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A Prescription for the Treatment of Product-by-Process Patent Infringement

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NOTES

A PRESCRIPTION FOR THE TREATMENT OF PRODUCT-BY-PROCESS PATENT INFRINGEMENT

Traditionally, products which defy description in terms of their structure have been protected by patents drawn using product-by-process claims.[1] It is recognized that the product-by-process patent affords infringement protection for the claimed product and not the process by which it was produced.[2] In two recent cases, the Court of Appeals for the Federal Circuit wrestled with the scope of the protection, specifically, whether a product patented using a product-by-process claim is to be afforded full product protection or protection limited to the product as manufactured by the process by which it was claimed.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*,[3] the Federal Circuit held that a product-by-process patent may be infringed by production of the same product using a different process.[4] In *Atlantic Thermoplastics Co. v. Faytex Corp.*,[5] however, the Federal Circuit effectively overruled *Scripps Clinic* by holding that a product claimed by a product-by-process description is only

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1 *See In re* Hughes, 496 F.2d 1216, 1218 (C.C.P.A. 1974).

> In *Painter*, a proper exception to the general rule was found on the ground that the product could not be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. This basic rule and the exception have been recognized and followed continuously by the Patent Office and the Courts.

Id.; *In re* Bridgeford, 357 F.2d 679, 682 n.5 (C.C.P.A. 1966) ("[W]here the structural formula of the chemical compound was known, product-by-process claims have been refused by the board.").

2 *Bridgeford*, 357 F.2d at 682 ("[T]he invention so defined is a product and not a process.").

3 927 F.2d 1565 (Fed. Cir. 1991).

4 *See id.* at 1583-84.

5 970 F.2d 834 (Fed. Cir. 1992).

infringed when the allegedly infringing product is produced via the same process as in the claim.[6] It is submitted that the current conflict arose because the holdings in these cases were overly broad. These decisions would be able to co-exist if it were recognized that not all product-by-process claims are the same.[7]

This Note examines the arguments concerning the scope of infringement protection for product-by-process claims and concludes with a proposal for legislative action to resolve the conflict created by the court. Part I describes the historical basis and evolution of product-by-process claims. Part II relates the history of *Scripps Clinic* and *Atlantic Thermoplastics*. Part III analyzes the holdings of the two cases, along with their subsequent history. Finally, Part IV proposes an amendment to the patent statutes to provide explicit statutory infringement protection for product-by-process claims which defy the typical structural definition.

I. BACKGROUND

The Constitution specifically provides for exclusive rights to one's invention.[8] To secure these rights, Congress has promulgated patent laws in Title 35 of the United States Code.[9]

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6 *Id.* at 846-47.

7 The actual results in *Scripps Clinic* and *Atlantic Thermoplastics* may have been correct in spite of the conflicting holdings passed down by the court. Breaking down product-by-process claims into different types rather than treating them all similarly would have allowed for the results to stand without conflict. *See infra* notes 47-49 and accompanying text (categorization of product-by-process claims); *see also infra* Part IV (proposed patent statute).

8 U.S. CONST. art. I, § 8, cl. 8. The Constitution states, in pertinent part, that "[t]he Congress shall have Power . . . [t]o 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." *Id.*

9 35 U.S.C. §§ 1-376 (1992). Congress, in turn, has authorized the Patent and Trademark Office to establish their own regulations. *Id.* § 6(a). Section 6(a) provides, in part, that "[t]he Commissioner [of Patents] . . . may, subject to the approval of the Secretary of Commerce, establish regulations, not inconsistent with law, for the conduct of proceedings in the Patent and Trademark Office." *Id.* These regulations are codified in Title 37 of the Code of Federal Regulations. The Patent and Trademark Office also provides further guidance for patent practitioners in U.S. DEP'T OF COMMERCE, PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (5th ed. rev. 15 1993) [hereinafter MPEP].

Patents for new inventions may be broadly divided into four categories: utility, design, plant, and reissue patents. *See* RONALD B. HILDRETH, PATENT LAW: A PRACTITIONER'S GUIDE 5-7 (1988) (providing further description of four categories). Utility patents are based on 35 U.S.C. § 101 which states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the condi-

To validate the securing of these rights, all patent applications must sufficiently describe the invention such that one skilled in the art is able to make and use the claimed invention and know that the inventor had possession of that invention.[10] Since it is often difficult to meet this requirement, broad discretion is given to the method by which the invention may be described.[11] The

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tions and requirements of this title." 35 U.S.C. § 101 (1984). Product patents fall into the category of utility patents because they primarily involve either a composition of matter or a manufacture. *See* HILDRETH, *supra*, at 6.

> A composition of matter is a combination of two or more substances. It can include chemical elements, chemical compounds, or other components. For example, pulp for making paper is a composition of matter.
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> A manufacture is a category for the remaining statutory subject matter that is not a process, machine, or composition. For example, a human-made genetically engineered bacterium capable of breaking down crude oil is patentable subject matter.

Id. (footnotes omitted).

[10] 35 U.S.C. § 112 (1984). The statute provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is mostly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
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> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Id.

[11] *See In re* Steppan, 394 F.2d 1013, 1019 (C.C.P.A. 1967). The court in *Steppan* stated that "[b]y statute, 35 U.S.C. § 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention." *Id.*

The manner in which this requirement is to be met has been given broad scope. *See, e.g., In re* Edwards, 568 F.2d 1349, 1351-52 (C.C.P.A. 1978) (purpose of description is to ensure that inventor had possession of claimed subject matter); *In re* Moore, 439 F.2d 1232, 1236 (C.C.P.A. 1971) (noting that concern is whether disclosure contains sufficient information to enable one skilled in art to make and use claimed invention); *Steppan*, 394 F.2d at 1013 (no limitation on method of claiming invention so long as claims particularly point out and distinctly claim invention); *see* Ralston Purina Co. v. Far-Mar-Co, Inc., 586 F. Supp. 1176, 1219 (D. Kan. 1984), *aff'd in part, rev'd in part*, 772 F.2d 1570 (Fed. Cir. 1985).

> "The patent statute contemplates the protection of bona fide inventions, whether or not those inventions are capable of precise definition. Since inventions are not always capable of descriptions in terms of exact measurements, symbols and formulas, if the claims, when read in light of the specifications, reasonably inform those skilled in the art of both the use and scope of the invention, and if the delineation is as precise as the subject matter will permit, the requirement of specificity will be satisfied."

Id. (quoting Congoleum Indus., Inc. v. Armstrong Cork Co., 339 F. Supp. 1036, 1055 (E.D. Pa. 1972), *aff'd*, 510 F.2d 334 (3d Cir.), *cert. denied*, 421 U.S. 988 (1975)).

usual method for claiming a product is in terms of its properties or structure.[12] These claims are often referred to as "true" product claims.[13]

In contrast to true product claims, product-by-process claims fully or partially define the product by describing the process or method by which the product is made.[14] In 1891, *In re Painter* introduced the concept of product-by-process patents.[15] In *Painter*, the court reasoned that an inventor should not be penalized when it is impossible to sufficiently describe an invention in standard product terms.[16] Although upholding the validity of the patent in *Painter*, the court noted that product-by-process patenting is an exception to the general rule of using true product claims.[17]

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12 *See* Atlantic Thermoplastics v. Faytex Corp., 970 F.2d 834, 845 (Fed. Cir. 1992) ("[T]he PTO and the CCPA acknowledged product-by-process claims as an exception to the general rule requiring claims to define products in terms of structural characteristics."); *In re* Hughes, 496 F.2d 1216 (C.C.P.A. 1974) (product-by-process claims allowed where invention can not be described in terms of structure or physical characteristics); *see also* David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 DENV. U. L. REV. 173, 175 (1991) ("In the field of pharmaceuticals, the patented product is usually described in terms of the structure of an active ingredient of the drug substance.").

13 2 DONALD S. CHISOLM, PATENTS § 8.79 (1991). "A 'true' product claim is one in which the product is defined in terms of structural characteristics only." *Id.*

14 *Id.* § 8.05. "A 'product-by-process' claim is one in which the product is defined at least in part in terms of the method or process by which it is made." *Id.*

15 1891 C.D. 200, 57 O.G. 999 (Comm'r of Pats. 1891).

16 *Id.* at 200-01.

> It 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 a claim properly 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 prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule.

Id. (emphasis omitted). The courts have consistently followed the *Painter* rule in upholding the validity of patents obtained via a product-by-process description. *See, e.g.*, *In re* Edwards, 568 F.2d 1349, 1351-52 (C.C.P.A. 1967).

> To comply with the description requirement it is not necessary that the application describe the claimed invention in ipsis verbis . . . all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

Id.; *see In re* Moore, 439 F.2d 1232 (C.C.P.A. 1971) (claim allowed so long as there is sufficient teaching); *In re* Bridgeford, 357 F.2d 679 (C.C.P.A. 1966) (right to patent should not be denied because of language limitations).

17 *See supra* note 16 (*Painter* court statement concerning claim content).

After *Painter*, product-by-process claims were available only where there was no other way to describe the invention.[18] Modern courts, however, have shown leniency in allowing product-by-process claims where other descriptions are possible.[19] The Patent and Trademark Office synthesized the case law which expanded the permissible use of product-by-process claims into guidelines for patent practitioners in the *Manual of Patent Examining Procedure*.[20]

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[18] *See In re* Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985). "Product-by-process claims are not specifically discussed in the patent statute. The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made." *Id.*; Pfizer, Inc. v. International Rectifier Corp., 538 F.2d 180, 188 n.15. (8th Cir. 1976) ("A 'product-by-process' claim is a form of *product* patent for a compound that cannot be described other than by reference to the process of making it."), *cert. denied*, 429 U.S. 1040 (1977); Westwood Chem., Inc. v. Dow Corning Corp., 189 U.S.P.Q. (BNA) 649, 665 (E.D. Mich. 1975) ("Claims defining a product by the process of making it are permissible only when the product cannot be otherwise defined."); *Ralston Purina Co.*, 586 F. Supp. at 1219 ("[P]roduct-by-process claims are proper even if the product is capable of description in an allowable product claim, if the product is incapable of description by product claims which are of a different scope."); *see also supra* note 14 and accompanying text (defining product-by-process claim).

[19] *See In re* Pilkington, 411 F.2d 1345, 1349-50 (C.C.P.A. 1969). In *Pilkington*, a patent examiner rejected the applicant's product claim because it could have been drafted without the use of a process description. *Id.* at 1349. The court, quoting *In re* Steppan, 394 F.2d 1013 (C.C.P.A. 1967), stated that 35 U.S.C. § 112 "placed no limitations on *how* an applicant claims *his invention*" thereby finding "that the present product-by-process claim satisfies the requirements of 35 USCS § 112, and is appropriate here." *Pilkington*, 411 F.2d at 1349-50; *see Ralston Purina*, 586 F. Supp. at 1219 ("A claim for a product defined by the process of making the product, or product-by-process claim, is proper and not indefinite when the product is not fairly susceptible to description by its properties structure.").

[20] MPEP § 706.03(e).

> An article may be claimed by a process of making it provided it is definite. *In re Moeller*, 1941 C.D. 316; 48 USPQ 542; 28 CCPA 932; *In re Luck*, 177 USPQ 523 (CCPA 1973); *In re Steppan*, 156 USPQ 143 (CCPA 1967); and *In re Pilkington*, 162 USPQ 145 (CCPA 1969).
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> 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 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063 [sic], 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).
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> Where an applicant's product is incapable of description by product

While the Patent and Trademark Office promulgates the rules concerning patent applications, the resolution of patent disputes usually falls upon the courts. In product-by-process litigation, courts agree that the patented item is a product, as opposed to a process.[21] Courts disagree, however, about whether the same criteria used to evaluate patent validity should be applied to evaluate patent infringement actions.[22] In determining validity, the focus is solely on the product itself.[23] By contrast, when determining infringement some courts view the process description as a limitation on the product claim.[24] The ultimate resolution of infringement protection depends upon whether a product-by-process claim is viewed as: (1) a "true" product claim,[25] which would focus solely on the product for validity and infringement;[26] (2) a product

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claims which are of differing 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 USPQ 106 (CCPA 1974).

The fact that it is necessary for an applicant to describe his product in product-by-process terms does not prevent him from presenting claims of varying scope, *Ex parte Pantzer and Feier*, 176 USPQ 141 (Board of Appeals, 1972).

Id.

21 *See In re* Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985) ("[D]etermination of patentability is based on the product itself."); *In re* Brown, 459 F.2d 531, 535 (C.C.P.A. 1972) ("[I]t is the patentability of the *product* claimed and *not* of the recited process steps which must be established."); *In re* Taylor, 360 F.2d 232, 234 (C.C.P.A. 1966) ("[T]he Patent Office cannot here rely on . . . the proposition . . . that a product-by-process claim defines a process.").

22 *Compare Scripps Clinic*, 927 F.2d at 1583 ("[C]laims must be construed the same way for validity and for infringement . . . .") *with Atlantic Thermoplastics*, 970 F.2d at 846 ("The PTO's treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest reasonable interpretation. The same rule, however, does not apply in validity and infringement litigation.").

23 *See supra* note 22 (showing focus of validity actions).

24 *See* General Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 373 (1938) ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced."). However, the crux of the decision in *Wabash* was based on the inadequacy of the description. *Id.* at 369. *See generally* Eric P. Mirabel, *Product-By-Process Claims: A Practical Perspective*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 3, 35-43 (1986) (citing cases limiting product infringement cause of action to situations where identical or equivalent processes were used).

25 *See supra* note 13 (defining "true" product claim); *see also Scripps Clinic*, 927 F.2d at 1583.

26 If an invention has been patented, the patent requirements concerning the sufficiency of the description, the invention's unobviousness, and the novelty of the invention would provide enough specificity to enable the courts to determine both valid-

claim taken in conjunction with process limitations,[27] which might use different criteria for validity and infringement; or (3) a distinct type of claim,[28] which would be evaluated according to a prescribed method, based on the specific interaction between the product and the claim.[29]

II. THE CURRENT CONFLICT

The Court of Appeals for the Federal Circuit handed down conflicting rulings less than one and one-half years apart concerning infringement of product-by-process claims. The first was *Scripps Clinic & Research Foundation v. Genentech, Inc.*,[30] in which the plaintiff patent owner of "Ultrapurification of Factor VIII Using Monoclonal Antibodies"[31] alleged that its product-by-process claims were infringed by Genentech.[32] Genentech countered that the Scripps claim was limited to the method by which it was produced; thus, Genentech argued its product did not infringe because the Genentech product was produced by a different method.[33] The district court denied summary judgment to Scripps on its product-by-process claims.[34]

On appeal, the Federal Circuit held that a product-by-process

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ity and infringement actions in the same manner. *See* 35 U.S.C. § 103 (1984) (requirement of "unobviousness"). This section provides, in part:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art 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. Patentability shall not be negatived by the manner in which the invention was made.

Id.; *see* 35 U.S.C. § 102 (patent statute section entitled "Conditions for patentability; novelty and loss of right to patent"); *supra* note 11 (*Ralston Purina* quote); *supra* note 10 (35 U.S.C. § 112 - patent statute concerning "sufficiency").

[27] *See Atlantic Thermoplastics*, 970 F.2d at 846.

[28] *See* Mirabel, *supra* note 24, at 3-4 n.2 (product-by-process claims should be distinguished from product claims with process limitation).

[29] *See infra* Part IV (proposing amendment to patent statutes).

[30] 927 F.2d 1565 (Fed. Cir. 1991).

[31] *Id.* at 1568. This invention involved the production of highly concentrated Factor VIII:C, a clotting or precoagulant factor found in blood plasma. *Id.* Researchers at Scripps managed to produce Factor VIII:C with a concentration at least 160,000 times as great as that naturally occurring in human plasma. *Id.* at 1570.

[32] *Id.* One example of the product-by-process claims in dispute is claim 13 which reads as follows: "Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1." *Id.*

[33] *Id.* at 1580.

[34] *See id.* at 1583. The court also took note of the district court's statement that

patent can be infringed by one who makes the product through a different process.[35] The court explained that

> [i]n determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. . . . Infringement of the product-by-process claims may be considered at trial.[36]

The Federal Circuit subsequently decided *Atlantic Thermoplastics Co. v. Faytex Corp.*[37] In that case, the products at issue were two shock absorbing shoe innersoles which used solid elastomeric inserts created by different processes.[38]

The district court determined that Atlantic Thermoplastics' patented innersole was limited by the claims which defined the process.[39] On appeal, Atlantic Thermoplastics, citing *Scripps Clinic*, argued that product-by-process claims should not be limited to the product created by the process described in the patent claim.[40] This time, the Federal Circuit held that product-by-process claims could only be infringed by producing the same product via the same process.[41] Furthermore, in a footnote to the decision, Judge Rader, author of the panel decision, criticized the *Scripps*

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the "product-by-process claims would not be infringed unless the same process were practiced." *Id.*

35 927 F.2d at 1583-84. This issue was remanded for further determination. *Id.* at 1584.

36 *Id.*

37 970 F.2d at 834.

38 *See id.* at 835. The patent in contention was for an innersole manufactured by Atlantic Thermoplastic's claimed process which included the insertion of a solid elastomeric material into the mold. *Id.* This material was required to be tacky so that it would stay in place during the injection of the polyurethane material. *Id.* at 835-36.

Faytex was a distributor of half-innersoles (heel cups) with an elastomeric insert which were manufactured by competitors of Atlantic Thermoplastics, Surge Products and Sorbothane. *Id.* at 836. The innersoles manufactured by Sorbothane used a process whereby a liquid elastomeric was injected into the mold. *Id.* This liquid then solidified to form the insert. *Id.* The Surge product was virtually identical to the process patented by Atlantic, and both parties agreed that the Surge innersoles infringed the Atlantic patent. *Id.* Thus, the Surge Products innersoles were not at issue. *Id.*

39 Atlantic Thermoplastics Co. v. Faytex Corp., No. 88-0210-H, 1990 U.S. Dist. LEXIS 20050, at *19-32 (D. Mass. July 27, 1990).

40 *Atlantic Thermoplastics*, 970 F.2d at 838.

41 *Id.* at 846-47. "In light of Supreme Court caselaw and the history of product-by-process claims, this court acknowledges that infringement analysis proceeds with reference to the patent claims. Thus, process terms in product-by-process claims serve as limitations in determining infringement." *Id.*

Clinic court for ignoring Supreme Court precedent when rendering their decision.[42]

Atlantic Thermoplastics was followed by two denials of rehearing en banc.[43] Upon the second denial for rehearing en banc, Judge Newman, author of the *Scripps Clinic* decision, wrote a scathing dissent criticizing the decision handed down by the *Atlantic Thermoplastics* court.[44] Judge Newman disputed Judge Rader's contention that the *Scripps Clinic* court ignored Supreme Court precedent.[45] Interestingly, the votes in favor of rehearing came from the four judges who had patent or intellectual property backgrounds, including the panel which decided *Scripps Clinic*.[46]

III. CATEGORIZATION OF PRODUCT-BY-PROCESS CLAIMS

As Judge Newman observed in her dissent, product-by-process claims generally can be categorized as follows: "(1) when the product is new and unobvious, but is not capable of independent definition; (2) when the product is old or obvious, but the process is new; and (3) when the product is new and unobvious, but has a

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[42] *Id.* at 838 n.2.

> This court in *Scripps Clinic* ruled without reference to the Supreme Court's previous cases involving product claims with process limitations. In the absence of responsive briefing of the issues by the *Scripps Clinic* parties, this court noted that it was reviewing an "undeveloped record," and devoted one paragraph to resolving the jurisdictional issue and one paragraph to the merits. . . . 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.

Id. (citation omitted).

[43] *See* Atlantic Themoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1299 (Fed. Cir. 1992) (Rader, J., concurring).

[44] *See Atlantic Thermoplastics*, 974 F.2d at 1281-98 (Newman, J., dissenting); *see also* Don J. DeBenedictis, *Inconsistent Patent Rulings: Federal Circuit Judge Laments "Mutiny" by Panel in Call for En Banc Hearing*, A.B.A. J., Dec. 1992, at 36 (discussing procedural history of two cases).

[45] *See Atlantic Thermoplastics*, 974 F.2d at 1289-93 (Newman, J., dissenting). Judge Newman individually addressed every issue raised by Judge Rader and detailed her interpretation of the caselaw which was consistent with the decision reached in *Scripps Clinic*. *Id.* at 1281-98 (Newman, J., dissenting).

One of the goals upon founding the U.S. Court of Appeals for the Federal Circuit was uniformity of decisions. *See* DeBenedictis, *supra* note 44, at 36. The overruling of the decision in *Scripps Clinic* without an en banc hearing was inconsistent with the intentions of the Federal Circuit's first Chief Judge, Howard Markey. *Id.* Chief Judge Markey envisioned that no panel of the court would overrule another without an en banc hearing. *Id.*

[46] *See* DeBenedictis, *supra* note 44, at 36 (discussing division of judges on vote for rehearing); *see also Scripps Clinic*, 927 F.2d at 1565.

process-based limitation (e.g. a 'molded' product)."[47]

It is suggested that only the first type of claim, as defined by Judge Newman, be considered a "true" product-by-process claim. Reasonably, one may conclude that the second and third types of claims cover products which are inextricably intertwined with the process. This is because either the novelty can be depicted only by describing the process, as in the second type of claim, or because the claim is self-limiting, as in the third type of claim. Therefore, it seems appropriate that the products listed as type two and three claims be termed process-limited product claims[48] and would *only* be infringed when the products are produced via the same process. By contrast, this would leave the first type of claim as the "true" product-by-process claim envisioned in *Painter*.[49]

In interpreting prior holdings, the majority in *Atlantic Thermoplastics* failed to differentiate between product-by-process claims in which the product could be defined by its structure or characteristics and those in which it could not.[50] The court simply

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[47] *Atlantic Thermoplastics*, 974 F.2d at 1284 (Newman, J., dissenting).

> Type (2) includes the *Atlantic* class of claim; such claims are examined as process claims, their validity depends on the novelty and unobviousness of the process and they are infringed only when the process is used.
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> Type (1) is the *Scripps* class of claim; such claims are examined as product claims, their validity depends on the novelty and unobviousness of the product, and they are infringed by the product however made. Indeed, claims of types (2) and (3) are not properly called "product-by-process" claims, if that term is used with precision.

Id. (Newman, J., dissenting) (footnotes omitted). Judge Newman based her categorizations on an article by Eric P. Mirabel. *Id.* at 1284 n.4 (Newman, J., dissenting). *See generally* Mirabel, *supra* note 24, at 3-11 (discussing classification and definition of product claims).

[48] *See* Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311 (1884) (patent for product cannot be obtained where new process yields known product); *see also* Tri-Wall Containers, Inc. v. United States, 408 F.2d 748, 750 (Ct. Cl. 1969) ("It is well established that a product claimed as made by a new process is not patentable unless the product itself is new."). Thus, we see that products are not patentable where their novelty lies merely in their production by a new process. Type (2) claims would therefore relate to products in which the novelty must be depicted by defining the product in terms of its difference in production.

[49] *See supra* note 13 and accompanying text (defining "true" product claim).

[50] *Atlantic Thermoplastics*, 974 F.2d at 1284 (Newman, J., dissenting).

> The cases that the Atlantic panel states support its conclusion that *Scripps* was wrongly decided do not relate to the class of "true" product-by-process claim that was at issue in *Scripps*. Most of the cases that the Atlantic panel relies on do not even concern new products. Indeed, most courts have avoided the pitfall that has befallen our colleagues in Atlantic; for most courts, interpreting claims in accordance with the classical criteria of the

combined all prior case law to formulate a "one-rule-fits-all law."[51]

In all likelihood, had Judge Rader followed the classification system outlined by Judge Newman,[52] the result in *Atlantic Thermoplastics* would be unchanged. The Atlantic Thermoplastics innersole falls into the second category of product-by-process claims.[53] Since the process was integral to the product, the infringement protection should be limited by the defining process.[54] The problem created by the *Atlantic Thermoplastics* court arose from the overly broad holding that product-by-process claims are infringed only when the allegedly infringing product is made by the same process.[55]

In his concurrence with the second denial of rehearing, Judge Rader interpreted the Supreme Court position to be that application of process limitations is not restricted to cases where the product is old.[56] His interpretation partly relied on the concept that "[s]ome processes—like a chemical purification process—might yield a different product each time performed."[57] If this were so, then the enabling requirements of the patent statute would not be fulfilled, thus precluding the original issue of the patent.[58] In addition, Judge Rader implied that without process

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specification, the prosecution history, and the prior art, have simply looked to see what the invention was, and interpreted the claims accordingly.

Id.

51 *Id.*

52 *See supra* note 47 and accompanying text (creating three categories of product-by-process claims).

53 *See supra* note 47 and accompanying text.

54 *See supra* text accompanying notes 47 and 48 (describing proposed limitations on type two and three claims).

55 *Atlantic Thermoplastics*, 970 F.2d at 846-47 ("[P]rocess terms in product-by-process claims serve as limitations in determining infringement.").

56 *Atlantic Thermoplastics*, 974 F.2d at 1302 (Rader, J., concurring). "'[N]othing can be held to infringe the patent which is not made by that process.' The Supreme Court enunciated that rule because otherwise the claims would 'give no information as to how [the product] is to be identified.'" *Id.* (Rader, J., concurring) (quoting Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884)) (citations omitted) (alteration in original).

57 *Id.* at 1302 n.4.

58 35 U.S.C. § 112 (1984). Section 112 provides, in pertinent part, that "[t]he specification shall contain a written description . . . in such . . . terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . . " *Id.* Thus, for a person to receive a patent, even via a product-by-process claim, the specification must provide sufficient information to allow the reproduction of the product. *See id.* Consequently, the fear of being unable to determine the product being produced seems unfounded. *See* Clairol Inc. v. Brentwood Indus., Inc., 193 U.S.P.Q. (BNA) 683, 687 (C.D. Cal. 1976) ("Such 'product-by-process' claims, however, must

limitations on the product, all product patent applicants would attempt to claim their inventions in product-by-process terms.[59] This concern conflicts with the previously recognized principle that the breadth of product coverage afforded by a product-by-process claim is much narrower than that of a "true" product claim.[60]

IV. Proposed Legislation

It is submitted that legislative action is necessary to resolve the contradictory holdings of the two Federal Circuit decisions. One likely solution is to modify Title 35 of the United States Code to provide special regulations for product-by-process claims.[61] A section should specify what would constitute infringement of "true" product-by-process claims, such as those claims fitting the *Painter* criteria.[62] As Judge Newman pointed out, "[t]he *Painter* 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."[63] Codification of the *Painter* rule, combined with the lenient claiming mechanism allowed by the Patent and Trademark Office, would provide the necessary guidance to mend the rift created by the court.[64]

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independently meet the statutory requirements of novelty (35 U.S.C. 102) and invention (35 U.S.C. 103)."). *See generally* Mirabel, *supra* note 24, at 28-35 (discussing enabling requirement and necessity that product be produced by recited process).

59 *See Atlantic Thermoplastics*, 974 F.2d at 1303 (Rader, J., concurring). Judge Rader noted that "[i]f courts did not enforce the only limitations in product-by-process claims, then every patent applicant would have an incentive to claim in process, rather than structural, terms because product-by-process claims would have few, if any, limitations." *Id.*

60 Pfizer Inc. v. International Rectifier Corp., 538 F.2d 180, 188 n.15 (8th Cir. 1976) ("A 'product-by-process' claim . . . is substantially narrower and less desirable than the broad product claims, covering hundreds of compounds . . . ."), *cert. denied*, 429 U.S. 1040 (1977); *see also* MPEP, *supra* note 20, ¶3; *infra* text accompanying notes 65-67 (limitations of proposed legislation).

61 Title 35 already provides distinct protection for other difficult patent areas such as design and plant patents. *See* 35 U.S.C. §§ 171-173 (1984) (statutory provisions concerning design patents); 35 U.S.C. §§ 161-164 (1984) (statutory provisions concerning plant patents).

62 *See supra* note 16 and accompanying text (*Painter* rule and rationale).

63 *Atlantic Thermoplastics*, 974 F.2d at 1288 (Newman, J., dissenting). It is posited that the codification of product-by-process claims into different categories would eliminate the conflicting decisions which arose from being able to structure claims in more than one fashion. Courts have historically litigated each case on its individual merits. *Id.* at 1284 (Newman, J., dissenting). A statutory amendment would ensure continued compliance by producing a framework for the courts.

64 *See, e.g.*, Sakraida v. Ag Pro, 425 U.S. 273, 279 (1976) (viewing 35 U.S.C. § 103

A potential statutory revision that synthesizes appropriate case law might read as follows:

Product-by-Process Patent.

(a) Products which defy description in terms of their structure or other physical characteristics may be claimed in terms of the process by which they are produced. These claims shall be infringed by unauthorized production, during the life of the patent, of the identical product produced by any means. Claims made under this section shall be specially designated as "product-by-process."

(b) Products which are capable of description in terms of their structure or other physical characteristics may be claimed in terms of the process by which they are produced. These claims shall be infringed by unauthorized production, during the life of the patent, of the identical product by the same or an equivalent process.

(c) Claims made under this section must still meet all other requirements contained within this title.

Any special protection afforded under this statute would actually be very narrow.[65] The scope of protection from infringement would only cover *the identical product* which results from the descriptive process, rather than the range of products often encompassed under a "true" product claim.[66] This statute would also require that the product defy definition by structural terms in order to obtain this special protection.[67] Availability of product-by-process claims for products which can be described in terms of

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"as a codification of judicial precedents" (quoting Graham v. John Deere Co., 383 U.S. 1, 17 (1966)) (referring to Hotchkiss v. Greenwood, 52 U.S. 248 (1851)).

[65] *See supra* note 60 and accompanying text (stating that product-by-process claims are narrower and less desirable than true product claims).

[66] *See* Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884) ("[T]he process described in th[e]se patents, to be a sufficient support for a valid patent, as being properly described, must be a process which will produce that article and no other . . . .").

[67] *See supra* note 16 and accompanying text (*Painter* rationale). The special protection of the proposed legislation would be consistent with the history of product-by-process case law. *See, e.g., In re* Johnson, 394 F.2d 591, 594 (C.C.P.A. 1968).

> This court has repeatedly held that a claim for an article capable of such definition must define the article by its structure and not by the process of making it. In re Butler, 37 F.2d 623, 17 CCPA 810; In re Grupe, 48 F.2d 936, 18 CCPA 1262; In re McKee, 25 CCPA 1000, 95 F.2d 264; 37 USPQ 209; In re Moeller, [28 CCPA 932, 117 F.2d 565, 48 USPQ 542]; In re Shortell, 173 F.2d 994, [sic] 36 CCPA 1013; In re Lifton, 189 F.2d 261, 38 CCPA 1119.

Id.

their structure would not be eliminated, but would be read as limited by the defining process.

CONCLUSION

The dissents and concurrences for denial of rehearing en banc in *Atlantic Thermoplastics* illustrate a court divided on a significant patent issue. This division raises the troublesome possibility that future decisions concerning infringement of product-by-process patents could vary based upon the panel the litigants receive. Resolution of this rift is essential to the stability and predictability of product-by-process patent infringement cases. The special protection provided by product-by-process patents is particularly necessary in the areas of pharmaceuticals and biotechnology, due to the high costs of research and investment.[68] Legislation at this

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[68] *See* Dan L. Burk, *Application of United States Patent Law to Commercial Activity in Outer Space*, 6 SANTA CLARA COMPUTER & HIGH TECH. L.J. 295, 306 (1991) ("In the biotechnology industry, where initial investment is already high and research and development costs may consume more than 40% of a firm's expected revenues, the assurance of patent protection seems especially important."); Carlos A. Fisher, Comment, *Unfair Trade Practices in Biotechnology: The Legacy of* In Re Durden, 21 SW. U. L. REV. 1103, 1138 (1992) ("The continued vitality of the United States biotechnology industry following such an enormous outlay of capital clearly depends on adequate patent protection of biological inventions.").

Recent product-by-process claim litigation reveals an upward trend in the areas of pharmaceuticals and biotechnology. *See, e.g.*, Fiers v. Sugano, 984 F.2d 1164 (Fed. Cir. 1993) (DNA for fibroblast beta-interferon); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir.) (DNA for erythropoietin), *cert. denied*, 112 S. Ct 169 (1991); Elan Transdermal Ltd. v. Cygnus Therapeutic Sys., 24 U.S.P.Q.2d 1926 (N.D. Cal. 1992) (transdermal nicotine delivery system). The complexities of chemical compounds and biological structures often necessitate that claims be grounded in the *Painter* rule. *See Amgen*, 927 F.2d at 1206 ("A gene is a chemical compound, albeit a complex one, and . . . our law . . . requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it."). The extensive investment necessary to develop these items mandates specific infringement protection. *See* Kenneth D. Sibley, *Practical Utility: Evolution Suspended?*, 32 IDEA: J.L. & TECH. 203, 230 (1992)

> Pharmaceutical research in particular is an expensive and risky undertaking. The highs costs and risks of this research, combined with the speculative nature of the protection available for the fruits of the research, creates a need in those investing in such research for as much certainty and predictability in the patent laws as the courts can provide.

Id. (footnotes omitted); Phillip B.C. Jones, *Patentability of the Products and Processes of Biotechnology*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 372, 373 (1991) ("[A] therapeutic product requires an average of $240 million and 10 to 12 years to bring the product to the market . . . ."). Failure to provide protection could have a "chilling" effect on research and testing efforts to develop new technology in these areas. *See* Elizabeth J. Hecht, Note, *Beyond* Animal Legal Defense Fund v. Quigg*: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1039 n.97 (1992) (ab-

juncture would foreclose potential problems. It is hoped that Congress will take the necessary measures to avoid future uncertainty for patent holders in actions for infringement of product-by-process patents.

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sence of patent protection would discourage private investment in biotechnology research); Reagan A. Kulseth, Note, *Biotechnology and Animal Patents: When Someone Builds a Better Mouse*, 32 ARIZ. L. REV. 691, 697 (1990) ("[U]nless patent protection for transgenic products is available, many corporations will lose their incentive to continue supporting biotechnology because generic companies will copy products and undersell the inventors.").