[T]he claims measure the invention.”).

<sup>152</sup> See, e.g., *Lemelson v. United States*, 752 F.2d 1538, 1551 (Fed. Cir. 1985) (“It is also well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device.”).

Enablement Requirement.<sup>153</sup> When patent applicants use this type of claiming, it inverts the whole purpose of the claim in patent law. Instead of using the claim to limit the invention, now the patent applicant is using the specification in tandem with a description of the process to help tell the patent office and the engineering community what the product actually is.

The requirement that claims give notice of the invention to the public creates unique problems when process steps are read out of product-by-process claims. The usual justification for using a product-by-process claim is that it gives the inventor a chance to claim the invention without completely knowing what the product is.<sup>154</sup> But if the *inventor* doesn't know what the product is, how is the rest of *the public* supposed to know what the product is from the process steps mentioned in the invention? Ignoring the process steps in an invention will only encourage the proliferation of patents that can be used as a way to litigate rather than innovate. The dispute between the *Scripps* and *Atlantic Thermoplastics* courts have done little to help make the scope of product-by-process patents any clearer.

#### *D. Problems with the Approach of Atlantic Thermoplastics*

Much of the problems that arise from the *Atlantic Thermoplastics* decision are not from the content of the holding, but because the court made the law of product-by-process claims completely unclear.<sup>155</sup> While the bulk of the Supreme Court and C.C.P.A. precedent was on that panel's side, courts have long been muddled in their approach to product-by-process claims—something not entirely admitted by the *Atlantic Thermoplastics* court.<sup>156</sup> However, the *Scripps* holding was clear, and there was some support for it in cases both from the Supreme Court and the C.C.P.A. Thus, the panel could have distinguished the *Scripps* holding in some way or stated that they were obligated to follow

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<sup>153</sup> See Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV. 101, 106–07 (2005).

<sup>154</sup> See *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1283 (Fed. Cir. 1992) (Newman, J., dissenting).

<sup>155</sup> *Atl. Thermoplastics*, 970 F.2d 834.

<sup>156</sup> *Id.*

the holding of *Scripps*. Instead, the panel vehemently disagreed with it.<sup>157</sup> Effectively, the court sacrificed clarity of the law for a favorable outcome in one case. The members of the panel also refused to revisit the issue in an en banc decision, which may well have cleared up the dispute once and for all.<sup>158</sup>

The holding in *Atlantic Thermoplastics* has only confused district courts that have had to construe product-by-process claims.<sup>159</sup> Some courts agreed with the way that *Atlantic Thermoplastics* addressed precedent, finding that the *Atlantic Thermoplastics* court correctly based its decision on prior Supreme Court precedent.<sup>160</sup>

Even a panel of the Federal Circuit itself in the *SmithKline Beecham* case refused to weigh in on the dispute.<sup>161</sup> It appears to reflect the practice of common law appellate courts to attempt to decide cases on the narrowest grounds and do everything possible to avoid overruling precedent.<sup>162</sup> Unfortunately, since the product itself was not novel,<sup>163</sup> this case was not an appropriate candidate for en banc review because the case really did not depend on

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<sup>157</sup> *Id.* at 839 n.2.

<sup>158</sup> *See Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299 (Fed. Cir. 1992) (Rader, J., concurring in the denial of rehearing en banc).

<sup>159</sup> *See Trs. of Columbia Univ. v. Roche Diagnostics, GmbH*, 126 F. Supp. 2d 16, 32 (D. Mass. 2000) (“Plainly, the law on this issue is in a state of uncertainty. By denying the rehearing en banc, not only are lower courts left with little guidance, but so are the inventors and investors of the biotechnology and pharmaceutical industries who must make research and development decisions not knowing how much protection is available to a claim for a novel biological or chemical product.”); *DeKalb Genetics Corp. v. Northrup King Co.*, 1997 U.S. Dist. LEXIS 14275, at \*5–6 (N.D. Ill. 1997) (“It cannot be questioned that there is a direct conflict between the rule enunciated in *Scripps* and the one set forth in *Atlantic Thermoplastics*.”); *Tropix, Inc. v. Lumigen, Inc.* 825 F. Supp. 7, 8 (D. Mass. 1993) (“Unfortunately, the judges of the Federal Circuit Court are in open disagreement on the point, making such prediction hazardous.”).

<sup>160</sup> *AK Steel Corp. v. Sollac*, 234 F. Supp. 2d 711, 739, n.1 (S.D. Ohio 2002).

<sup>161</sup> *SmithKline Beecham v. Apotex*, 439 F.3d 1312, 1316–17 (Fed. Cir. 2006).

<sup>162</sup> *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 854 (1992) (“Even when the decision to overrule a prior case is not, as in the rare, latter instance, virtually foreordained, it is common wisdom that the rule of stare decisis is not an ‘inexorable command’ . . . Rather, when this Court reexamines a prior holding, its judgment is customarily informed by a series of prudential and pragmatic considerations designed to test the consistency of overruling a prior decision with the ideal of the rule of law, and to gauge the respective costs of reaffirming and overruling a prior case.”).

<sup>163</sup> *SmithKline Beecham*, 439 F.3d at 1317.

whether the process steps were read into the claim.<sup>164</sup> However, the only action that will give lower courts some real guidance is an en banc decision by the Federal Circuit, review by the Supreme Court or a new statute by Congress. As of July 30, 2006, there is no plan to include any provision regarding product-by-process claims in the most recent round of statutory patent reforms.<sup>165</sup>

### III. BACK TO THE FUTURE: RE-EMPHASIZING DISTINCTIVE CLAIMING AND THE RULE OF NECESSITY

The solution to this labyrinth of conflicting precedent and unclear claiming schemes is twofold. First, the patent office should only accept product-by-process claims where there is no other alternative way at the time of filing to claim the product. The burden should be on the applicant to show that he must claim in this manner. Second, courts must construe product-by-process claims as limited by the process because that is the only way to solve the issue of definiteness and maintain the traditional role of claims in a patent. This part will argue for these reforms and also analyze foreign approaches to product-by-process claims, which largely support this thesis.

#### A. *The Rule of Necessity Should Be Revived*

The Rule of Necessity requires that patent applicants only claim using product-by-process language when there is no other way to claim the invention.<sup>166</sup> This rule should be re-emphasized because to do otherwise severely limits the ability of third parties to have a reasonable expectation of what the patent actually covers.<sup>167</sup> It also makes patent claims more clear because it

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<sup>164</sup> See *id.* at 1319 n.7.

<sup>165</sup> The most recent bill to comprehensively amend the patent laws will probably not pass during the 109th Congress. Dennis Crouch, *Patent Reform: Issa's Litigation Pilot Gains Support (HR 5418)*, July 28, 2006, PATENTLY-O, [http://www.patentlyo.com/patent/2006/07/patent\\_reform\\_i.html](http://www.patentlyo.com/patent/2006/07/patent_reform_i.html); see Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

<sup>166</sup> CHISUM, *supra* note 6, § 8.05[2][a].

<sup>167</sup> See *In re Hughes*, 496 F.2d 1216, 1218 (C.C.P.A. 1974) (“If there is a basis for the [Rule of Necessity], it resides in the fact that it may be more difficult to determine from a

resolves much of the ambiguity over whether to define the invention in terms of the claims, instead of indirectly through the specification.

As discussed *supra* in Part II, Section B of this Note, defining an invention in terms of the process used to make it is an inferior way to claim because it forces courts to make inferential steps that invite contradictory opinions.<sup>168</sup> The Rule of Necessity would address these concerns in many of these situations because it would limit the number of patents that incorporate product-by-process claims. There is no Constitutional right to obtain a patent for an invention that is merely difficult to claim without using the language of the process used to make it. If the invention is a useful product, there is no reason why the applicant cannot claim it in means-plus-function language as another way to avoid the structural requirements of traditional product claim language.<sup>169</sup> Also, if the product is really that difficult to characterize in structural terms, a patent examiner should be highly skeptical that the applicant actually possesses the invention that he claims. This may be one way to alter the substantive law of patents to encourage fewer frivolous patents.

Also, by limiting product-by-process claims to those that can be claimed in no other way, the process of interpreting the claims becomes easier by shifting the primary focus of the scope of the patent back to its claims. If there are ways to define an invention outside of claim language, courts will inevitably depend on the specification more heavily to describe the invention. But if the Rule of Necessity is followed, then courts will have to closely examine the process clauses in the claim because there is no other way to understand what the invention actually is. In sum, the Rule of Necessity would set up the right incentives for interpretation of claim language, imparting greater stability to the law.

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product-by-process claim what product is covered thereby. One cannot read the words of the claim on an article unless he is able to find out how the article was made.”).

<sup>168</sup> See *supra* Part III.B.

<sup>169</sup> 35 U.S.C. § 112, para. 6 (2006).

*B. Product-by-Process Claims Should Be Limited by the Process Steps Listed in the Claims*

Product-by-process claims should be limited to the process that is included in the language of the claims because it would also improve the definiteness of the claims. This rule would maintain the traditional role of patent claims as defining and limiting the invention.

Claims are the most crucial part of any patent—the foundation of the patent system—because they define the invention for comparison to the prior art for validity determinations and for comparison to the acts of the accused infringer.<sup>170</sup> It is an oft-repeated maxim that all claim language (except usually the preamble) serves to define and limit the invention.<sup>171</sup> Product-by-process claims provide a uniquely difficult problem because their very nature subverts this usual arrangement. After *SmithKline Beecham*, these claims require courts and patent examiners to examine the scope of the claims first by inferring what the product that the patent seeks to obtain protection for actually is.<sup>172</sup> If that product is novel, then claim construction depends on whether the *Atlantic Thermoplastics* or the *Scripps* decision should be followed.<sup>173</sup> One way to make these claims more definite is to use the language of the claim to define the invention. If the patentee does not know what product she has created from the process to define the claim, it is highly debatable that the notice function of claiming is satisfied.<sup>174</sup> Folding process limitations into infringement determinations will help make patent claims much clearer.

Another reason why process terms should be included in limiting the claims is that they restore the traditional role of the specification. The specification is a crucial part of any patent because it helps patent examiners and courts interpret the patent

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<sup>170</sup> See *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (“The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.”).

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

<sup>172</sup> See *SmithKline Beecham v. Apotex*, 439 F.3d 1312, 1317 (Fed. Cir. 2006).

<sup>173</sup> See *id.* at 1319 n.7.

<sup>174</sup> CHISUM, *supra* note 6, § 8.03.

and it serves to inform the public of the invention.<sup>175</sup> Without reading process terms of a claim into the scope of the claim, the process terms become simply a method of understanding what the invention actually is. Structuring a patent in this way removes any need to have a claim in the first place. Requiring the process terms to actually limit the invention would restore the traditional balance between the specification and the claims.

Another reason why process terms should be read into otherwise novel products for the purposes of infringement is that patent claims should be defined in the narrowest scope possible in the infringement context.<sup>176</sup> This traditional method of interpreting claims in infringement suits is an important way of making sure that patentees cannot exclude others from making, using or selling products that they did not themselves invent.<sup>177</sup> Making sure that process terms are read into the scope of the claims for infringement would reinforce this vital patent doctrine.

Limiting claims to the process included in the claim for purposes of infringement is complementary to the Rule of Necessity. The Rule of Necessity strongly discourages the use of product-by-process claiming, both when attempting to procure a patent and when examining the validity of the patent. Reading process limitations into the scope of the claim works from the opposite end of the patent statutory scheme, that of infringement. Because these claims are so difficult to interpret, every clue to determine the scope of the claims is important. These two rules serve the same master: increasing the distinctiveness of patent claiming.

### *C. The Approach of Foreign Patent Law Supports this Reform*

Even though many foreign patent law systems are more properly grounded in a trade-based rationale than the “inducement

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<sup>175</sup> See 35 U.S.C. § 112, para. 1 (2000).

<sup>176</sup> See *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 846 (Fed. Cir. 1992) (“The PTO’s treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest reasonable interpretation. That same rule, however, does not apply in validity and infringement litigation.”).

<sup>177</sup> See *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

to invent” rationale favored in the United States,<sup>178</sup> the approach of foreign patent systems to product-by-process claims is instructive to this discussion. To summarize, the approaches in Europe and Japan emphasize the Rule of Necessity, but are less clear on the subject of the scope of product-by-process claims for infringement.

### 1. European Union

The European Patent Office’s<sup>179</sup> (“E.P.O.”) approach to product-by-process claims is restrictive with respect to the permissibility of product-by-process claims, but expansive in its view of infringement. The E.P.O. also explicitly asserts that “[c]laims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil [sic] the requirements for patentability. . .”<sup>180</sup> But the E.P.O. also follows the Rule of Necessity, after the *International Flavors* case.<sup>181</sup> In its Guidelines for Examination, the E.P.O. makes clear the scope of product-by-process claims by stating, “[a] claim defining a product in terms of a process is to be construed as a claim to the product as such.”<sup>182</sup> The E.P.O. is also obligated to follow Article 64(2) of the European Patent Convention, which requires, “If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such

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<sup>178</sup> See U.S. CONST. art. I, § 8, cl. 8.

<sup>179</sup> “The European Patent Office (EPO) grants European patents for the contracting states to the European Patent Convention (EPC), which was signed in Munich on 5 October 1973 and entered into force on 7 October 1977. It is the executive arm of the European Patent Organisation, an intergovernmental body set up under the EPC, whose members are the EPC contracting states. The activities of the EPO are supervised by the Organisation’s Administrative Council, composed of delegates from the contracting states.” The European Patent Office, [http://www.european-patent-office.org/epo/pubs/brochure/general/e/epo\\_general.htm](http://www.european-patent-office.org/epo/pubs/brochure/general/e/epo_general.htm).

<sup>180</sup> Guidelines for Examination in the European Patent Office, European Patent Office, pt. C., ch. III., ¶ 4.7b, available at [http://www.european-patent-office.org/legal/gui\\_lines/pdf\\_2005/part\\_c\\_e.pdf](http://www.european-patent-office.org/legal/gui_lines/pdf_2005/part_c_e.pdf) [hereinafter E.P.O. Guidelines].

<sup>181</sup> Case T-150/82, *Int’l Flavors & Fragrances, Inc.*, 1984 O.J. E.P.O. 309 (TBA 1984) (“The Board takes the view that in order to minimise uncertainty, the form for a claim to a patentable product as such defined in terms of a process of manufacture (i.e. ‘product-by-process claims’) should be reserved for cases where the product cannot be satisfactorily defined by reference to its composition, structure or some other testable parameters.”).

<sup>182</sup> E.P.O. Guidelines, Part C., Ch. III., ¶ 4.7b.

process.”<sup>183</sup> So, in the E.P.O., there really isn’t the same rationale for allowing product-by-process claims because process claims already supply the scope of coverage necessary to provide for product-by-process claims as such claims exist in the United States and the United Kingdom.<sup>184</sup>

## 2. United Kingdom

In the U.K. (a European Patent Convention member state), the most recent authoritative opinion on product-by-process claims is a decision written by Lord Hoffmann on behalf of the House of Lords.<sup>185</sup> In *Kirin-Amgen*, Amgen held a European patent for making erythropoietin using recombinant DNA technology and sued for infringement.<sup>186</sup> Two of the claims in Amgen’s patent were product-by-process claims.<sup>187</sup> The defendant asserted that the claims were invalid for anticipation.<sup>188</sup> On the question of invalidity for the first claim, the court held that since the patentee could depend on a process claim and Article 64(2) of the European Patent Convention to gain protection, the claim was invalid because it violated the Rule of Necessity.<sup>189</sup> For the second claim, the court held that the claim was invalid for “insufficiency” (the U.K. analog to the enablement requirement in the U.S.) because the specification did not tell the public which method of purification would produce the purified erythropoietin.<sup>190</sup> So, while the court did not have the occasion to determine the scope of the claims for infringement, it did uphold the Rule of Necessity in European patent law.

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<sup>183</sup> European Patent Convention, art. 64(2), available at <http://www.european-patent-office.org/legal/epc/e/ar64.html#A64>.

<sup>184</sup> See *Kirin-Amgen, Inc. v. Hoechst Marion Roussel, Ltd.*, [2004] UKHL 46, at para. 90 (U.K.).

<sup>185</sup> *Kirin-Amgen*, [2004] UKHL 46.

<sup>186</sup> *Id.* at para. 1.

<sup>187</sup> *Id.* at paras. 14–15.

<sup>188</sup> *Id.* at para. 2.

<sup>189</sup> See *id.* at para. 101.

<sup>190</sup> *Id.* at paras. 130–31.

### 3. Japan

The Japanese Patent Office (“J.P.O.”) takes its own unique approach to the patentability of product-by-process claims.<sup>191</sup> The J.P.O. has a two-part inquiry.<sup>192</sup> A patent is clear enough for patentability when “a person skilled in the art can conceive a concrete product to be manufactured by such manufacturing process by taking into consideration the common general knowledge as of the filing. . .”<sup>193</sup> But if it fails this form of a reasonable inventor standard, it can still be patented if it “cannot be properly identified unless defining the product by its manufacturing process” and “the relation between the product to be manufactured by such manufacturing process and the technical standard as of the filing can be understood.”<sup>194</sup> The Guidelines go on to explain that “when the relation (difference) between the product to be manufactured by such manufacturing process and known products are shown with the experimental result or theoretical explanation, etc., the relation with the technical standard can be understood.”<sup>195</sup> So in essence, the J.P.O. uses a reasonable inventor standard coupled with a modified form of the Rule of Necessity.

These examples from other well-developed patent systems are useful to show alternative ways to address an extremely knotty problem. These patent systems give strong support to the need in the United States to revive the Rule of Necessity. However, they do not definitively side with either the *Scripps* or *Atlantic Thermoplastics* line of cases.

#### *D. Ways Future Litigants Can Argue Around the Scripps and Atlantic Thermoplastics Conflict*

As evidenced from the preceding sections of this Note, product-by-process claim construction precedent is extremely

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<sup>191</sup> Examination Guidelines for Patent and Utility Model, Japanese Patent Office, Part I, Ch. 1, § 2.2.2.1, available at [http://www.jpo.go.jp/tetuzuki\\_e/t\\_tokkyo\\_e/Guidelines/PartI-1.pdf](http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/PartI-1.pdf).

<sup>192</sup> *Id.*

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

<sup>194</sup> *Id.*

<sup>195</sup> *Id.*

contradictory and bright line rules are difficult to determine. However, litigants will continue to argue in *Markman* hearings over the scope of product-by-process claims, without the benefit of a precedential decision that clearly informs the parties what the rules of the game actually are. This section addresses the types of arguments that litigants may make to distinguish their case.

Now that the *SmithKline* decision is available to litigants,<sup>196</sup> the most obvious way that parties will attempt to avoid the conflicting decisions in *Scripps*<sup>197</sup> and *Atlantic Thermoplastics*<sup>198</sup> is by latching onto the language in *SmithKline* stating, “[r]egardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process.”<sup>199</sup> Therefore, in lawsuits where anticipation is at issue, like in *SmithKline*, the patentee should try to argue that the product implied by the claims is new compared to the prior art without any analysis of the process used to make it. In some ways, this is simply verbal trickery because it does not really solve anything except giving courts a way to ignore the decisions in *Scripps* and *Atlantic Thermoplastics*. One still has to interpret claims to a product based on what the process terms in the claim say because that is *how the invention is defined*. However, there was room for the panel in *SmithKline* to agree with that argument, but only Judge Newman thought that the issue was fully reserved on appeal<sup>200</sup> and that the product was actually new.<sup>201</sup>

The real essence of the dispute between the decisions in *Scripps* and *Atlantic Thermoplastics* is: how will the courts construe product-by-process claims for the purposes of *infringement*? One tactic is to argue that the decisions are not actually in conflict, similar to the argument that Judge Newman made in her *SmithKline* dissent.<sup>202</sup> In this line of reasoning, one

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<sup>196</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006).

<sup>197</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

<sup>198</sup> *Atl. Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), *reh'g en banc denied*, 974 F.2d 1279 (Fed. Cir. 1992).

<sup>199</sup> *SmithKline Beecham*, 439 F.3d at 1317.

<sup>200</sup> *Id.* at 1324–25.

<sup>201</sup> *Id.* at 1324.

<sup>202</sup> *Id.* at 1323.

would argue that the *Scripps* decision applies only to “true product-by-process” claims, where the process is necessary to define the invention because there is no other way to define it.<sup>203</sup> If, instead, the litigant wanted to argue that the process terms should limit the claim, that litigant would argue that it really is a “product of the process” claim, where the court in *Atlantic Thermoplastics* interpreted process terms as limiting the scope of the invention.<sup>204</sup> This argument uses Judge Newman’s distinction between the different classes of claims in *Scripps* versus *Atlantic Thermoplastics*, but leaves untouched the different standards from the two cases. The danger in this tactic is that cogent dissents by Judge Newman, rather than any Federal Court majority opinion, provide the best support for this approach.<sup>205</sup>

Another way that a litigant might effectively navigate the troubled waters of product-by-process jurisprudence is by arguing that the en banc decision in *Phillips v. AWH*<sup>206</sup> suggests that the specification should be relied on more heavily when interpreting the claims. As discussed earlier in this Note,<sup>207</sup> product-by-process claims almost inevitably lead to increased reliance on the specification to determine the scope of the patent. While on one hand, the court in the *Phillips* decision stated that “[i]t is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude,’”<sup>208</sup> on the other hand, the court re-emphasized the importance of the specification in claim interpretation.<sup>209</sup> Since product-by-process claims are so difficult to interpret and the disclosure in the specification is helpful to a litigant’s case, the litigant should convince the court that the specification controls, rather than getting pulled into an uncertain argument over whether *Scripps* or *Atlantic Thermoplastics* applies.

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<sup>203</sup> *Atl. Thermoplastics*, 974 F.2d at 1282.

<sup>204</sup> *See id.*

<sup>205</sup> *SmithKline Beecham*, 439 F.3d at 1323; *Atl. Thermoplastics*, 974 F.2d at 1281–84 (Newman, J., dissenting the denial of rehearing en banc).

<sup>206</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).

<sup>207</sup> *See discussion supra* Parts III.B., III.C., IV.A. and IV.B.

<sup>208</sup> *Phillips*, 415 F.3d at 1312 (citations omitted).

<sup>209</sup> *Id.* at 1315–17.

Unfortunately for savvy litigants, trial court forum shopping is unlikely to pay dividends. Since the *Atlantic Thermoplastics* decision was handed down, at least two identical U.S. District Courts have discussed the conflicting law of product-by-process claims. However, these two courts have either followed opposing rules or distinguished the cases such that they did not have to address the dispute. In the District of Massachusetts, the *Tropix* court held that it would follow *Atlantic Thermoplastics* because it reflected the opinion of the majority of the Federal Circuit and it was more properly grounded in prior precedent.<sup>210</sup> Also in the District of Massachusetts, the *Trustees of Columbia University* court did not treat the *Tropix* decision as controlling law and applied *Scripps* because it was the prior precedent, controlling under the Federal Circuit Rules.<sup>211</sup> In the District of Delaware, the *Mannington Mills* court applied *Scripps*,<sup>212</sup> but a recent decision also in Delaware distinguished its case from the conflict over product-by-process claims based on the definition of claim terms in the specification.<sup>213</sup> This most recent decision did not even cite *Mannington Mills*.<sup>214</sup> Therefore, there is little hope that a litigant will be able to find a forum where the court will predictably apply either *Atlantic Thermoplastics* or *Scripps*.

#### IV. CONCLUSION

The history of product-by-process claim construction and use is one of conflicting precedent. It is time for an authority such as the en banc Federal Circuit to take up an appropriate case and decide on a single rule. Because product-by-process claims are such an inferior way to describe an invention, the Federal Circuit should adopt a Rule of Necessity, requiring that patent applicants only use product-by-process claims when necessary. The burden to show

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<sup>210</sup> See *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 10 (D. Mass. 1993).

<sup>211</sup> *Trs. of Columbia Univ. v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 32 (D. Mass. 2000).

<sup>212</sup> *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 218 F. Supp. 2d 594 (D. Del. 2002).

<sup>213</sup> *Cryovac, Inc. v. Pechiney Plastic Packaging, Inc.*, 2006 U.S. Dist. LEXIS 19144, at \*13 (D. Del. 2006).

<sup>214</sup> *Cryovac*, 2006 U.S. Dist. LEXIS 19144.

that product-by-process claims are necessary should be borne by the patent applicant. The Federal Circuit should also hold that process limitations should be read into every product-by-process claim because the claims are indefinite. Process limitations also make sense because it reaffirms the principle that the claims should define the limits of the invention, not the specification. These reforms would restore a sense of balance to the patent system by limiting issued patents to the narrowest scope of invention for what the applicant actually has invented.