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# SCRIPPS OR ATLANTIC: THE FEDERAL CIRCUIT SQUARES OFF OVER THE SCOPE OF PRODUCT-BY-PROCESS PATENTS

## INTRODUCTION

In 1982, Congress created the Court of Appeals for the Federal Circuit ("CAFC" or "Federal Circuit") to bring greater stability to patent law by granting a single court exclusive appellate jurisdiction in patent cases.<sup>1</sup> In general, the court has succeeded in standardizing patent law.<sup>2</sup> Product-by-pro-

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<sup>1</sup> Congress established the Court of Appeals for the Federal Circuit ("CAFC" or "Federal Circuit") in the Federal Court Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982) (relevant provisions codified as amended in scattered sections of 28 U.S.C.). The Court of Customs and Patent Appeals ("CCPA") and the Court of Claims were the precursors to the CAFC. The Federal Circuit adopted CCPA and Court of Claims decisions as binding precedent in *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982) (en banc).

The Federal Circuit's patent jurisdiction consists primarily of hearing appeals from United States district courts and from the Patent and Trademark Office's ("PTO") Board of Patent Appeals and Interferences. 28 U.S.C. § 1295(a)(1), (a)(4)(A) (1988). In addition, the Federal Circuit hears appeals from the United States Court of Claims (§ 1295(a)(3)); appeals from the United States Court of International Trade (§ 1295(a)(5)); and final determinations relating to unfair trade practices in import trade from the United States International Trade Commission (§ 1295(a)(6)). The highest percentage of CAFC cases relate to patents.

A patent is a right to exclude others from making, using or selling the claimed product or process in the United States. 35 U.S.C. § 154 (1988). The right is conferred on an individual who has met the requirements of the patent statutes set out under Title 35 of the United States Code. One court has described a patent as a

written contract between an inventor and the government. . . . The consideration given on the part of the inventor to the government is the disclosure of his invention. . . . The consideration on the part of the government given to the patentee for such disclosure is a monopoly for seventeen years of the invention disclosed to the extent of the claims allowed in the patent.

*Amgen Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94, 99 (D. Mass. 1989).

<sup>2</sup> Prior to the establishment of the CAFC, attorneys characterized circuits as "pro-patent" or "anti-patent." See H.R. REP. NO. 312, 97th Cong., 1st Sess. 1 (1981). A patentholder therefore would bring a case against alleged patent infringers before a "pro-patent" circuit, as it was more likely to uphold the patent and find the defendant guilty of infringement. Likewise, an alleged infringer would attempt to defend the case in an "anti-patent" circuit because the court was likely

cess law, however, is in considerable confusion as a result of the CAFC's recent decision in *Atlantic Thermoplastics Co. v. Faytex Corp.*<sup>3</sup>

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to invalidate the patent and find no infringement. The creation of the CAFC primarily was aimed at remedying this type of forum shopping. See S. REP. 97-275, 97th Cong., 1st Sess. 5 (1982), reprinted in 1982 U.S.C.C.A.N. 11, 15; see also *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544 (Fed. Cir. 1987), vacated on jurisdictional grounds and remanded, 486 U.S. 800 (1988). See generally Robert Desmond, *Nothing Seems "Obvious" to the Court of Appeals for the Federal Circuit: The Federal Circuit, Unchecked by the Supreme Court, Transforms the Standard of Obviousness Under the Patent Law*, 26 LOY. L.A. L. REV. 455, 457-64 (1993) (historical look at the debate leading to the creation of the CAFC and the concerns regarding the formation of a specialized court that lacks Supreme Court oversight); Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989) (review of the first five years of CAFC's existence and its effect on patent law).

One commentator, while referring to the goal of achieving uniformity within patent law, observed that "as the only appellate court dealing with the substantive law of patents, [the CAFC] could hardly fail." ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT at ix (2d ed. 1991). The CAFC essentially is the final arbiter for patent disputes, as the Supreme Court rarely grants certiorari in patent cases. Indeed, the Supreme Court has heard only four substantive patent law cases since the creation of the CAFC in 1982: *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451 (1992); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989); and *Dennison Mfg. v. Panduit Corp.*, 475 U.S. 809 (1986).

The danger associated with an exclusive jurisdiction is that absent any appreciable appellate oversight the court may decide issues too hastily. Nearly two years after the creation of the circuit, Senior Circuit Judge Nichols warned:

I think we are painting ourselves into corners by our eagerness to pronounce legal doctrines not immediately necessary to make our decisions, and the more important our words are, the more confining will be the corners into which we have painted ourselves. I further think that our exclusive jurisdiction, over certain areas of law, is not to be construed as a legislative direction to ignore the efforts of other courts to deal with the same problems, efforts exerted when over many years they shared the responsibility that is now ours.

*Wejnar v. Rollform, Inc.*, 744 F.2d 797, 811 (Fed. Cir. 1984).

<sup>3</sup> 970 F.2d 834 (Fed. Cir. 1992). One month after the initial opinion, Chief Judge Nies moved *suu sponte* to rehear *Atlantic en banc*. In two votes by the full circuit panel the rehearing *en banc* was denied; the first vote by a 7 to 3 margin, the second vote, 6 to 4. Following this opinion, those judges who voted to rehear the case *en banc*, Chief Judge Nies and Circuit Judges Rich, Newman and Lourie, wrote dissenting opinions to the denial of rehearing, which are collected at *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992). In addition, Circuit Judge Rader wrote a concurrence to the denial of the rehearing *en banc* in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299 (Fed. Cir. 1992). The initial opinion and the concurring and dissenting opinions will be referred to collectively as *Atlantic*.

The Federal Circuit's most senior judge, Judge Rich, censured the *Atlantic* panel, citing its most egregious act as "its defiant disregard, for the first time in

In *Atlantic*, a Federal Circuit panel implicitly overruled a prior panel's decision in *Scripps Clinic & Research Foundation v. Genentech, Inc.*<sup>4</sup> The *Atlantic* and *Scripps* decisions disagree on the extent of the monopoly granted to an inventor who uses a product-by-process claim to obtain a patent. A product-by-process claim allows an inventor to patent a product by describing the process used to manufacture it.<sup>5</sup> This method is of particular importance in fields like biotechnology where often the knowledge does not exist to describe adequately a product's structure or characteristics with the level of detail required to obtain a conventional product patent.

*Scripps* offers a typical example of this dilemma. In *Scripps*, a pharmaceutical company that had patented a blood-clotting agent using a product-by-process claim subsequently brought an infringement suit against a defendant who used a different process to produce a purer version of the blood-clotting agent. A Federal Circuit panel held that the product-by-process claim should be treated as a product claim for the

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this court's nearly ten-year history, of its rule that no precedent can be disregarded or overruled save by an in banc court." *Atlantic*, 974 F.2d at 1281 (Rich, J., dissenting from the denial of rehearing *en banc*). Judge Rich found the panel's explanation of its decision "not only insulting to the *Scripps* panel[,] . . . [but] mutiny. It is heresy. It is illegal." *Id.*

Interestingly, the 6 to 4 split in the court reflects the judges' backgrounds. The majority group of judges has a largely non-technical background, while the minority group has had extensive technical experience. Three of the four judges in the minority group—Chief Judge Nies and Judges Newman and Rich—have extensive training in patent law. Two of these judges had earlier careers as research chemists. *Atlantic*, 974 F.2d at 1281 (Rich, J., dissenting). Among the minority, two have served as directors of Patent Divisions of large corporations, two were partners with intellectual property law firms and one taught patent law at Columbia Law School. All have served in key positions with multiple intellectual property organizations.

On average, the minority group also has had more experience on the bench than the majority group. The four judges in the minority averaged 15 years on the CAFC or CCPA, while the judges in the majority group averaged four years on the CAFC and, in one case, the Court of Claims. Search of WESTLAW, WLD-Judge database (Oct. 1994).

<sup>4</sup> 927 F.2d 1565 (Fed. Cir. 1991). As Circuit Judge Newman stated: "[T]hese overtly conflicting decisions will repose in the official reporters, I suppose some day to be resolved, but meanwhile to place this law in disarray." *Atlantic*, 974 F.2d at 1282 (Newman, J., dissenting from the denial of rehearing *en banc*).

<sup>5</sup> See 2 DONALD S. CHISUM, PATENTS § 8.05 (1994). For a discussion of the patentability and infringement of product-by-process claims, see *infra* notes 47-63 and accompanying text.

purpose of infringement.<sup>6</sup> Thus, if the *products* in question were sufficiently alike, there would be infringement.<sup>7</sup>

Little more than a year later, a different panel of Federal Circuit judges faced a similar problem in *Atlantic*. As in *Scripps*, plaintiff Atlantic used a product-by-process claim to patent its product, a shoe innersole, and brought an infringement suit against a party that had distributed an innersole similar to Atlantic's product.<sup>8</sup> This time, however, the panel held that Atlantic's product-by-process claim could only be infringed if the *processes* in question were sufficiently similar.<sup>9</sup> *Atlantic* plainly, if not explicitly, overruled *Scripps*.

By narrowly interpreting the scope of a product-by-process claim, the *Atlantic* panel limited product protection to only that product actually produced by *the process* claimed in the patent. The *Scripps* panel, in contrast, interpreted the scope of a product-by-process claim broadly, extending product protection to the claimed *product* regardless of the process by which it was made.<sup>10</sup> In short, the *Atlantic* panel pared the scope of a product-by-process patent to that of a glorified process patent,<sup>11</sup> while the *Scripps* panel treated it as the equivalent of a

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<sup>6</sup> *Scripps*, 927 F.2d at 1583.

<sup>7</sup> The court remanded to the lower court to determine whether the two products were sufficiently similar under the doctrine of equivalents. *Id.* at 1584. For an explanation of the doctrine of equivalents, see *infra* note 55 and accompanying text.

<sup>8</sup> *Atlantic*, 970 F.2d at 836.

<sup>9</sup> *Id.* at 846-47.

<sup>10</sup> *Scripps*, 927 F.2d at 1583. In her dissent to the denial of rehearing in *Atlantic*, Judge Newman, the author of the *Scripps* opinion, alluded to a significant restriction in her broad interpretation of product-by-process patents: prior to an examiner decision on the validity of a product-by-process claim, the applicant would be required to show the necessity for using that type of claim. *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1298 (Fed. Cir. 1992) (Newman, J., dissenting from the denial of rehearing *en banc*). In contrast, the *Atlantic* panel did not require a showing of necessity as they interpreted the scope of the product-by-process claim narrowly.

Thus, both the Federal Circuit minority view as expressed by Judge Newman, and the Federal Circuit majority view, as expressed by Judge Rader, would restrict the use of product-by-process claims. Judge Newman would restrict the use of the claims procedurally, by requiring that the applicant show the necessity of using the product-by-process claim, *Atlantic*, 974 F.2d at 1298, while Judge Rader would restrict the use of the claims substantively, by minimizing the protection afforded by such a claim. *Atlantic*, 970 F.2d at 846-47.

<sup>11</sup> The scope of the product-by-process claim under the majority's view is slightly broader than a process claim. Essentially, the protection is the same as a pro-

conventional product patent.

This dissonance has two important consequences. First, it engenders confusion in lower courts as to which decision provides the controlling law. Prior to rejecting *Scripps*, the *Atlantic* panel stated: "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."<sup>12</sup> These conflicting opinions leave the precedential status of *Atlantic* and *Scripps* in question and offer little guidance to lower courts.

Second, the conflict clouds an area of law in which stability is crucial to investment decisions. The negative repercussions of this instability will be especially felt in the biotechnology industry. Driven by massive investment, the American biotechnology industry has become the world leader in developing genetically engineered products.<sup>13</sup> Two particular areas of research, recombinant DNA<sup>14</sup> and molecular purification,<sup>15</sup>

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cess patent, except that a patentee may prevent others from importing into the United States a product made in a foreign jurisdiction by using the process claimed in the product-by-process claim. See *infra* notes 175-81 and accompanying text.

<sup>12</sup> *Atlantic*, 970 F.2d at 839 n.2. The court cited *Tucker v. Phyfer*, 819 F.2d 1030, 1035 n.7 (11th Cir. 1987), as supporting its rationale for not following the precedent in *Scripps*. *Tucker* was a juvenile incarceration case that cited no authority for its ruling. *Id.* In dissent of this view, Judge Rich cited an internal Federal Circuit rule that "no precedent can be disregarded or overruled save by an in banc court." *Atlantic*, 974 F.2d at 1281 (Rich, J., dissenting). Further, Judge Rich asserted another rule that states "where there are conflicting precedents, the earlier precedent controls." *Id.*

<sup>13</sup> Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 2 (1991); Cheryl D. Hardy, Note, *Patent Prosecution and Raw Materials: The Convention on Biological Diversity and Its Implications for U.S. Policy on the Development and Commercialization of Biotechnology*, 15 U. PA. J. INT'L BUS. L. 299, 302 (1993). The pharmaceutical industry invested almost \$11 billion in research and development in 1992. Roger A. Brooks, Address Before the American Intellectual Property Law Association (May 14, 1992), in *AIPLA BULL.*, Apr.-June 1992, at 475; see also Philip Yip, *Product and Process Patent Protection in Biotechnology: Too Much or Too Little?*, 17 J. CORP. L. 659, 661 (1992) (sales of bioengineered human pharmaceuticals estimated to be \$6 billion by the year 2000). One industry expert has predicted that U.S. sales of biotechnology-derived products will reach \$40 billion by the year 2000. Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1051 (1992). Worldwide sales could exceed \$100 billion by that year. *Id.*

<sup>14</sup> DNA is an abbreviation for "deoxyribonucleic acid", the chemical compound of which genetic material is composed. Recombinant DNA technology is the isolation

have produced many significant discoveries. Significantly, inventors in these industries often have little choice but to patent their products by reference to the process used to manufacture it—i.e., by using a product-by-process claim. As a result of the confusion generated in product-by-process patent law following the *Atlantic* decision, companies that invest in biotechnology may alter their investment strategies.<sup>16</sup>

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and replication of a desired gene of one species and insertion of it into the cells of another species (host cells). The foreign gene takes proteins generated by the host cell and codes or arranges them into a new product. Thus, the host cell becomes a factory that produces proteins. Proteins produced by this process include insulin for diabetics, a blood-clotting serum for hemophiliacs, and other important medical, environmental and agricultural products.

For a discussion of the patent laws' impact on recent cases in recombinant DNA technology, see Greenfield, *supra* note 13. See also Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 783-89 (1992) (explanation of the production techniques of recombinantly derived products).

<sup>15</sup> This type of technology involves isolating materials that occur naturally in humans or other animals. For example, in an early case of this type, a patentee sought to patent a purified version of human adrenalin. See *Park-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911).

<sup>16</sup> Investment in biotechnology is largely contingent on certainty in patent law. See Burk, *supra* note 13, at 10-12.

Although the efficacy of patents in achieving [a "level playing field" between American and foreign biotechnology concerns and stimulating innovation in biotechnology] remains a topic of legislative and academic debate, one concrete fact is clear: patents are critical to the growth and competitiveness of American biotechnology because patents are something investors expect.

. . . .  
[I]nvestors are themselves reluctant to put money into biotechnology ventures where the patent protection is lacking, or where the rights of the patent holder are unclear. Investors are well aware that the enormous costs of patent litigation may make serious inroads into the profit margin of a small biotechnology firm.

*Id.* at 12; see also Kevin J. McGough & Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology Inventions*, 6 HARV. J.L. & TECH. 85, 101 (1992) ("Since further [biotechnological] innovation will require great expense and laborious research, investors need reasonable assurances that expansive product or product-by-process patent protection will facilitate attractive returns on investment."); Yip, *supra* note 13, at 688 (many biotech companies are small and lack financial strength and thus require equitable patent laws to provide incentive to take risks).

While it is difficult to predict how a change in this area of law will affect corporations, the cost of developing a new pharmaceutical product indicates that it may be enormous. For example, the cost in 1990 dollars associated with taking a new chemical entity from conception to market has increased five-fold since 1976, from \$54 million to approximately \$230 million. Brooks, *supra*, note 13, at 475. An illustration of the risk involved with pursuing the development of a new medicine

Part I of this Comment reviews the history of product-by-process claims and the standards used to determine patentability and infringement. Part II then examines the *Scripps* and *Atlantic* decisions, including the opinions generated by the application for rehearing in *Atlantic*. Part III focuses on the *Atlantic* panel's interpretations of early Supreme Court product-by-process decisions and the dissents to the denial of rehearing in *Atlantic*. This section identifies how each side, using the same case law, came to diametric conclusions, before it explores the policy considerations that underlie the two positions. Part IV argues that precedent supports the *Scripps* panel's interpretation of the scope of product-by-process claims and asserts that courts should grant product-by-process claims the same scope of protection afforded to conventional product claims—to do otherwise when a patentee has satisfied a showing of utility, novelty and nonobviousness, would be inequitable. The Comment concludes therefore that the Patent and Trademark Office should not require an inventor to prove a specific need for claiming an invention with a product-by-process claim.

## I. PATENT BACKGROUND

### A. *The Origin of Patents*

The 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>17</sup> Accordingly, the second session of the First Congress established the patent system by granting inventors certain exclusive rights<sup>18</sup> in their inventions for a period of time, in exchange for the disclosure

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is provided by Pharmaceutical Manufacturers Association statistics, which estimate that only one out of every 5000 to 10,000 compounds discovered ever makes it to market. *Id.*

<sup>17</sup> U.S. CONST. art. I, § 8, cl. 8; see also *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) (“Within the scope established by the Constitution, Congress may set out conditions and tests for patentability.”).

<sup>18</sup> A patent does not grant exclusive property rights in the patented subject matter, only the right to exclude others from making, using and selling the patented invention. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985).



of the invention to the public.<sup>19</sup> This system "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"<sup>20</sup> The patent system has since undergone many changes, always with an eye to the original policies.

Under the current statute, patentable subject matter is restricted to useful processes, machines, manufactures or compositions.<sup>21</sup> Inventions containing patentable subject matter also must display "novelty"<sup>22</sup> and be "nonobvious"<sup>23</sup> to one of ordinary skill in the particular art to which the invention pertains, at the time the invention was made. When an invention satisfies these three requirements, the inventor may obtain a patent for the final product, the starting material used to produce the final product, the process by which a final product is made, or any combination of these categories.<sup>24</sup>

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<sup>19</sup> Effective June 8, 1995, the grant of exclusive rights will begin on the date the patent issues and end 20 years from the date on which the application for the patent was filed. Pub. L. No. 103-465, Title V §§ 532(a)(1), 534, 108 Stat. 4983, 4990 (1994). Previously, the grant of exclusive rights lasted 17 years from the issue date. 35 U.S.C. §§ 154, 271(a) (1988).

<sup>20</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

<sup>21</sup> 35 U.S.C. § 101.

<sup>22</sup> The requirement of "novelty" is extracted from § 102:

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States . . . .

*Id.* § 102. Section 102(a) and (b) operates to "exclude from consideration for patent protection knowledge that is already available to the public." *Bonito Boats*, 489 U.S. at 148.

<sup>23</sup> See 35 U.S.C. § 103.

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

*Id.* The requirement of nonobviousness dictates that even if an invention is novel and useful it will not qualify for patent protection "if its contours are so traced by the existing technology in the field that the 'improvement is the work of the skillful mechanic, not that of the inventor.'" *Bonito Boats*, 489 U.S. at 150. (quoting *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1851)).

<sup>24</sup> 35 U.S.C. § 100. The process of using a starting material also may be pat-

The scope of protection offered by a patent corresponds to the type of patent sought. Given the choice among different categories under which to patent an invention, an inventor naturally will opt for the patent category that grants the greatest rights in the invention. Therefore, if possible, the inventor will describe the invention as a product, because this method grants the patentee the right to prevent others from making, using or selling the product.<sup>25</sup> The other available forms of patent grant lesser rights. For example, a process patent prevents others from using or selling rights to employ a specific process.<sup>26</sup>

To obtain a patent in any subject matter, the inventor must negotiate a stringent application process known as patent prosecution. The inventor submits an application to the Patent and Trademark Office ("PTO") consisting of a specification, a drawing and an oath.<sup>27</sup> The inventor's specification must describe the invention in terms that would enable a person of ordinary skill in the art of the invention to recreate the invention.<sup>28</sup> The specification must conclude with one or more "claims" that specify and distinctly claim the subject matter that the inventor regards as the invention.<sup>29</sup> The claims serve both to distinguish the invention from the prior art and to define the scope of protection the patent will afford.<sup>30</sup> A PTO examiner scrutinizes the application to ensure it complies with the statute before ruling on its validity.<sup>31</sup> An inventor who is

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ented. See *In re Pleuddemann*, 910 F.2d 823, 825-26 (Fed. Cir. 1990).

<sup>25</sup> 35 U.S.C. § 154.

<sup>26</sup> During the patent application process, it remains uncertain whether the product of a process will meet the requirements of novelty, usefulness and nonobviousness. Thus, an inventor who submits a product claim may hedge that claim with one which covers the process of making the product. See Yip, *supra* note 13, at 678 ("A product-by-process claim is usually presented as a 'fall back' in patent applications in case the product claim is rejected.").

<sup>27</sup> 35 U.S.C. § 111.

<sup>28</sup> The inventor must describe the "manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." *Id.* § 112.

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

<sup>30</sup> *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985) ("[C]laims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed which define the area conveyed but do not describe the land.").

<sup>31</sup> 35 U.S.C. § 131.

dissatisfied with the PTO's initial determination may request a reexamination.<sup>32</sup> If the patent is again rejected, the inventor may pursue an appeal to the Board of Patent Appeals and Interferences, and ultimately, to the Court of Appeals for the Federal Circuit.<sup>33</sup>

In addition to the initial application, a patent's validity also may be challenged during an infringement suit.<sup>34</sup> An alleged infringer may raise the question of the patent's validity as a defense to an infringement action,<sup>35</sup> or, alternatively, the court may raise the issue while interpreting the scope of the patent. Although these two circumstances involve different procedures for determining validity, in either event a finding of invalidity precludes infringement. In the case of a product patent, regardless of how the patentability is challenged, the determination hinges on whether at the time of the patent application, the challenged product was novel and nonobvious to those with ordinary skill in the art.<sup>36</sup> In an infringement proceeding, however, the challenged patent is presumed valid because it already has satisfied the application process.<sup>37</sup>

In examining the validity of a patent, the court or examiner analyzes the language of the patent claim<sup>38</sup> by considering

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<sup>32</sup> *Id.* § 132.

<sup>33</sup> *Id.* §§ 134, 141.

<sup>34</sup> A patent holder brings an infringement suit to prevent another from making, using or selling her patented invention. Essentially, the patent holder claims that the infringer has copied her invention. To prove this allegation, the patentee attempts to show that the product in question falls within the boundaries of her invention (literal infringement) or that any difference between the two are insignificant (doctrine of equivalents). Infringement is discussed more fully, *infra* notes 51-56 and accompanying text.

<sup>35</sup> This type of defense is common to nearly all infringement cases and was used in both *Scripps*, 927 F.2d 1565, 1571-80 (Fed. Cir. 1991), and *Atlantic*, 970 F.2d at 836 (Faytex asserted that Atlantic's patent was invalid because the innersole was on sale more than one year before the filing date of the patent application).

<sup>36</sup> 35 U.S.C. § 103.

<sup>37</sup> See *id.* § 282. Section 282 provides: "A patent shall be presumed valid. Each claim of a patent . . . shall be presumed valid independently of the validity of other claims. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

Where an infringer challenges the validity of a patent, the Federal Circuit has adopted a burden of proof that requires the infringer to introduce clear and convincing evidence of invalidity. *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1459 (Fed. Cir. 1984) (citing *RCA v. Radio Eng'g Labs, Inc.*, 293 U.S. 1 (1934)).

<sup>38</sup> The matter of claim adequacy or definiteness is a question of law. Morton

the specification, the drawings and the prosecution history.<sup>39</sup> Normally the claim will describe the invention by the product's characteristics and structure. In some instances, however, the patentee may claim a product by referring only to the process.<sup>40</sup> This type of claim is known as a product-by-process patent.

### B. *Product-by-Process Patents*

The statutes governing patents do not specify product-by-process claims as a method of obtaining a patent.<sup>41</sup> These claims are a judicial construct that recognizes that due to the limitations of language some products may be described only by the process used to make it. In *Ex parte Painter*,<sup>42</sup> the first case to acknowledge the validity of product-by-process claims, Patent Commissioner Simonds described the predica-

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*Int'l v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469 (Fed. Cir. 1993); *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1579-80 (Fed. Cir. 1989). For a general overview of the rules on interpretation of patent claims, see *Autogiro Co. v. United States*, 384 F.2d 391 (Ct. Cl. 1967).

<sup>39</sup> *Autogiro*, 384 F.2d at 397. The "prosecution history" (historically referred to as the "file wrapper" history) includes the entire record of the proceedings in the Patent Office, from the first application papers to the issued patent.

This record often is used to invoke "file wrapper" estoppel during Patent Office prosecutions and patent infringement litigation. File wrapper estoppel occurs when a patent applicant is unable to convince the patent examiner that his invention meets the statutory requirements of novelty, utility and nonobviousness. After the inventor's application is rejected, the applicant proceeds to insert limitations and restrictions on the patent for the purpose of inducing the Patent Office to grant the patent. When the patent is issued, the patentee is estopped from disclaiming the limitations and restrictions when attempting to determine the scope of protection afforded to the invention. *Id.* at 398-99. See generally Kurt F. James, *Patent Claims and Prosecution History Estoppel in the Federal Circuit*, 53 MO. L. REV. 497 (1988) (discussion of different approaches taken by the Federal Circuit with regard to file wrapper estoppel).

<sup>40</sup> A product is a machine, manufacture or composition. These are distinguished from a process or method patent, which describes a new way of producing a product.

<sup>41</sup> That is, the patent statute does not list it as a method of obtaining a patent. The statute, however, also does not limit the means of describing a patent. Moreover, the *Manual of Patent Examining Procedure* states: "An article may be claimed by a process of making it provided it is definite." PATENT AND TRADEMARK OFFICE, U.S. DEPT OF COMMERCE, *MANUAL OF PATENT EXAMINING PROCEDURE* § 706.03(e) (rev. ed. 1993) [hereinafter MPEP]. The MPEP is used as a guide by PTO examiners in resolving patent applications.

<sup>42</sup> *Ex parte Painter*, 1891 Dec. Comm'r Pat. 200.

ment as follows:

[I]t requires no argument to establish the proposition that *as a rule* a claim for an article of manufacture should not be defined by the process of producing that article. On the other hand, when a man has made an invention his right to a patent for it, or his right to claim property defining it, is not to be determined by the limitations of the English language. 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 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>43</sup>

The Patent Office used the criterion of necessity to determine patentability over many years and consistently was affirmed by the Court of Claims and the Court of Customs and Patent Appeals ("CCPA").<sup>44</sup>

The necessity requirement has been relaxed somewhat in recent years, relieving the applicant of proving an absolute need for reciting the process. Indeed, as early as 1966, in *In re Bridgeford*, the CCPA moved towards allowing product-by-process claims without a showing of necessity.<sup>45</sup> In *Bridgeford*,

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<sup>43</sup> *Id.* at 200-01.

<sup>44</sup> See, e.g., *In re Lifton*, 189 F.2d 261, 263 (C.C.P.A. 1951); *In re Shortell*, 173 F.2d 993, 996 (C.C.P.A. 1949); *In re McKee*, 95 F.2d 264, 266 (C.C.P.A. 1938); *In re Butler*, 37 F.2d 623, 626 (C.C.P.A. 1930); *In re Brown*, 29 F.2d 873, 874 (D.C. Cir. 1928). For example, in *In re Moeller*, 117 F.2d 565 (C.C.P.A. 1941), a patent applicant developed an improved method for producing molded cement products by using corrugated sheets instead of woven fabric. The applicant was granted a patent for the process of cement molding, but the product-by-process claim directed at obtaining protection for the resulting cement product was rejected. *Id.* at 566. The Court of Customs and Patent Appeals held that because the molded cement articles could have been defined in terms of their physical and chemical characteristics, the claim did not fall within the narrow exception afforded by a product-by-process claim. *Id.* at 567; see also *In re Johnson* 394 F.2d 591 (C.C.P.A. 1968) (court rejected product-by-process claims because the articles were capable of structural description, and so clearly did not fall into the "necessity" exception).

<sup>45</sup> 357 F.2d 679 (C.C.P.A. 1966). The appellant in *Bridgeford* attempted to patent a type of wood by first claiming the product by a product-by-process claim and then by a product claim. The appellant asserted that he needed the product claim to properly protect his invention because a product claim is broader in scope than the product-by-process claim and does not contain any process limitations. *Id.* at 681. The court relied on statutory language to deny the appellant the opportunity to patent the same subject matter by two different methods. The court acknowledged, however, that other courts have "construed [product-by-process] claims as covering only a product made by the particular process set forth in the claim and not to the product per se." *Id.* at 683. Thus, without ruling on future infringe-

the court found that the method used to define the invention is not dispositive of the type of protection granted it. According to the *Bridgeford* court:

Whether the invention be defined in terms of the structure of the compound, or its novel physical characteristics, or by defining it in terms of the process by which it is produced or in a proper case, by employing more than one of these methods of defining the invention, the right to a patent on the invention is the ultimate consideration. . . . "In a proper case" does not mean that an applicant must prove the impossibility of defining the invention other than by using more than one of the above methods.<sup>46</sup>

The court's focus of inquiry therefore shifted from the necessity of describing the process to determining first whether the invention, and more specifically the product, was patentable and, second, whether the claim met the statutory requirements.

Subsequent cases followed the reasoning in *Bridgeford*, holding that the patent statutes do not limit how a patent applicant claims his or her invention, so long as it is "definite."<sup>47</sup> Whether a product-by-process claim is definite depends on the patentability of the product itself.<sup>48</sup> Thus, the court or examiner does not evaluate whether the stated *process* is novel or nonobvious, but instead scrutinizes the *product* produced by that process. In 1974, in *In re Hughes*, the CCPA dispelled any confusion over the propriety of utilizing product-

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ment matters, the court intimated that the scope of the patent may be limited because the patentee had submitted the product-by-process claim first.

<sup>46</sup> *Id.* at 682-83.

<sup>47</sup> See *In re Steppan*, 394 F.2d 1013, 1019 (C.C.P.A. 1967). The appellant in *Steppan* argued that a claim was invalid because it was in an improper form, i.e., a product-by-process claim. The court held that the relevant inquiry in determining the appropriateness of a claim is whether it complies with § 112 of Title 35: "The problem, in essence, is thus one of determining who shall decide how best to state what the invention is. By statute, 35 U.S.C. § 112, Congress has placed no limitations on *how* an applicant claims *his invention*, as long as the specification concludes with claims which particularly point out and distinctly claim that invention." *Id.* (emphases added). See also *In re Pilkington*, 411 F.2d 1345 (C.C.P.A. 1969), where the court reversed the Patent Office's rejection of a claim for a glass product. The Patent Office had stated that the glass could have been claimed without resorting to a process description. *Id.* at 1346-47. It held, however, that as the qualities of the glass were not "particularly susceptible to definition by the conventional recitation of properties or structure," the product-by-process claims were valid. *Id.* at 1349 (footnote omitted).

<sup>48</sup> *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985) (the determination of product-by-process claims is based on the product itself).

by-process claims.<sup>49</sup> The CCPA stated that even if the product can be defined broadly without process limitations, product-by-process claims are permissible as a hedge against invalidity of the broader product claims.<sup>50</sup>

As with all patent claims, if a product-by-process claim does not clearly delineate what the patentee claims as his invention, others cannot avoid inadvertently infringing the patent.<sup>51</sup> As a result, the Patent Office is particularly wary of inadequate product-by-process claims during the application process. The examiner may require an applicant to demonstrate the difference between the subject of the product-by-process claim and a sufficiently similar product that exists in the prior art. If the products are either identical or only slightly different, the examiner may reject the application for non-obviousness or for a lack of novelty.<sup>52</sup> This policy results from the practical limitations of the application process; namely that the PTO lacks the resources and capability to manufacture products by the processes described in product-by-process claims in order to make physical comparisons to products that

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<sup>49</sup> 496 F.2d 1216 (C.C.P.A. 1974).

<sup>50</sup> *Id.* at 1219. More recently, the Supreme Court and the Federal Circuit implicitly reaffirmed that a product could be claimed by way of a product-by-process claim. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158-59 n.\* (1989) ("As long as the end product of the process is adequately defined and novel and nonobvious, a patent in the process may support a patent in the resulting product."); *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993) ("a chemical material can be claimed by means of a process"). *Hughes*, however, raised the policy issue of the public's interest in clearly-defined claims, which generally work against allowing product-by-process claims.

One cannot read the words of the claim on an article unless he is able to find out how the article was made. Therefore, there may be a sound policy reason behind the rule, as a general proposition, requiring articles to be defined without reference to process. It is a rule of public convenience and we have, therefore, often approved its application.

*Hughes*, 496 F.2d at 1218.

<sup>51</sup> Judge Rader argued that as a product-by-process claim refers only to the process, the claimed product is necessarily indefinite. See *Atlantic*, 970 F.2d 834, 846 (1992) ("to disregard the claim limitations also would require this court to determine infringement by comparing an accused product with an embodiment of the claims, not the claims themselves").

<sup>52</sup> The *Manual of Patent Examining Procedure* states: "When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 [novelty] or 103 [nonobviousness] of the statute is appropriate." MPEP, *supra* note 41, at § 706.03(e).

exist in the prior art. The PTO therefore carries a lesser burden of proof to make out a case of prima facie obviousness in product-by-process claims than in a conventional product claim.<sup>53</sup>

In addition to the patentability issue, a product-by-process patent presents a unique problem for the courts during infringement proceedings. In a standard product patent infringement case, the court first examines whether the alleged infringing device is identical—whether it literally infringes.<sup>54</sup> If the product does not literally infringe, the court next determines whether the accused product is equivalent to the patented product; that is, whether the device “performs substantially the same function in substantially the same way to obtain substantially the same result.”<sup>55</sup> Although courts use the same standard as an ordinary product case to determine infringement of a product-by-process patent, they lack a description of the initial product to compare to the alleged infringing product.<sup>56</sup> This difficulty is the primary reason behind the

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<sup>53</sup> *Id.* To avoid the potential problem of obviousness faced during either the patent application process or infringement proceedings, commentators have advised adding sufficient information to a claim so that it avoids the product-by-process label and becomes a “fingerprint” claim. Rochelle K. Seide & Andrew S. Reiskind, *Drafting Claims for Biotechnology Inventions*, in *PLI PATENTS, COPYRIGHTS, TRADEMARKS AND LITERARY PROPERTY COURSE HANDBOOK* 383, 391 (1992) (Series No. 353). Rather than claiming a product by describing its structure, a “fingerprint” claim claims the product by its characteristics; e.g., claiming a chemical compound by mass-spectrometry and infra-red readings. *Id.* at n.113.

<sup>54</sup> Literal infringement occurs when the infringing product or process claim contains the same limitations contained in the patented product or process. *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (1991). For example, when a patented product is claimed as “comprised of A, B and C,” and the product accused of infringement contains A, B and D, the accused product does not literally infringe. The accused product may, however, infringe under the doctrine of equivalents.

<sup>55</sup> *Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994). The doctrine of equivalents is an equitable device which recognizes that future infringers may alter their claim slightly and thereby fall outside the literal scope of the original patentee's claim. *Graver Tank & Mfg. v. Linde Air Prods.*, 339 U.S. 605, 607 (1950). The Court of Claims has phrased the concern underlying the requirement of literal infringement aptly: “To allow literality to satisfy the test for infringement would force the patent law to reward literary skill and not mechanical creativity.” *Autogiro*, 384 F.2d at 399. The doctrine of equivalents allows courts to overlook words which may unnecessarily limit the scope of a patent in view of the disclosed invention, the prior art and the actions of the patent examiner. Even where the product does not literally infringe a claim of a patent, it infringes the patented product if it essentially appropriates the invention.

<sup>56</sup> Some courts have touched on the problem of defining the scope of a product-



*Atlantic* panel's decision to limit product-by-process claims to products made by the process described in the patent.

## II. TAKE OFF THE GLOVES: DISAGREEMENT WITHIN THE FEDERAL CIRCUIT

The collegial existence of the Federal Circuit was altered dramatically when Judge Randall Rader handed down *Atlantic Thermoplastics Co. v. Faytex Corp.*,<sup>57</sup> which implicitly overruled *Scripps Clinic & Research Foundation v. Genentech, Inc.*,<sup>58</sup> a decision written by Judge Pauline Newman just one term earlier. The denial of rehearing in *Atlantic* prompted both sides of the controversy to release opinions stating their positions on the scope of product-by-process patents. The dispute started innocently enough: Judge Newman's *Scripps* opinion contained only two paragraphs dealing with a product-by-process issue.<sup>59</sup>

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by-process patent. In *In re Bridgeford*, 357 F.2d 679 (C.C.P.A. 1966), while discussing the implications of double patenting the same subject matter, the CCPA stated: "While there is some language in *Freeman* to support the contention that a product-by-process type claim differs only 'in scope' from a process type claim and they therefore 'are directed to a single invention,' so far as this is inconsistent with our holding here it must be overruled." *Id.* at 683 n.6. The court explicitly acknowledged that although the product and product-by-process claims define the same patentable subject matter, the patents themselves differ in scope. *Id.* at 683. The court therefore intimated that a product-by-process patent is not equivalent to a product patent. This discussion, however, is pure dicta, as the court had to decide only whether double patenting had occurred, not the scope of the patent.

One article concerning product-by-process patents suggests that a product-by-process patent is literally infringed only when the process defined by the claim is used to make the infringing product. See Lawrence A. Hymo and Richard A. Anderson, *Product-by-Process Claims: Time for Reexamination*, 3 FED. CIR. BAR J. 131 (1993). Thus, it may be argued that if the scope of a product-by-process claim includes the product of the process, then infringement only can occur under a doctrine of equivalents analysis.

<sup>57</sup> 970 F.2d 834 (Fed. Cir. 1992).

<sup>58</sup> 927 F.2d 1565 (Fed. Cir. 1991).

<sup>59</sup> Judge Newman's opinion mainly was devoted to analyzing Scripps' product claims and Genentech's defenses. Genentech claimed *inter alia* that Scripps' patent claims were unenforceable for the following reasons: Scripps engaged in inequitable conduct during the patent process, *id.* at 1571-74; Scripps did not provide sufficient information about the invention to enable another with ordinary skill in the field to make and use the invention without undue experimentation, *id.*; Scripps did not properly reissue the patent, *id.* at 1574-76; the patents were anticipated by the prior art, *id.* at 1576-78; and Scripps did not provide the best mode to produce the invention, *id.* at 1578-80. Only two paragraphs of the 19-page opinion

In 1983, Scripps Clinic & Research Foundation ("Scripps") brought an infringement suit against Genentech, Inc. Scripps owned a patent that claimed a product, a protein used to treat hemophilia, and the process used to produce the protein, by using product-by-process claims and process claims respectively.<sup>60</sup> Scripps contended that Genentech, which had discovered an alternative method of producing the protein by using a process involving recombinant DNA, had infringed Scripps' patent either literally or by application of the doctrine of equivalents.<sup>61</sup>

During the litigation Scripps's motion for summary judgment on the infringement of its product-by-process claims was denied on the ground that its claims had not been infringed unless Genentech used the same process to produce the protein identified in the Scripps patent.<sup>62</sup> Scripps appealed and the Federal Circuit determined that the district court's finding "appears to diverge from our precedent."<sup>63</sup> Writing for the panel, Judge Newman acknowledged that although the precedent from which the district court diverged "arose in the context of patent prosecution, not patent infringement[,] . . . [s]ince 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>64</sup> A product-by-process patent thus protects the product as broadly as if it had been claimed under a product patent. In short, the court considered the protection granted products patented by conventional product claims to be no different from that granted to products patented through a product-by-process claim.

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were devoted to infringement of the product-by-process claims.

<sup>60</sup> *Id.* at 1569. The protein was termed Factor VIII:C. Scripps' claims to the blood-clotting factor were product-by-process claims. Claim 13 is a representative claim: "Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1." *Id.* at 1570. Claim 1 describes a process of producing Factor VIII:C by purifying existing Factor VIII:C from human or pig blood. *Id.*

<sup>61</sup> *Id.* at 1583. For a discussion of literal infringement and the doctrine of equivalents, see *supra* notes 54-55 and accompanying text.

<sup>62</sup> *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1386-87 (N.D. Cal. 1987).

<sup>63</sup> *Scripps*, 927 F.2d at 1583.

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

Although the district court had misstated the standard, Judge Newman found that its conclusion had been correct: the summary judgment motion on infringement was properly denied because a question remained as to whether the products were equivalent.<sup>65</sup> The court directed that on remand the infringement analysis should not hinge on whether Genentech had used the same process to produce the protein, but should attempt to determine whether the product made by Genentech avoided infringing Scripps' patent by the reverse doctrine of equivalents.<sup>66</sup>

The following year, *Atlantic Thermoplastics Co. v. Faytex Corp.*<sup>67</sup> presented a situation similar to *Scripps*, although for a low-tech application—Atlantic owned a patent for a shock-absorbing shoe innersole. As in *Scripps*, Atlantic's patent claimed both the process for making the product<sup>68</sup> and the

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<sup>65</sup> *Id.* at 1583-84.

<sup>66</sup> *Id.* at 1581, 1583-84. "The so-called 'reverse doctrine of equivalents' is an equitable doctrine invoked in applying properly construed claims to an accused device. Just as the purpose of the 'doctrine of equivalents' is to prevent 'pirating' of the patentee's invention[,] . . . so the purpose of the 'reverse' doctrine is to prevent unwarranted extension of the claims beyond the fair scope of the patentee's invention." *Id.* at 1581. If an accused article is within the literal words of a claim, it may avoid infringement if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way." *Graver Tank & Mfg. v. Linde Air Prods.*, 339 U.S. 605, 608-09 (1950).

<sup>67</sup> 970 F.2d 834 (Fed. Cir. 1992).

<sup>68</sup> Claim 1 of the patent defined the process as:

In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:

- (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.

product itself through a product-by-process claim.<sup>69</sup> Atlantic brought an infringement suit against Faytex for distributing innersoles similar to those patented by Atlantic. Faytex's innersoles were manufactured by two different companies, using two different processes.<sup>70</sup> The district court found infringement by Faytex only where the product was produced by a process similar to the one described in the Atlantic claim.<sup>71</sup>

On appeal to the Federal Circuit, a panel of judges who had not participated in the *Scripps* decision agreed with the district court infringement findings. Writing for the panel, Judge Rader held that the scope of a product-by-process claim is not the same as that of a product claim; rather, the scope of a product-by-process claim is limited by its process terms.<sup>72</sup> Judge Rader stated that the *Scripps* panel's reading of the case law was not controlling because it had "ruled without reference to the Supreme Court's previous cases involving product claims with process limitations."<sup>73</sup> Furthermore, he maintained that the "invitation [to follow *Scripps*] would require this court to directly ignore basic patent principles."<sup>74</sup>

Judge Rader concentrated on digesting those early Supreme Court cases that he asserted the *Scripps* panel had ignored.<sup>75</sup> He then briefly examined relevant district court decisions and commentators' analyses before reviewing PTO and CCPA precedent. The panel concluded that "courts regard-

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*Id.* at 835-36.

<sup>69</sup> The product claim stated: "The molded innersole produced by the method of claim 1." *Id.* at 836.

<sup>70</sup> *Id.* The manufacturers were Surge Products, Inc. and Sorbothane, Inc. The district court found that while the innersoles made by Surge infringed Atlantic's patent, Sorbothane's innersoles did not. *Id.*

<sup>71</sup> *Id.*; see *Atlantic Thermoplastics Co. v. Faytex Corp.*, No. 88-0210-H (D. Mass. July 27, 1990).

<sup>72</sup> *Atlantic*, 970 F.2d at 846-47.

<sup>73</sup> *Id.* at 839 n.2. The court cited an Eleventh Circuit case to support its decision to contradict the prior Federal Circuit panel's opinion: "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. See *Tucker v. Phyfer*, 819 F.2d 1030, 1035 n.7 (11th Cir. 1987)." *Id.* See *infra* note 100 and accompanying text for a discussion of the propriety of the *Tucker* analysis.

<sup>74</sup> 970 F.2d at 846. "This court, therefore, rejects Atlantic's invitation to ignore the process limitations in its product-by-process claims." *Id.* at 847.

<sup>75</sup> This series of cases is dealt with *infra* at notes 106-54 and accompanying text.

ed the language in product-by-process claims as limiting the claim."<sup>76</sup>

Judge Rader recognized that by limiting a product-by-process patent to the process, the panel was allowing the claim to be treated differently in litigation than in the initial application proceeding. He justified this disparate treatment by asserting that it accommodated the demands of the administrative process during application while also recognizing the capabilities of trial courts during litigation.<sup>77</sup> In other words, although "claims mean the same for infringement and validity," the PTO and courts treat claims differently because of their dissimilar abilities to address this type of determination:<sup>78</sup> the PTO "gives claims the broadest reasonable meaning when determining patentability," while courts "consult the specification, prosecution history, prior art and other claims to determine the proper construction of the claim language."<sup>79</sup>

Judge Rader also recognized that treating the product-by-process claims as product claims would create two problems. First, it would require courts to ignore the limitations described in the product-by-process claim, a practice that "would clash with basic patent principles."<sup>80</sup> Second, ignoring the claim limitations would require courts to measure infringement by comparing the alleged infringing device with an embodiment of the claims, rather than the actual claims themselves.<sup>81</sup>

Judge Newman's dissent to the denial of rehearing *en banc* did not concentrate on what the correct interpretation of *Atlantic* should have been. Instead, she limited her review of cases to those cited by the *Atlantic* panel to "explain why the question [in *Atlantic*] should have been taken *en banc*."<sup>82</sup> While surveying the relevant Supreme Court precedent, Judge Newman declared that although dicta in some cases suggested, at times correctly, limitations based on the process when deal-

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<sup>76</sup> *Atlantic*, 970 F.2d at 845.

<sup>77</sup> *Id.* at 846.

<sup>78</sup> *Id.*

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

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

<sup>81</sup> *Atlantic*, 970 F.2d at 846.

<sup>82</sup> *Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1293 (Fed. Cir. 1992) (Newman, J., dissenting from denial of rehearing *en banc*).

ing with a product-by-process claim,<sup>83</sup> the Supreme Court had not decided a case that was factually similar to *Scripps*. Judge Newman reasoned that since the Supreme Court had not ruled upon a situation where the product was new and patented by a product-by-process claim, the CAFC was free to consider this factual situation in a manner consistent with Supreme Court precedent.<sup>84</sup>

In addition to disputing the majority's interpretation of Supreme Court precedent, Judge Newman's opinion contained two interesting contentions. First, she maintained that the bulk of the *Atlantic* opinion was dicta because under the facts of the case, it was unnecessary for the court to consider the validity of *Scripps*. Second, her opinion implied that the patentee should be allowed to claim a product via a product-by-process claim only after proving the need to use such a claim by showing the impossibility of defining the product in a conventional sense.

Judge Newman's dissent demonstrated the weakness and overreaching of the majority opinion. Prior to scrutinizing the Supreme Court precedent, Judge Newman had raised an argument that would eliminate the need for lengthy analysis. She asserted that the types of claims in *Scripps* and *Atlantic* were distinguishable and, therefore, that the *Atlantic* panel had overruled *Scripps* unnecessarily.<sup>85</sup> She postulated three possible combinations of claims that contain both product and process terms:

- (1) when the product is new and unobvious, but is not capable of independent definition;

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<sup>83</sup> See *General Elec. v. Wabash Appliance Co.*, 304 U.S. 364, 373 (1938); *Cochrane v. BASF*, 111 U.S. 293, 310 (1884); see *supra* notes 119-31, 140-44 and accompanying text.

<sup>84</sup> *Atlantic*, 974 F.2d at 1289.

<sup>85</sup> *Id.* at 1283 ("[I]t is apparent that there is no need whatsoever for the conflict that the *Atlantic* panel created. The claims in *Atlantic* and those of *Scripps* are different classes of claims, with a long history recognizing the difference."). Judges Rich and Lourie also dealt with a related issue in their dissents. Judge Lourie commented: "The patentee in this case itself characterized [the claim] as being limited to the process by which the claimed innersole was made. An inventor determines what he or she regards as his or her invention. 35 U.S.C. § 112." *Id.* at 1299 (Lourie, J., dissenting from denial of rehearing *en banc*). Judge Rich agreed: "There was, therefore, no occasion to review the law to determine how the claim should be construed. It was *not an issue* in the case." *Id.* at 1280 (Rich, J., dissenting from denial of rehearing *en banc*).

- (2) when the product is old or obvious, but the process is new;
- (3) when the process is new and unobvious, but has a process-based limitation (e.g. a "molded" product).<sup>86</sup>

Judge Newman placed the *Scripps* claims in the first class—termed "true" product-by-process claims—because the product patented (purified blood-clotting protein) was new and the patentee could not describe it without reference to the purification process.<sup>87</sup> In contrast, according to Judge Newman, *Atlantic's* claims fell into the second category—"product of the process" claims—because during the prosecution of the original patent, Atlantic had argued to the PTO that their claims were patentable solely on the basis of the process, thereby estopping them from claiming the product.<sup>88</sup> Although the prosecution history had acknowledged that the product was old,<sup>89</sup> the process used to create the innersoles still was found to be new.<sup>90</sup> Thus, Judge Newman argued that the *Atlantic* panel should have limited itself to ruling on the second type of claims, and should not have addressed the validity of *Scripps*.<sup>91</sup>

Judge Newman's argument for re-establishing the necessity requirement was grounded on the fact-sensitive quality of the cases decided by the CCPA, the Court of Claims and the Supreme Court. These cases all required courts to "approach[ ] claim interpretation in the classical way: they . . . consider[ ]

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<sup>86</sup> *Id.* at 1284. Judge Newman's categories are drawn from an insightful article by Eric Mirabel entitled *Product-By-Process: A Practical Perspective*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 3 (1986). Mirabel describes three separate categories of claims that form a claims spectrum: "true" product-by-process claims (where the product is described primarily by process terms), product claims with a process limitation, and product claims with a structural limitation. *Id.* at 4-11.

<sup>87</sup> *Atlantic*, 974 F.2d at 1284.

<sup>88</sup> *Id.* at 1281. "Atlantic was estopped by the prosecution history from taking the position that these claims are free of process limitations, for Atlantic had argued to the examiner that these claims were patentable solely because the process had been examined and found patentable." *Id.* at 1282 (emphasis added). See *supra* note 39 for a discussion of prosecution history estoppel.

Judge Rader responded to this argument in his concurrence to the denial of rehearing. He stated that Atlantic did not limit its claim to a process; they had, in fact, claimed the product. *Atlantic*, 974 F.2d at 1301. Furthermore, he stated, the prosecution history did not show that Atlantic limited itself to claiming the process. *Id.*

<sup>89</sup> 974 F.2d at 1301.

<sup>90</sup> *Id.* at 1282.

<sup>91</sup> "The stretch of the Atlantic panel to reach out for the *Scripps* decision is unnecessary in law, as well as incorrect in practice." *Id.* at 1283.

the specification, the prosecution history, and the prior art."<sup>92</sup>

While her review of the CCPA was comprehensive,<sup>93</sup> Judge Newman failed to cite the broader language contained in *In re Hughes*.<sup>94</sup> In *Hughes*, the CCPA suggested that a product still could be claimed by reference to the process used to make it even if it was possible to claim the product without such reference.<sup>95</sup> Judge Newman instead emphasized the propriety of claiming the product by way of the process only when necessity required it.<sup>96</sup> In effect, while arguing for the validity of product-by-process claims, she limited their use to cases which could prove the need for their use. After examining nearly all relevant precedent concerning product-by-process patents (excluding the important language in *Hughes*), Judge Newman stated: "The *Painter* [necessity] rule is a practical solution to an important problem, whereby law and practice are adapted to complex products in order to implement the purposes of the patent law. This rule continues to serve the purposes of the law."<sup>97</sup>

### III. WHICH IS THE PRECEDENT THAT BINDS?

The net result of the profusion of opinions in *Atlantic* is confusion in the lower courts as to which precedent is controlling. While the most recent precedent normally is considered binding, the *Atlantic* panel's undermining of the *Scripps* decision is far from the typical technique employed to modify earlier precedent. Rather than factually distinguishing *Scripps*, or defining a new rule that could apply either to *Scripps* or *Atlantic*,<sup>98</sup> Judge Rader instead chose to ignore *Scripps* altogether. He justified this treatment by a footnote citation to an Elev-

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<sup>92</sup> *Id.* at 1284.

<sup>93</sup> Judge Newman surveyed the CCPA cases that laid the groundwork for the acceptance of "true" product-by-process patents. *Id.* at 1285-89; see *supra* notes 41-50 and accompanying text.

<sup>94</sup> 496 F.2d 1216, 1218 (C.C.P.A. 1974); see *supra* text accompanying note 49-50.

<sup>95</sup> See *supra* notes 49-50 and accompanying text.

<sup>96</sup> *Atlantic*, 974 F.2d at 1288.

<sup>97</sup> *Id.*

<sup>98</sup> See *Planned Parenthood v. Casey*, 112 S. Ct. 2791, 2808-16 (1992) (Justice O'Connor discusses the importance of stare decisis and what situations justify a departure from precedent).



enth Circuit juvenile incarceration case, *Tucker v. Phyfer*,<sup>99</sup> which held that a panel is not bound by a prior panel's decision if it determines that the prior panel would have reached a different conclusion had it considered controlling precedent.<sup>100</sup>

This unusual maneuver prompted an outcry from the dissenters to the denial of the rehearing in *Atlantic*. Judge Rich cited two internal Federal Circuit rules which he claimed preserved the precedential value of *Scripps*. First he noted that "no precedent can be disregarded or overruled save by an *in banc* court."<sup>101</sup> The judge also asserted that "where there are two *conflicting* precedents, the *earlier* precedent controls."<sup>102</sup> Thus, the conflicting precedent and conflicting opinions on its value leave lower courts without guidance as to which decision to follow.<sup>103</sup>

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<sup>99</sup> 819 F.2d 1030, 1035 n.7 (11th Cir. 1987).

<sup>100</sup> *Atlantic*, 970 F.2d at 839 n.2. In *Tucker*, however, the panel noted that the prior panel failed to consider two specific Supreme Court cases that would have required the same conclusion reached by the *Tucker* panel. Conversely, in *Atlantic* the allegedly ignored Supreme Court precedent by no means requires a different ruling from that found in *Scripps*, nor is there proof that the *Scripps* panel did not consider the Supreme Court precedent. In fact, the district court in *Scripps* forcefully argued that a product-by-process claim is limited to the process based on precedent from the Supreme Court (*Cochrane v. BASF*) and two circuit courts. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1386-87 (N.D. Cal. 1987). Thus, the *Scripps* panel did not fail to consider the Supreme Court cases. To suggest that the situation in *Scripps* was like that in *Tucker* is, at best, disingenuous.

<sup>101</sup> *Atlantic*, 974 F.2d at 1281 (Rich, J., dissenting from denial of rehearing *en banc*).

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

<sup>103</sup> The only lower court to elect between the precedent followed the *Atlantic* panel. See *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7 (D. Mass. 1993). Following the pattern established in *Scripps* and *Atlantic*, Tropix brought suit against Lumigen claiming infringement of its patent for a purified chemiluminescent, water-soluble derivative. Lumigen produced the derivative by a different process than the process described in the Tropix claim. Tropix, relying on *Scripps*, claimed that its patent was infringed whenever the derivative product was manufactured, regardless of the process. *Id.* at 7. Lumigen, on the other hand, placed its faith in the *Atlantic* decision, which would not find infringement where the defendant manufactured the same product by a different process. *Id.* at 8.

The district court resolved the conflict based upon its prediction of the precedential effect that the Federal Circuit will give to each of the cases. *Id.* The court pronounced that it did not find any prior authority for the propositions set forth by the *Scripps* decision and thus concluded that even on the confused state of the record, a majority of the judges on the Federal Circuit would rule that *Atlantic* states the controlling law. *Id.* The district court failed to discuss the mer-

The majority may have anticipated the confusion which would develop surrounding its interpretation of Supreme Court precedent. Judge Rader's majority opinion addressed this issue in a footnote where he stated that the conclusion of the *Scripps* panel could be examined anew because it had failed to consider Supreme Court precedent.<sup>104</sup> Accordingly, Judge Rader devoted the bulk of his opinion to reviewing Supreme Court cases in which products were claimed by using process terms.

In response to Judge Rader's challenge, Judge Newman's dissent focused in part on distinguishing the Supreme Court precedent that she had "overlooked" in *Scripps*. In short, she claimed that the Supreme Court never had considered a product-by-process claim for a new product akin to that found in *Scripps*; therefore, any discussion related to product-by-process claims in the Supreme Court cases cited by Judge Rader was dicta.<sup>105</sup>

Initially, Judge Rader's view of Supreme Court precedent is persuasive insofar as much of the language of the cases supports his position. A closer examination of the precedent, however, reveals that Judge Newman's view of the cases is closer to their true import. The first set of cases considered by both Judges Rader and Newman dated from 1876 and involved a patent granted for false teeth with a rubber base. Judge Rader borrowed the Court's language from two earlier decisions—the *Goodyear* decisions—to support his claim that a product-by-process patent would be infringed only if the same process were used to produce the allegedly infringing product. This rationale is flawed, however, because unlike *Scripps*, the *Goodyear* cases did not involve a new product.

In *Smith v. Goodyear Dental Vulcanite Co.*,<sup>106</sup> Smith challenged the validity of a patent claiming a "plate of hard

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its of the arguments presented in both *Scripps* and *Atlantic*, instead basing its decision on the votes to rehear *Atlantic*.

<sup>104</sup> See *Atlantic*, 970 F.2d at 838-39 n.2. Most of the Supreme Court precedent at issue in *Atlantic* dates to the late nineteenth century. Although early Supreme Court precedent rarely plays a significant role in most areas of the law, in patent law it often is important due to a lack of modern precedent. See Harold C. Wegner, *Equitable Equivalents: Weighing the Equities to Determine Patent Infringement in Biotechnology and Other Emerging Technologies*, 18 RUTGERS COMPUTER & TECH. L.J. 1, 24-25 (1992).

<sup>105</sup> *Atlantic*, 974 F.2d at 1289.

<sup>106</sup> 93 U.S. 486 (1876).

rubber, or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described."<sup>107</sup> The false teeth in *Smith* were given patent protection because the introduction of the rubber component was novel, even though false teeth had existed before the Goodyear patent was issued. Although false teeth previously had existed in a different form, the Supreme Court held that the process and the product of that process both exhibited the requisite novelty to support a patent.<sup>108</sup>

Four years later, the court in *Goodyear Dental Vulcanite Co. v. Davis*<sup>109</sup> was required to limit the patent protection to the process and the resulting product. In *Davis*, the defendant had manufactured its false teeth with celluloid instead of rubber. As the process was different, the Court held that there was no infringement of the Goodyear patent.<sup>110</sup> The Court

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<sup>107</sup> *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493 (1876). In *Smith*, the Court interpreted the phrase "substantially as described" to mean "formed as described." *Id.* Therefore, as the process was not included as an independent claim, the process as described in the specification was incorporated into the claim. "The claim refers in terms to the antecedent description, without which it cannot be understood. The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed." *Id.*

<sup>108</sup> The Court, however, was explicit in limiting the patent protection to just the process and the product it produces:

[t]he invention, then, is a product or manufacture made in a defined manner. It is not a product alone separated from the process by which it is created. The claim refers in terms to the antecedent description [of the process], without which it cannot be understood. The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed.

*Id.* at 493. Because false teeth existed in the prior art, the Court was constrained to granting protection only for the process and the product made by that process.

<sup>109</sup> 102 U.S. 222 (1880). In *Davis*, Goodyear claimed that Davis infringed the patent it had gained in *Smith v. Goodyear Dental Vulcanite Co.* Davis manufactured artificial teeth by a process that used celluloid rather than rubber as the material in which the teeth were embedded. In addition, the process Davis used to embed teeth into the base material was different. Rather than starting with a soft material such as rubber, which hardened with the application of heat, Davis started with celluloid, a hard material that was heated to allow the teeth to be inserted into it and then allowed to harden as it cooled.

<sup>110</sup> The *Goodyear* cases illustrate the problem that arises when text is divorced from context. While the Court seemed to grant a product patent in *Smith*, it recognized in an infringement context that the initial product was not new. The product had existed in the prior art, although not made of a rubber material. The correct construction of the patent therefore was to limit the scope of the patent to the process and the product of that process. In fact, in *Smith*, the Court determined that "[t]he invention, then is a product or manufacture made in a defined

narrowed the patent's scope to the process and the product made by the process by reading Goodyear's process of manufacturing the dental plate as a limitation on the claim<sup>111</sup> and stating that

when a product arrived at by certain defined stages or processes is patented, only those things can be considered equivalents for the elements of the manufacture which perform the same way. The same result may be reached by different processes, each of them patentable, and one process is not infringed by the use of any number of its stages less than all of them.<sup>112</sup>

Therefore, as Davis' celluloid process did not involve vulcanization, the Court did not find an infringement of Goodyear's patent.

The next case considered by Judges Rader and Newman was *Merrill v. Yeomans*.<sup>113</sup> Judge Rader used *Merrill* to illustrate a pattern of strict claim interpretation in Supreme Court precedent. In *Merrill*, the Court looked at the entire claim to interpret the scope of a patent involving a deodorized oil that Merrill claimed Yeomans had infringed. The patentee described the process in minute detail in the specification and described the product by referring to the process: "I claim the above-described new *manufacture* of the deodorized heavy hydrocarbon oils, . . . by treating them substantially as is hereinbefore described."<sup>114</sup> After examining the construction of the entire claim, the Court interpreted "manufacture" to refer to the process, not the product, and therefore found that the claim protected the process only.<sup>115</sup> On this basis, Judge

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manner. It is not a product alone separated from the process by which it is created." 93 U.S. at 493.

<sup>111</sup> "The material is, so far as possible, restricted to a substance either vulcanized or capable of vulcanization." *Davis*, 102 U.S. at 226.

<sup>112</sup> *Id.* at 230.

<sup>113</sup> 94 U.S. 568 (1876).

<sup>114</sup> *Id.* at 571 (emphasis added).

<sup>115</sup> *Id.* at 571. This case stands for the proposition that the claim will be interpreted strictly according to its content in order to protect the public. According to the *Merrill* Court,

[t]he growth of the patent system in the last quarter of a century in this country has reached a stage in its progress where the variety and magnitude of the interests involved require accuracy, precision, and care in the preparation of all the papers on which the patent is founded. . . . The developed and improved condition of the patent law, and of the principles which govern the exclusive rights conferred by it, leave no excuse for

Rader claimed that *Merrill* supported the limitation of product-by-process patent protection to the process. In response, Judge Newman asserted that the *Atlantic* panel had misapplied *Merrill*. Judge Newman instead interpreted *Merrill* as holding that since the deodorized oil had been an old product, the patent protection was limited to the process.<sup>116</sup>

The language of *Merrill*, however, does not support either argument. Nowhere in its decision does the *Merrill* Court describe the product as old. In addition, the Court did not hold that the word "manufacture" necessarily limited the patent to the process. Rather, *Merrill* was decided, as the Court stated, "solely upon a correct construction of the plaintiff's patent, and the accompanying specifications."<sup>117</sup>

Regardless of the spin each judge placed on the *Merrill* decision, the *Merrill* Court did not foreclose the possibility that a new, properly claimed product, patented by a product-by-process claim, could be infringed if someone were to produce the product by a different process. The *Merrill* Court stated that if the patent claimed "was for a new oil, . . . the defendants may be liable [as infringers]."<sup>118</sup> Alternatively, if the patent claimed only the process, the defendants would not infringe because they did not use the claimed process. The Court therefore had found that the patent did not claim the product, but instead claimed the process used to manufacture the product so that determining the scope of a new product was unnecessary. It is unclear, however, whether the Court would have concluded that the defendant had infringed if the term "manufacture" had been interpreted to mean the product.

The next disputed precedent, *Cochrane v. BASF*, presented the Supreme Court with a case that seemingly tested the limits of product-by-process claims.<sup>119</sup> As in *Merrill* and *Good-*

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ambiguous language or vague descriptions. The public should not be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights. The genius of the inventor . . . should not be restrained by vague and indefinite descriptions of claims in existing patents . . . .

*Id.* at 573.

<sup>116</sup> *Atlantic Thermoplastics Co. v. Faytex Co.*, 974 F.2d 1279, 1289-90 (Fed. Cir. 1992).

<sup>117</sup> *Merrill*, 94 U.S. at 569.

<sup>118</sup> *Id.* at 568 (emphasis added).

<sup>119</sup> 111 U.S. 293 (1884).

year, the patentee in *BASF* had described the process used to make its product and had relegated the product description to merely a paragraph. The product claim added one twist, however. It claimed a dye "produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result."<sup>120</sup> *BASF* argued that by specifying the dye as they had, the claim covered the dye, regardless of the process used to manufacture it. Nevertheless, the Court once again found the patent protection limited to the process and the product made by that process.<sup>121</sup>

Given the factual situation, the *BASF* Court took a complicated approach to a simple question. The Court unnecessarily used language which, when read literally, restricts the scope of product-by-process claims to the process.<sup>122</sup> A close examination of the case, however, reveals that the language is dicta.<sup>123</sup> *BASF* explicitly claimed an entire product, a dye, although the claim only cited a process used to make the product.<sup>124</sup> The Supreme Court held that the defendant was not guilty of infringement unless the plaintiff could show that the defendant had used the same process cited in the plaintiff's claim.<sup>125</sup>

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<sup>120</sup> *Id.* at 296 (emphasis added).

<sup>121</sup> *Id.* at 311. In *BASF*, the defendant, Cochrane, produced the dye by a sulfuric reaction process rather than by the bromine reaction process used by *BASF*. Although the *BASF* claim explicitly claimed the product, the Court focused on the ramifications of allowing a patentee to claim a product while only referring to the process used to make it. The Court stated that there was no way for a court to determine if another process would produce the exact same product. Therefore, the Court found that "unless it is shown that the [patented] process . . . 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 [patented] process." *Id.* at 310.

<sup>122</sup> "Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process." *Id.* at 310.

<sup>123</sup> See Mirabel, *supra* note 86, at 36-38 ("an examination of the facts [of *BASF*] shows that the statement made by the court made sense in the light of those facts, but should probably be limited accordingly").

<sup>124</sup> The claim specified a dye "produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." *BASF*, 111 U.S. at 296 (emphasis added).

<sup>125</sup> *Id.* at 310. Underlying the Court's holding was its concern that *BASF*'s method of claiming the dye would grant an overly broad monopoly on a product which did not exist in a singular form. *Id.*

Judge Rader seized upon this part of the holding and construed it as a rule to be applied in questions of infringement regardless of the factual situation.<sup>126</sup> Judge Rader recognized, however, that an alternative view of the case could be formulated based on the fact that BASF's original patent did not pertain to the product because the dye had existed in the prior art.<sup>127</sup> Thus, the most BASF could have asserted was protection for a new process. Since the defendant used a different process to manufacture the dye, it could not have infringed on BASF's patent.

Judge Rader submitted that which view is to be applied depends upon whether the question at hand is infringement or patentability.<sup>128</sup> Judge Rader suggested that courts focus on the process when deciding product-by-process infringement issues and on the product when deciding product-by-process patentability issues.<sup>129</sup> These rules do not follow from *BASF* and indicate that Judge Rader misinterpreted both "views" of the case.<sup>130</sup> The *BASF* Court, after a long discussion about whether there had been infringement, merely appreciated that a much simpler solution existed: if the original patent did not protect the product, and the process the defendant had used was different, infringement was not possible.<sup>131</sup>

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<sup>126</sup> *Atlantic*, 970 F.2d at 841.

<sup>127</sup> *BASF*, 111 U.S. at 464-65.

<sup>128</sup> *Atlantic*, 970 F.2d at 841. Judge Rader stated:

Thus, in *BASF*, the Supreme Court addressed both infringement and validity . . . of product claims containing process limitations. In judging infringement, the Court treated the process terms as limitations on the patentee's exclusive rights. In assessing validity in terms of patentability, the Court forbade an applicant from claiming an old product by merely adding a new process. The infringement rule focused on the process as a limitation; the other rule focused on the product with less regard for the process limits.

*Id.*

<sup>129</sup> *Id.*

<sup>130</sup> See Kenneth R. Adamo, *The Double Standard: In re Bond, the Office*, 35 U.S.C. § 112, 6 and *Atlantic Thermoplastics Co.*, 2 FED. CIR. B.J. 137 (1992) ("BASF is hardly clear precedent for anything about a proper product-by-process claim. . . . [T]he court's conclusion that *BASF* was the proper progenitor of a product-by-process claim double standard, appears to be bootstrapping").

<sup>131</sup> The first step in an infringement suit in any type of patent claim is to determine the scope of the original patent. If while determining the scope, the court finds that the product existed in the prior art, the court must limit the patent scope to the process (provided it is novel). Hence, as Rader would have it, the focus is on the product. If the product is old, as was the case in *BASF*, the

Judge Rader next considered product-by-process claims in *Plummer v. Sargent*,<sup>132</sup> an infringement case with facts similar to those in *Atlantic*. *Plummer* involved a patent for a process that, when applied to iron, caused the iron to mimic the appearance of bronze.<sup>133</sup> The process claimed by *Plummer* consisted of covering iron with a very thin coating of linseed oil, and subjecting it to heat, resulting in the oil becoming bonded as a varnish on the iron.<sup>134</sup> *Sargent's* process differed slightly from *Plummer's*: *Sargent* heated the iron prior to applying the oil and then heated it to a higher temperature.<sup>135</sup> Thus, as in *Atlantic*, each party performed essentially the same steps but in a different order.<sup>136</sup> After reviewing the prior art and the descriptions of both patents, the Court stated:

[I]t may be assumed that the new article of manufacture . . . is a product which results from the use of the process described in the patent, and not one which may be produced in any other way. So that, whatever likeness may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process.<sup>137</sup>

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court next determines whether the processes are different. If the processes are different, there is no infringement. See *Mirabel*, *supra* note 86, at 36-38 (examining what constitutes infringement of a product-by-process claim and concluding that the accepted rule—product-by-process claims can only be infringed by a process—is built on dicta). Had the court found the patent to be valid for the product, the focus logically should have been on the product to attempt to discern if there were differences.

<sup>132</sup> 120 U.S. 442 (1887).

<sup>133</sup> *Id.* at 443. Soon thereafter, *Plummer* gained additional coverage for the product made by that process in a reissue. *Id.* at 445. The claim provided as follows: "What I claim and desire to secure by letters patent is the new manufacture hereinabove described, consisting of oil and heat, substantially as described." *Id.*

A reissue is a method of correcting errors which were made without deceptive intent that caused a patent to be wholly or partially inoperative or invalid by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he has a right to claim. 35 U.S.C. § 251. See generally 4 CHISUM, *supra* note 5, § 15.01.

<sup>134</sup> *Plummer*, 120 U.S. at 444-45.

<sup>135</sup> *Id.* at 445.

<sup>136</sup> *Atlantic's* process involved placing a *solid* elastomeric material in the heel section of an innersole and introducing polyurethane foam around it to form the remainder of the heel. *Atlantic*, 970 F.2d at 835 (emphasis added). By contrast, the Sorbathane innersoles, distributed by Faytex, were produced by injecting a *liquid* elastomeric material into the innersole mold, and injecting the surrounding polyurethane while this material was solidifying. *Id.* at 836.

<sup>137</sup> *Plummer*, 120 U.S. at 448.



The *Plummer* Court thus held that there was no infringement as the processes were different.

Judge Rader derived from *Plummer* the rule that a product-by-process claim is not infringed if the defendant's process differs from the patentee's.<sup>138</sup> Judge Rader, however, ignored that the *Plummer* Court explicitly had limited the patentee's claim because the process patented by *Plummer* was substantially identical to a prior art process.<sup>139</sup> In an attempt to uphold a patent which never should have been granted, the Supreme Court gave the patent the thinnest of protections, restricting infringement to products made exactly as the patentee described.

The last Supreme Court precedent cited by Judge Rader, *General Electric Co. v. Wabash Appliance Corp.*,<sup>140</sup> involved a patent held by GE for a tungsten filament used in incandescent lamps that included product and process claims.<sup>141</sup> GE sued Wabash for infringing its patent. In its defense, Wabash contended that GE's patent was invalid. The Supreme Court held that GE's patent was invalid on its face because "it fail[ed] to make a disclosure sufficiently definite to satisfy the requirements of [35 U.S.C. § 112]."<sup>142</sup> The Court then speculated as to what would occur if a patent such as GE's were definite enough to satisfy the statutory requirements of disclosure. According to the Court:

Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by ref-

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<sup>138</sup> *Atlantic*, 970 F.2d at 842.

<sup>139</sup> The *Plummer* Court found:

It seems necessary to follow from this view either that the Tucker patents are void by reason of the anticipation practiced by [another in the prior art], or that the patented process and the product must be restricted to exactly what is described. . . . To that extent the patents may be sustained, but upon that construction they do not include the process and product of the defendants; there is consequently no infringement.

*Plummer*, 120 U.S. at 449. For an analysis of *Plummer* and related cases, see Mirabel, *supra* note 86, at 41-44.

<sup>140</sup> 304 U.S. 364 (1938).

<sup>141</sup> The claim in question in *Wabash* reads: "A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting . . . ." *Id.* at 368.

<sup>142</sup> *Id.*

erence, express or constructive, to the process by which he produced it, cannot secure a monopoly by whatever means produced.<sup>143</sup>

The Court then relied upon *Cochrane v. BASF* to emphasize that "[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process."<sup>144</sup> Thus, the Court clearly stated that a product-by-process claim's scope would not protect the patentee against another making the product by a different method.

In response, Judge Newman noted that while *Wabash* provides language helpful to Judge Rader's argument, the case itself did not involve a product-by-process claim. Rather, it was concerned with whether the patentee adequately had described a product in a product claim under the previous patent statute.<sup>145</sup> The Court held the claim invalid on its face because it failed to make a sufficiently definite statement of the characteristics of the product.<sup>146</sup> Thus, although the Court discussed product-by-process claims, it did so unnecessarily.<sup>147</sup>

Judge Newman used the Supreme Court decisions to highlight her approach to *Scripps*. She emphasized in her dissenting opinion that "claims are interpreted in accordance with the nature of the claimed invention, as elucidated by the specification, the prior art, and the prosecution history."<sup>148</sup> As she surveyed the Supreme Court precedent, Judge Newman distinguished four of the five Supreme Court cases relied upon by

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<sup>143</sup> *Id.* at 373 (footnote omitted).

<sup>144</sup> *Id.* at 373-74 (quoting *Cochrane v. BASF*, 111 U.S. 293, 310 (1884)).

<sup>145</sup> See *supra* notes 27-33 and accompanying text.

<sup>146</sup> The claim for a tungsten filament described the product as a "filament . . . composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life." *Wabash*, 304 U.S. at 368.

<sup>147</sup> See Mirabel, *supra* note 86, at 36 ("That the *Wabash* proposition is dictum is clear"). Mirabel analyzes the dicta in *Wabash*, which stated that product-by-process claims cannot be infringed unless one uses the same process, by examining the precedent upon which the *Wabash* Court relied. Mirabel, *supra* note 86, at 35-43. He concludes that none of the precedent cited in *Wabash* supports its broad conclusion. Mirabel, *supra* note 86, at 40. But see J.S. Saxe & J.S. Levitt, *Product-By-Process Claims and their Current Status in Chemical Patent Office Practice*, 42 J. PAT. OFF. SOC'Y 528, 530 (1960) (concluding that "the courts uniformly hold that only a product produced by the claim-designated process may be held to infringe [a product-by-process] claim").

<sup>148</sup> *Atlantic*, 974 F.2d at 1289.

Judge Rader by noting that the patentee in each of those cases had attempted to use a product-by-process claim to patent an old product.<sup>149</sup> Therefore, regardless of the method used to patent those products, the maximum patent protection available to the patentee was the scope argued by Judge Rader—protection of the process and the product made from that process. The fifth case, *BASF*, had not involved a product-by-process patent, and thus any references to product-by-process patents were dicta.

The Supreme Court precedent gathered by Judge Rader does not support the proposition that the Court intended to limit a product-by-process claim's scope to the process and the product made by that process. Instead, as Judge Newman states, the *Atlantic* decision is "a collection of dicta lifted out of context, until a new structure has been built on the most tenuous of supports."<sup>150</sup> Because *Atlantic* rests on such tenuous reasoning, it is important to explore the underlying principals and policies that courts are likely to evaluate when faced with a *Scripps*-like case in the future.

#### IV. POLICY CONSIDERATIONS

Although lower courts often find it comforting to rest their decisions on "binding" precedent, seldom does precedent alone decide a case. Courts generally weigh prior precedent against public policy considerations.<sup>151</sup> Cases such as *Scripps* and *Atlantic* implicate many such concerns. For example, certainty to third parties concerning the scope of claimed inventions is important for people wishing to avoid infringement. Furthermore, bright-line rules for product-by-process claims facilitate courts' decisions in this area. Finally, certainty in the law must be balanced with the need to provide incentives for inventors to disclose information and the inequity of limiting claims that satisfy statutory requirements.

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<sup>149</sup> *Id.* at 1289-92.

<sup>150</sup> *Id.* at 1297. See Michael J. Schutte, Note, *Controversy in the Federal Circuit Over Product-By-Process Claims*, 19 U. DAYTON L. REV. 283, 307 (1993) ("The precedent relied upon by the *Atlantic* majority does not stand for a singular rule that applies to all product-by-process claims.").

<sup>151</sup> Both Judge Newman and Judge Rader acknowledged the importance of policy in their opinions. See *Atlantic*, 974 F.2d at 1282, 1303.

### A. *Third Party Certainty*

The foremost concern of the patent system is to clearly define the scope of patents so that people may avoid actions that infringe. Judge Rader argues that, because a product-by-process claim refers only to the process, it necessarily creates a greater chance of others infringing it. Admittedly, a product-by-process claim burdens the public with determining what the product of the process is. If another person arrives at the product by a different process, that person may not realize that the products are substantially similar.

This problem is not unique to product-by-process claims, however; it occurs in conventional product patents as well.<sup>152</sup> Manufacturers often are unsure as to whether a proposed product will infringe a patented product. As a result, clients seek the advice of attorneys, and at times court proceedings are the only method of determining infringement. All patent claims contain a degree of uncertainty. The uncertainty caused by product-by-process claims does not merit holding an inventor to a higher standard of definition.

Furthermore, courts and the PTO have created mechanisms for alleviating some of this uncertainty. As part of its initial review during patent prosecution, the PTO insures that every patent issued satisfies the statutory requirements and that the claim adequately describes the invention.<sup>153</sup> Moreover, the Federal Circuit, by ruling that claim construction is a question of law,<sup>154</sup> has provided an additional check on the PTO's determination by conducting a *de novo* review during

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<sup>152</sup> In fact, individuals attempting to invent around an existing patent of any type "not only must deal with the precise language of existing patent claims, but also must evaluate the penumbra created by the possibility of equitable infringement." Wegner, *supra* note 104, at 30. Thus, the uncertainty produced by product-by-process claims is not unique. It exists in all patents to some degree.

<sup>153</sup> The test for adequacy is whether one of ordinary skill in the art would understand, in light of the specification, what the inventor claims. 35 U.S.C. § 103; *Ryko Mfg. v. Nu-Star, Inc.*, 950 F.2d 714, 716 (Fed. Cir. 1991); *Orthokinetics, Inc. v. Safety Travel Chairs*, 806 F.2d 1565 (Fed. Cir. 1986); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540 (Fed. Cir. 1984); *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976). See *supra* notes 21-33 and accompanying text for a review of how a patent is obtained.

<sup>154</sup> *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1577 (Fed. Cir. 1993), *cert. denied*, 114 S. Ct. 1540 (1994); *Senmed, Inc. v. Richard-Allan Med. Indus.*, 888 F.2d 815, 818 (Fed. Cir. 1989).

infringement proceedings. This extra audit makes it even less likely that an unclear claim will confuse the true limits of the patent.

Judge Rader exaggerated the danger presented by unclear product-by-process patent claims. He bases his explanation of why the PTO focused on the product (rather than the process) during a determination of patentability on what he viewed as the difficulty with providing a third party with sufficient notice. Judge Rader recognized that during the examination of a patent's validity ambiguous products present PTO examiners with the same problems faced by third parties. The increased numbers of product-by-process claims place an enormous administrative burden on the PTO, who often "lack facilities to replicate processes and compare the resultant product with prior art."<sup>155</sup> This difficulty, in Judge Rader's view, leads the PTO to assess patentability by concentrating on the product rather than the process, thereby preventing an applicant from "obtaining exclusive rights to an old product by merely claiming a new process."<sup>156</sup>

This proposition is the primary weakness of Judge Rader's argument. Because he could not deny that the PTO, with the CCPA's blessing, always has examined the product in a product-by-process claim for the requisite showing of novelty, usefulness and nonobviousness, Judge Rader rationalized the procedure by arguing that the PTO examines the product to prevent the patentee from obtaining rights to an old product. According to Judge Rader, the only benefits gained by the patentee from a product-by-process claim are the "protections against infringement 'if the machine or process was used in another country and the product imported.'"<sup>157</sup> Thus, Judge Rader asserted that the PTO begins examining the product of product-by-process claims only after it has perceived that a patentee could misappropriate an old product.

When the PTO begins to scrutinize the product during

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<sup>155</sup> *Atlantic*, 970 F.2d at 844; see also *In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972) (the PTO is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons).

<sup>156</sup> *Atlantic*, 970 F.2d at 844-45.

<sup>157</sup> *Id.* at 844 (quoting *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274, 279 (2d Cir. 1935) (Hand, J.)).

product-by-process claim prosecutions, however, this added protection against foreign importation of infringing products is not considered an issue. Indeed, Judge Learned Hand foresaw the protection as potentially beneficial, but was not sure that the PTO granted patents in such a form.<sup>158</sup> In *Buono v. Yankee Maid Dress Corp.*, which involved an infringement suit for a type of blind stitch produced by a sewing machine, Judge Hand held that because the patent was for a product and “not for the product of a machine,”<sup>159</sup> the product must be of the requisite novelty. Judge Hand found that the stitch claimed was not new, and concluded that the patent was invalid and therefore could not be infringed.<sup>160</sup> During the explanation of his findings, Judge Hand considered limiting a product-by-process patent—as Judge Rader later would suggest—but found that

[a]t any rate a product patent not so limited . . . must be new as such, that is, regardless of the process or machine which makes it; and it must stand upon its own invention, again independently of the machine or process which makes it.<sup>161</sup>

Thus, Judge Hand examined the product of the product-by-process claim because that is what the patentee had claimed. A patentee would not endure the burden of proving that the product satisfied the requirements of the patent law if there was no benefit to doing so. As the court did in *Buono*, the PTO similarly focuses on the product not to prevent claims for old products but because the applicant has sought protection for the product regardless of the process.

In fairness to Judge Rader, however, a patentee's desire to claim the product using a product-by-process claim does not eliminate the PTO's problem of ensuring that the product is new in comparison with the prior art. The Federal Circuit developed an administrative technique to address this problem because the PTO cannot be expected to manufacture and compare products in the patent application process with products

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<sup>158</sup> “[I]t is hard to find instances [of product-by-process patents only infringed by the product of a machine or of a process], probably because the Patent Office does not grant product patents in that form.” *Buono*, 77 F.2d at 279.

<sup>159</sup> *Id.*

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

<sup>161</sup> *Id.*

in the prior art. The PTO need only establish a *prima facie* showing that a product is obvious in view of the prior art. A *prima facie* case of obviousness is established when the teachings from the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art.<sup>162</sup> At that point the burden of proof shifts to the applicant to rebut the *prima facie* case by presenting evidence that the prior art does not anticipate the claimed invention.<sup>163</sup>

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<sup>162</sup> See *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (finding that examiner did not establish *prima facie* case of obviousness in claim for an amino acid sequence where the gene and its encoded protein were in the prior art); *In re Thorpe*, 777 F.2d 695, 697-98 (Fed. Cir. 1985) (after the examiner noted the similarities between the product in the prior art and the applicant's product, the burden shifted to the applicant "to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"); *In re Marosi*, 710 F.2d 799 (Fed. Cir. 1983) (court upheld rejection of product-by-process claims because appellants had not produced evidence which showed the unobvious difference between the claimed product and the prior art); *In re Fessmann*, 489 F.2d 742 (C.C.P.A. 1974). In *Fessmann*, the court described the procedure first articulated in *In re Brown*, 459 F.2d 531 (C.C.P.A. 1972), to support its reasoning:

[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the *product* claimed and *not* of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.

*Fessmann*, 489 F.2d at 744 (quoting *Brown*, 459 F.2d at 535). The court found that the applicant did not meet his burden for patentability because he failed to show that his product possessed unobvious differences from the prior art. See also *Mirabel*, *supra* note 86, at 16 ("The practical effect of [*Brown*] is that if the claimed product and the prior art product appear *similar* following a perusal of the application and the prior art, a *prima facie* case is established and the claim will be rejected.").

<sup>163</sup> *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990); *In re Wright*, 848 F.2d 1216 (Fed. Cir. 1988). *Dillon* provides an example of how this procedural tool works in practice. In *Dillon*, the applicant claimed hydrocarbon fuel/*tetra*-orthoester compositions and related methods of use, which exhibited the unexpected property of reducing particulate emissions during combustion. The PTO rejected the claim for obviousness because prior art references disclosed that: 1) hydrocarbon fuel/*tri*-orthoester compositions also reduced particulate emissions; and 2) *tri*- and *tetra*-orthoesters reacted similarly under related conditions. The PTO found that the prior art supported *prima facie* obviousness and that the applicant failed to provide evidence rebutting obviousness, such as evidence that showed some unexpected superiority of the claimed *tetra*-orthoester compositions in comparison with the *tri*-orthoester compositions.

The Federal Circuit affirmed the PTO decision, finding that

*Atlantic* provides an example of this procedure's usefulness. Faytex distributed innersoles that were produced by a process with steps different from Atlantic's process.<sup>164</sup> In an infringement case, the Federal Circuit found no clear error in the district court's holding that the processes were substantially different.<sup>165</sup> Had Faytex claimed its innersole product in the form of a product-by-process claim after the Atlantic innersole already had been manufactured (before the PTO could grant a patent), the examiner would have been required to determine whether Faytex's innersole was nonobvious. The PTO would have been confronted with seemingly identical products with no way of discerning their differences.

The PTO would have to establish only a *prima facie* case of obviousness and could do so simply by pointing out the similarities between the two products to shift the burden to Faytex. Faytex would carry the heavy burden of showing that the different process created a substantially different product. Thus, the PTO is not required to manufacture a product in order to make comparisons for questions of patentability, but need establish only some similarity between the claimed and prior art subject matter. The PTO accomplishes this by combining references where the prior art gives reason or motivation to make the claimed compositions.<sup>166</sup> The PTO's application procedures, thus, already deter patent applicants from attempting to patent old products by using a product-by-process claim.

Despite these protections, application of Judge Rader's rule remains significant in patent validity proceedings. When

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structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case. Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have . . . .

919 F.2d at 692-93. Thus, the PTO's burden of comparison is diminished by this procedural tool. If faced with a product-by-process claim that may be taught by the prior art, the PTO need only point to the similarities between the claimed composition and the prior art and wait for the applicant to rebut the *prima facie* showing.

<sup>164</sup> *Atlantic*, 970 F.2d at 836.

<sup>165</sup> *Id.* at 834, 837-38.

<sup>166</sup> *Dillon*, 919 F.2d at 692-93.



confronted with an infringement action a court first must interpret the allegedly infringed patent claims. The court also must classify the claim as either a product claim, a process claim or a product-by-process claim. This classification will determine the scope of the protection granted to the patentee. A patentee with a product claim may exclude others from making, using or selling the patented product. If, however, the court construes the patentee's claim as a product-by-process claim, according to the rule in *Atlantic*, the scope of the patent is relatively limited. A product-by-process claim would only grant a monopoly on the process and the product made from that specific process.<sup>167</sup> In many cases, therefore, the initial classification of the claim determines whether a defendant has infringed.

The *Atlantic* panel's decision to limit the scope of product-by-process claims to the process and the product made by the process offers a clear-cut rule that courts may follow easily. In practice, however, it is difficult to distinguish a product-by-process claim from product claims with structural<sup>168</sup> or process limitations.<sup>169</sup> One commentator, who reviewed CCPA decisions that questioned the classification of a claim as either a product claim or a product-by-process claim, concluded:

[T]here are hazy lines separating "true" product claims from product claims which include a process limitation from "true" product-by-process claims. The determination seems to focus on the degree of specificity with which the product is defined in the absence of the process limitations. The more precise that definition, the greater the chance that the claim will be considered a "true" product claim. As the structural definition disappears there is a shift towards "product claims with a process limitation" and ultimately to the product-by-

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<sup>167</sup> *Atlantic*, 970 F.2d at 847.

<sup>168</sup> Consider, for example, the claim in *In re Steppan*, 394 F.2d 1013 (C.C.P.A. 1967). The claim read as follows: "An acid phosphate of a condensation product selected from the group consisting of [named acid phosphates] . . . the acid phosphate having the general formula  $\text{ArN}_2\text{H}_2\text{PO}_4\text{H}_3\text{PO}_4$ , in which  $\text{ArN}_2$  is . . . condensed with formaldehyde." *Id.* at 1019. One could argue that as the product itself is not described specifically, but instead is referred to as a "condensation product" or "condensed with formaldehyde," the claim describes a product in terms of the process which it must undergo, and as such is a product-by-process claim. The court, however, found that it was a product claim with structural limitations. *Id.*

<sup>169</sup> See Mirabel, *supra* note 86, at 3-11 (the difference between product-by-process claims and product claims with process limitations is extremely subtle). A process limitation describes the manner in which the product is made. *Id.* at 4.

process end of the spectrum.<sup>170</sup>

Ultimately, the degree of structural specificity in the claim will be used to define the breadth of a monopoly (regardless of whether the product otherwise satisfies the statutory requirements) because the line between product-by-process claims and product claims with process limitations is too "hazy" to be determinative.<sup>171</sup> In the final analysis, the court will decide, based on a subjective finding, whether the claim satisfies the degree of specificity required to attain product status. A claim that fails this test will be relegated to a product-by-process claim and the scope of protection granted will be reduced significantly.

### B. *The Patent Compact: Protection for Disclosure*

Courts determining patent validity also will be concerned about maintaining an incentive to pursue new inventions. The most significant right a patent grants is that of exclusivity: the right to prevent others from making, using or selling the patentee's invention.<sup>172</sup> In exchange for this grant of monopoly, the inventor must disclose his or her invention in enough detail to enable one skilled in the art to reproduce the invention without undue experimentation.<sup>173</sup> Generally, the level of disclosure determines the extent of the patent monopoly. Disclosure theory is based on the rationale that without patent protection inventors would conceal their inventions to prevent exploitation by others.<sup>174</sup> In exchange for the gains in effi-

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<sup>170</sup> Mirabel, *supra* note 86, at 10.

<sup>171</sup> As a consequence of the *Atlantic* decision, rarely will an inventor claim his invention as a product-by-process claim. More likely, the inventor will use product-by-process claims as a hedge against the court invalidating a product claim. See MPEP, *supra* note 41, at § 706.03(e). The *Manual of Patent Examining Procedure* follows the decision in *In re Hughes* in allowing the product to be patented by reference to the process:

Where an applicant's product in [sic] incapable of description by product claims which are of different scope, he is entitled to product-by-process claims that recite his novel process of manufacture as a hedge against the possibility that his broader product claims may be invalidated. *In re Hughes*, 182 U.S.P.Q. (BNA) 106 (C.C.P.A. 1974).

*Id.*

<sup>172</sup> 35 U.S.C. § 154.

<sup>173</sup> *Id.* § 112.

<sup>174</sup> Ko, *supra* note 14, at 795-96; Greenfield, *supra* note 13, at 1059.

ciency by the scientific community and the resulting benefits to society, the government uses its court system to enforce a patentee's monopoly.

Product-by-process claims, however, do not fit this theory as easily as conventional product claims. A standard product patent discloses the structure of the product, leaving little mystery as to its identity. Science builds upon the disclosed information to increase the existing level of knowledge. One commentator describes this tradeoff in patent law as "fully satisfied only when the scope of the patent grant is commensurate with the discovery, and not so broad as to stifle further advances in the state of the art."<sup>175</sup> Because a product-by-process claim only discloses the process for producing the product, science does not obtain the amount of knowledge normally gained through a product patent.

Product-by-process claims often benefit society in other potentially more meaningful ways, however. As discussed earlier, inventors frequently are driven to use product-by-process claims out of necessity when they lack the requisite knowledge to establish the level of disclosure a conventional product claim requires. The disclosure of the process is itself a great benefit to society.<sup>176</sup> For example, the method used to purify human insulin in the *Scripps* claim enabled subsequent researchers to develop a more cost-effective method of producing insulin.<sup>177</sup> Granting diminished patent rights for product-by-process claims not only discourages the release of a means of producing important medical compounds, but also discourages investment in these areas of study.<sup>178</sup>

The patent system was created to encourage innovation in science and the useful arts. Inventors who must use a product-by-process claim to patent their inventions are dedicated to a science that often cannot be described by existing language. Providing broader "conventional" product protection to product-by-process patents does not encourage fraud. On the contrary, this type of claim dissuades such behavior because it is diffi-

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<sup>175</sup> Wegner, *supra* note 104, at 31.

<sup>176</sup> See McGough & Burke, *supra* note 16, at 101 ("Public policy is advanced by broad biotechnology patent prosecutions . . .").

<sup>177</sup> See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

<sup>178</sup> See *supra* note 13 and accompanying text.

cult to prove that a particular product is the patented one. For those who have enough information about the structure of the product they wish to patent, it would be unwise to attempt to patent using a product-by-process claim as there is no guarantee that it will succeed. Nor is there a guarantee as to which approach a reviewing court will take.

*Atlantic* presents two opposing approaches to dealing with product-by-process claims. Judge Rader would limit the scope of a product-by-process claim to protect both the process and the product made by that process. Judge Newman would not limit the scope but instead would reinstate the showing of necessity prior to allowing an applicant to use a product-by-process claim. Both approaches in effect limit an inventor's options when confronting stringent patent application requirements.

Courts should not require a showing of necessity in product-by-process claims but instead should afford the two claims equally broad scopes. Judge Newman disagreed with the *Atlantic*'s definition of the scope of product-by-process claims, yet would restrict the use of product-by-process claims as well. For example, Judge Newman advocated returning to the necessity rule first defined in *Ex parte Painter*,<sup>179</sup> because she viewed it as a "practical solution to an important problem."<sup>180</sup> In other words, Judge Newman's opinion suggests that the necessity rule is an outgrowth of the application process, which requires that the claim be definite and the specification reveal the "best mode"<sup>181</sup> of carrying out the claimed invention.<sup>182</sup>

Federal Circuit precedent supports the *Painter* rule when one considers that the Federal Circuit never has explicitly overruled the necessity requirement.<sup>183</sup> Yet strong policy rea-

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<sup>179</sup> 1891 Dec. Comm'r Pat. 200; see *supra* text accompanying notes 42-43.

<sup>180</sup> *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279, 1288 (Fed. Cir. 1992).

<sup>181</sup> The best-mode requirement's purpose is to prevent an inventor from disclosing the invention while withholding from the public the preferred embodiments of the invention. See generally 2 CHISUM, *supra* note 5, § 7.05.

<sup>182</sup> 35 U.S.C. § 112.

<sup>183</sup> The court in *In re Hughes* went the farthest toward stating this proposition when it held that product-by-process claims can be made along with "conventional" product claims as a hedge against the narrower product claims' invalidation. 496 F.2d 1216, 1219 (C.C.P.A. 1974). See *supra* text accompanying notes 49-50.

The patent statutes, however, do not require an inventor to claim an inven-

sons support allowing the patentee to determine which method to use when drafting a patent claim. An inventor applying for a patent confronts an enormous task of describing the invention so that it establishes the requisite novelty, usefulness and nonobviousness, while also being definite. Inventors frequently disagree over the best approach to patenting the invention. (While the PTO rules on whether the claim is valid, it does not inform the inventor how to patent an invention.) Occasionally, the inventor decides that she cannot define a product by its structure, and instead opts for a product-by-process claim. One court recognized the importance of giving the inventor the choice of how to define her own invention:

An invention exists most importantly as a tangible structure or a series of drawings. A verbal portrayal is usually an afterthought written to satisfy the requirements of patent law. This conversion of machine to words allows for unintended idea gaps which cannot be satisfactorily filled. Often the invention is novel and words do not exist to describe it. The dictionary does not always keep abreast of the inventor. It cannot. Things are not made for the sake of words, but words for things. To overcome this lag, patent law allows the inventor to be his own lexicographer.<sup>184</sup>

To grant the inventor the freedom to formulate his patent claim, the necessity rule should not be reinstituted. The rule would force the inventor to claim in a conventional form if the PTO examiner determines that a necessity to claim by a product-by-process does not exist.

Finally, the patent application process contains enough hurdles to expose any fraudulent inventor who attempts to gain the wider scope available through a product-by-process claim that ultimately is treated as a conventional product claim. The burden of proving a product patent valid while only referring to the process is significant.<sup>185</sup> Among the hurdles

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tion by any particular method. Even more telling is the fact that the *Painter* necessity rule was not grounded in any statute, nor did it state any solid policy reason for its conclusion. The Federal Circuit should not rest its decisions on precedent that has been clearly undermined over the years, see *supra* notes 47-50 and accompanying text, and that is not supported by convincing argument.

<sup>184</sup> *Autogiro Co. v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967).

<sup>185</sup> As one commentator stated, the product-by-process claim "is disadvantageous in many respects. . . . Given [product-by-process claim's] other disadvantages . . . one would rarely want to use this format absent 'necessity.'" Mirabel, *supra* note 86, at 3, 15.

an inventor faces is the standard of definiteness and the prima facie standard, either of which the PTO may use to force the patentee to prove that the product is nonobvious.<sup>186</sup>

Judge Learned Hand recognized the difficulty of satisfying the requirements of patent prosecution in *Buono v. Yankee Maid Dress Corp.* Judge Hand suggested that since a product-by-process claim is based on the product, the scope of the patent should protect the product regardless of how it was made:

It would seem to follow that the invention in the case of such a product patent [gained by product-by-process claim] must lie exclusively in the conception of the product, and regardless of any method of its production, though of course the patent must disclose one way by which it can be made. While that imposes a severe standard, it is no severer than it should be, if the monopoly is to extend to the product however made.<sup>187</sup>

Thus, Judge Hand recognized that a new product could be claimed by a process so long as the product fulfills the statutory requirements. He based his conclusion on the "severe standard" demanded by the patent application process. If the invention attempted to be patented by a process proved not to be innovative, then the product-by-process claim would fail, and the inventor would gain a patent on a "product produced by other machines and processes, to which by hypothesis he has contributed nothing."<sup>188</sup>

Limiting a product-by-process claim's scope to only the process and the product made by the process is inequitable if the patent already has survived the PTO's heightened scrutiny. An inventor who has patented a product with a product-by-process claim has satisfied the more difficult task of convincing a PTO examiner that the product is novel, useful and non-obvious while only referring to the process used to make the product.<sup>189</sup> This accomplishment merits the monopoly granted by a product patent.

During an infringement proceeding the court should focus

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<sup>186</sup> See *supra* notes 165-69 and accompanying text.

<sup>187</sup> *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274, 279 (2d Cir. 1935).

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

<sup>189</sup> As noted earlier, the PTO has a lesser burden of proof to establish obviousness during a patentability proceeding because the PTO cannot be expected to manufacture allegedly patentable products and compare them to the prior art. *SSIH Equip. S.A. v. United States ITC*, 718 F.2d 365 (Fed. Cir. 1983).

on the patentee's burden of proving beyond a preponderance of evidence that the opposite party infringed the patented product, rather than on whether the claim is a product-by-process claim or a product claim. If the party who claimed the product in a product-by-process claim is unable to show that "more likely than not" the accused product infringes upon the patent, then the infringement suit fails. Thus, the burden of proof serves as a last check on the definiteness of the claim: the more unclear the definition of the product is, the less likely the court will find infringement.

## CONCLUSION

The Court of Appeals for the Federal Circuit was created to promote stability in the nation's patent laws. In addition, Congress devised the Federal Circuit in recognition of the fact that investors need a level of security in the law to enable sound economic decisions. To this end, the Federal Circuit developed operating procedures to permit the law to develop in a principled fashion. A majority in the Federal Circuit seems to have lost sight of that purpose while considering *Atlantic v. Faytex*. Rather than debating an important issue *en banc*, they chose to ignore past precedent and instead, building on Supreme Court dicta, drastically altered the level of protection granted to product-by-process claims.

A close examination of the result of this decision reveals that applicants who use a product-by-process claim to patent a product are burdened with the same requirements as those who patent using a conventional product claim. As such, they should be entitled to the same protection as conventional product claims. Additionally, over the years the Patent Office appropriately has developed a liberal attitude towards allowing an inventor to choose how he or she wishes to claim an invention. Requiring a showing of necessity denies this choice and mistakenly empowers the patent examiner to make decisions which may affect the scope of the patent.

Product-by-process claims fill an important gap in patent law by furnishing an inventor who cannot describe her invention in terms precise enough to gain a conventional product patent with the means to gain the same protection. This type of claim must be preserved so that inventors who push the

envelope scientifically are encouraged to disclose inventions that push the envelope linguistically.

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