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Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act

Mark D. Passler

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Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act

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I. Introduction

Patent law arises under Article 1, Section 8, Clause 8 of the United States Constitution, which gives 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." Invention occurs in many forms, and patent law expressly protects both processes and products, the latter in the nature of machines, articles of manufacture, and compositions of matter.² As early as 100 years ago, however, this short listing proved to be inadequate to protect all types of inventions. Accordingly, courts began to recognize a hybrid: a product-by-process patent claim, that describes the invention of an end product in terms of how it is produced, rather than through the more typical functional or structural description.³

A product-by-process patent claim is distinguishable from both process claims and product claims. If a claim is phrased to protect a product, that is, the product is described functionally or structurally, then that

^{1.} U.S. CONST. art. I, § 8, cl. 8.

^{2. 35} U.S.C. § 101 (1984).

^{3.} See, e.g., Ex parte Painter, 1891 C.D. 200 (Comm'r of Pats. 1891).

Product-by-process patent claims describe an invention in terms of how it is produced rather than through the more typical functional or structural description. Eric P. Mirabel, *Product-by-Process Claims: A Practical Perspective*, 68 J. Pat. & Trademark Off. Soc'y 3 (1986). Such claims are often used by companies to patent complex drug or chemical products whose structure is not completely understood and, therefore, can only be accurately described by the process through which it is made. Don J. DeBenedictis, *Inconsistent Patent Rulings*, A.B.A. J., Dec. 1992, at 36.

product will be the subject of any litigation that ensues. For example, if an inventor creates a new chemical named "X", and the inventor wishes to acquire a patent for X, he should file a product claim. Suppose that chemical X is a zeolite compound (a substance commonly used as a catalyst to "crack" heavy crude oil to produce lighter fractions) such as gasoline. To claim this compound, the inventor might use the following language: "The product is a nitrogen crystalline metal silicate having a zeolite structure." This language would protect the product.

If the inventor instead develops a new, more efficient method of producing X, rather than inventing X itself, a process claim would be proper. The process inventor would not seek to claim X itself; the application would only cover the newly discovered method. He could claim this new process as follows: "The process consists of adding a metal oxide and a silicon dioxide source that is essentially free of alkali metal to a 90% aqueous solution of chemical A. The mixture is then heated, producing chemical X." This language would protect the new process.

Assume again that the inventor has created X. This X, however, is a new, state-of-the-art product, and neither the inventor nor the most brilliant engineers understands its structure. The inventor knows the steps he used to make X, but is unsure of the exact structural makeup of X. The inventor would best protect the invention from infringement by filing a product-by-process claim.

In a product-by-process claim, a product is protected, even though the product is described by the process that produces it. An infringement suit involving a product-by-process claim is complicated, in that such a claim often protects a product that can only be described by explaining how it is made, using process terms. Chemical X could be described in product-by-process terms as follows: "Chemical X is made by adding a metal oxide and a silicon dioxide source that is essentially free of alkali metal to a 90% aqueous solution of chemical A. The mixture is then heated, producing X." The subtle, but extremely significant, difference between the process claim and the product-by-process claim is that the process claim protects only the process used to create X. The product-by-process claim does not necessarily protect the process, but it does protect the end product, X. Product-by-process claims are frequently used by pharmaceutical and chemical companies to protect the fruits of their expensive research and development.⁴

^{4.} The price of developing new chemicals continues to rise each year. Jim Impoco, Green Genes: The Biotechnology Industry Struggles Once Again to Splice a Healthy—and Profitable—Future, U.S. News & World Rep., Oct. 18, 1993, at 58, 59. In 1990, the pharmaceutical industry spent an average of \$230 million to bring a new chemical from the laboratory to the market, and only one out of every 5,000 or 10,000 compounds discovered actually reached the market. Roger A. Brooks, Statement Made at AIPLA Meeting (May 14, 1992), in Am. INTELL. PROP. L. ASS'N

Although product-by-process patents are relatively easy to describe and claim, their recognition and protection results from a somewhat tortured history. Furthermore, these patents have been the center of recent and apparently conflicting decisions by the Court of Appeals for the Federal Circuit. In 1991, that court held in Scripps Clinic & Research Found. v. Genentech Inc.⁵ that an inventor who holds a product-by-process patent claim can maintain an infringement suit against anyone who makes the same product, even if the product is produced through a different process.⁶ Sixteen months later, however, in Atlantic Thermoplastics Co. v. Faytex Corp.,⁷—a ruling that some experts labeled "heresy" and others acclaimed a separate panel of the Court determined that a product-by-process patent holder can only sue those who make the same product by the identical process.¹⁰

The court's internal debate over the proper scope of protection for product-by-process claims continued when the ten active judges of the Federal Circuit decided first by a vote of 7-3, and later by a vote of 6-4, against rehearing *Atlantic Thermoplastics* en banc.¹¹ The second denial sparked four vigorous dissents¹² and, one month later, a lengthy concurrence by Judge Randall R. Rader, author of the *Atlantic Thermoplastics* decision.¹³

This Comment traces and analyzes the history of infringement of

- 5. 927 F.2d 1565 (Fed. Cir. 1991).
- 6. Scripps, 927 F.2d at 1583-84.
- 7. 970 F.2d 834 (Fed. Cir. 1992).

- 9. Wayne State University Law School professor Martin J. Adelman commented that the *Atlantic Thermoplastics* panel's narrow view of product-by-process patent claims is preferable and that Judge Rich's dissent was "intemperate." DeBenedictis, *supra* note 3, at 36.
 - 10. Atlantic Thermoplastics, 970 F.2d at 846-47.
- 11. Although there were fifteen judges sitting on the Federal Circuit when the Court declined en banc review, only judges with active, and not senior, status consider actions en banc. See FED. R. App. P. 47, 35(a).
- 12. Atlantic Thermoplastics, 974 F.2d at 1280-99 (Nies, C.J., and Rich, Newman, and Lourie, J.J., dissenting from the denial of rehearing en banc). The most detailed dissent came from Judge Pauline Newman, who authored the Scripps opinion. Judge Newman exclaimed: "[s]hould this court now wish to restrict patent protection for inventions of complex biological products that are necessarily identified by how they were made, it should be done en banc" Id. at 1298.
- 13. Atlantic Thermoplastics, 974 F.2d at 1299 (Rader, J., concurring in the denial of rehearing en banc).

Bull, 1992, at 475. The 1993 price tag for bringing a new drug to market is \$125 million. Impoco, *supra*. The costs for both chemicals and drugs will continue to rise, partly because the United States government is funding less research. *Id.* at 59. As a result, the struggling biotechnology and pharmaceutical industries can no longer afford to invest in risky projects. *Id.*

^{8.} Judge Giles S. Rich, a co-author of the 1952 Patent Act who was originally appointed to the Court of Customs and Patent Appeals ("CCPA") by President Eisenhower in 1956, asserted that the *Atlantic Thermoplastics* opinion insulted the *Scripps* panel and described it as "mutiny." Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1281 (Fed. Cir. 1992) (Rich, J., dissenting from the denial of rehearing en banc).

product-by-process patent claims. It also examines the diametrically opposed rulings of the Federal Circuit, looking for consistency with Title 35 of the United States Code. 14 This analysis requires an inquiry into the purpose behind patent protection—the promotion of science and useful arts 15—and the uniqueness of products that can, and often can only, be described by the process that makes them.

The remainder of this Comment is divided into four sections. Part II provides an overview of the conflict; specifically, it offers a description of Scripps and Atlantic Thermoplastics, and a look at the difficulty federal district courts have had, and will continue to have, in interpreting these cases. Part III presents the genesis of product-by-process patent claims, from their inception to the present. Part IV examines the nexus between the purpose of patent protection and the tension which exists between the Scripps panel and the Atlantic Thermoplastics panel. It analyzes the reasoning of the two panels, considers whether each fits or conflicts with product-by-process claim precedent, and proffers a suggested method for district courts to utilize when analyzing the proper scope of protection for product-by-process claims. The final section, Part V, addresses what the current state of the law holds for biotechnology companies who wish to patent their pharmaceutical and chemical discoveries, and suggests a policy which would encourage these companies to create products that biotechnology, and society as a whole, will demand in the future.

II. SCRIPPS CLINIC & ATLANTIC THERMOPLASTICS

A. Scripps Clinic

Scripps Clinic & Research Foundation v. Genentech, Inc. 16 involved a patent infringement suit over a substance labeled human Factor VIII:C, a complex protein that occurs naturally in normal blood and is essential to blood clotting. 17 Before the discovery of the invention claimed in Scripps, researchers had been able to concentrate Factor VIII:C in plasma, and doctors had used it to treat hemophilia. Unfortunately, the process was too expensive and inefficient, forcing scientists to search for an improvement. 18

Dr. Zimmerman and Dr. Fulcher, working at the Scripps Clinic &

^{14.} The Patent Act of 1952 is codified as amended in Title 35 of the U.S.C.

^{15.} U.S. CONST. art. I, § 8, cl. 8.

^{16. 927} F.2d 1565 (Fed. Cir. 1991).

^{17.} Id. at 1568.

^{18.} Some of the inefficiencies included the possibility of contamination and disease from impurities in the source blood, and the large volume of whole blood needed as starting material. *Id.* at 1568-69.

Research Foundation ("Scripps Clinic"), discovered that improvement by isolating and characterizing Factor VIII:C through a process of chromatographic absorption.¹⁹ Scripps Clinic secured a patent describing the process, entitled "Ultrapurification of Factor VIII Using Monoclonal Antibodies."²⁰

Genentech began manufacturing its version of the substance using recombinant-DNA production techniques. Scripps filed an infringement claim in a federal district court,²¹ asserting that Genentech's recombinantly-produced Factor VIII:C infringed its product-by-process claims, either literally or under the doctrine of equivalents.²² After a somewhat complex procedural history, including litigation in four separate cases,²³ consolidated appeals and cross-appeals reached the Federal Circuit.

The central issue in *Scripps* was whether product-by-process claims are limited to the process set forth in the claim, or whether they cover the product even if created by a different process. The *Scripps* panel expressly held in favor of the latter.²⁴ The court authorized Scripps Clinic to claim purified Factor VIII:C having the characteristics of human Factor VIII:C whether derived through Scripps's disclosed process or *any other* process achieving the same result.²⁵ The court noted that the patentability of a product is based on its utility, novelty and nonobviousness, even if the claim is a process claim.²⁶ The court further reasoned that it is the inherent characteristics of the product that are claimed, and that the process limitations are needed only to define these characteristics.²⁷

B. Atlantic Thermoplastics

The Atlantic Thermoplastics case involved a dispute between Atlantic Thermoplastics Co. ("Atlantic"), owner of a patent for a shock absorbing shoe innersole that included a product-by-process patent

^{19.} Id. at 1569. The process utilizes monoclonal antibodies specific to Factor VIII:RP and, when completed, yields isolated Factor VIII:C. Id. RP stands for "related protein." Id. at 1568. 20. Id. at 1568.

^{21.} See id. at 1568 n.1.

^{22.} Id. at 1583. See generally Arthur R. Miller & Michael H. Davis, Intellectual Property: Patents, Trademarks, and Copyright in a Nutshell 124-37 (1990).

^{23.} Scripps, 666 F. Supp. 1379 (N.D. Cal. 1987) (granting partial summary judgment in favor of Scripps Clinic on infringement); Scripps, 678 F. Supp. 1429 (N.D. Cal. 1988) (granting partial relief to defendants on motion for reconsideration); Scripps, 707 F. Supp. 1547 (N.D. Cal. 1989) (granting summary judgment in favor of defendants on patent invalidity); Scripps, 724 F. Supp. 690 (N.D. Cal. 1989) (awarding defendants' attorney fees for plaintiff's inequitable conduct).

^{24.} Scripps, 927 F.2d at 1583.

^{25.} Id.

^{26.} See id.

^{27.} Id.

claim,²⁸ and Faytex Corp. ("Faytex"), which marketed innersoles manufactured by two separate companies—Surge Products and Sorbothane.²⁹ Atlantic filed a claim against Faytex, asserting that both the Surge Products and the Sorbothane innersoles infringed its patent, and that Faytex was liable for distributing these innersoles.³⁰

Only the Sorbothane process was at issue before the district court.³¹ Faytex defended, arguing that the Sorbothane process did not constitute infringement because the process used to make the Sorbothane innersole was different from the process in Atlantic's product-by-process claim. The district court agreed with Faytex.³² Atlantic appealed, arguing that because the Sorbothane process innersoles were indistinguishable from the infringing innersoles made through the Surge process, infringement had been established,³³ and that *Scripps* required a reversal of the non-infringement finding.³⁴ The *Atlantic Thermoplastics* panel, however, rejected this argument.³⁵

In reaching its conclusion, Atlantic Thermoplastics expressly rejected the broad definition of product-by-process rights endorsed by the Scripps panel. In the view of the Atlantic Thermoplastics panel, the Scripps panel erroneously failed to consider United States Supreme Court precedent³⁶ when it held that product-by-process claims are not limited to the process set forth in the claim, but instead cover the product even if produced by a different process. Instead, the Atlantic Thermoplastics panel held that the process in a product-by-process claim should be considered to limit the patent's claim when determining infringement.³⁷ Because the Sorbothane process was different than the claimed process, the court concluded that the Sorbothane process could not violate the patent.

C. Federal District Court Reaction

A split within the Federal Circuit is bound to create uncertainty in

^{28.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 836 (Fed. Cir. 1992).

^{29.} Id. at 836.

^{30.} Id. Surge Products and Sorbothane utilized different manufacturing processes. Id. Atlantic asserted that both processes infringed its patent. Id.

^{31.} Id. at 837. The parties agreed that the Surge Products process infringed Atlantic's patent. Id.

^{32.} Id.

^{33.} Id. at 838.

^{34.} Id.

^{35.} See id. at 838-39, 838 n.2.

^{36. &}quot;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.* at 839 n.2 (citing Tucker v. Phyfer, 819 F.2d 1030, 1035 n.7 (11th Cir. 1987)).

^{37.} Atlantic Thermoplastics, 970 F.2d at 846-47.

the federal district courts. At least one court, the United States District Court for the District of Massachusetts, has already expressed confusion over which holding it should apply.³⁸ In *Tropix, Inc. v. Lumigen, Inc.*, the plaintiff relied upon *Scripps* and the defendant supported its argument with *Atlantic Thermoplastics*.³⁹ The district court noted that its dispute turned upon a prediction of the precedential effect the Federal Circuit would give *Scripps* and *Atlantic Thermoplastics*.⁴⁰ The district court judge, forced to choose between the two rules, adopted the *Atlantic Thermoplastics* approach simply because he believed that a majority of the active members of the Federal Circuit bench would prefer that approach.⁴¹ The court acknowledged that its predicament was an uncomfortable one because whether its opinion would be affirmed or reversed on appeal depended largely upon the randomly selected appellate panel.⁴² Until the dispute is resolved, other district courts will undoubtedly feel similarly conflicted.

III. THE EVOLUTION OF PRODUCT-BY-PROCESS PATENT CLAIMS

Pursuant to 35 U.S.C. § 101, four categories of inventions are patentable: processes, machines, articles of manufacture, and compositions of matter. And Machines, articles of manufacture, and compositions of matter are physical entities, and are therefore classified as product claims. Similarly, claims which describe a physical activity are termed process claims. Product-by-process claims are an amalgamation of the two in that, although the patent cannot be issued without a new product being invented, it is the process, rather than the end result, that is primarily described in the patent claim.

^{38.} See Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7 (D. Mass. 1993). But see Fairfax Dental v. Sterling Optical, 808 F. Supp. 326, 338 (S.D.N.Y. 1992) (determining that the Atlantic Thermoplastics panel represented the entire Federal Circuit's opinion).

^{39.} Tropix, 825 F. Supp. at 7-8.

^{40.} Id. Curiously, the Tropix court denied a motion for certification of a question concerning the proper precedent.

^{41.} Id. at 10. Since the dissenting and concurring opinions to the second denial of rehearing en banc of Atlantic Thermoplastics were issued, an eleventh active judge has joined the court. Whether this addition would affect the outcome of a vote if a similar issue was presented for en banc review today is difficult to predict. Only one of the judges who voted to deny rehearing en banc wrote an opinion, making it impossible to determine whether the rest of the Federal Circuit judiciary supported the reasoning of the Atlantic Thermoplastics panel, or just believed that the panel's interpretations of precedent were merely dictum.

^{42.} See id.

^{43.} Section 101 provides, in pertinent part:

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 conditions and requirements of this title.

³⁵ U.S.C. § 101 (1984).

Traditionally the end product, and not the process for producing it, is protected by a product-by-process claimant.⁴⁴ Because product-by-process claims describe an article of manufacture or composition of matter in terms of how the product is made,⁴⁵ it is important to remember that the product itself must be new, useful and nonobvious to be afforded protection.⁴⁶

Acceptance of product-by-process patent claims began over a century ago, in Ex parte Painter,⁴⁷ and was based on the inability of patent lawyers to effectively describe the end product that resulted from the inventor's mechanisms. Painter's claim was for a bottle-stopper that could only be described through product-by-process terms.⁴⁸ The Painter court noted that "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."⁴⁹ The court therefore determined that when an invention "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 [that inventions should not be described in process terms]."⁵⁰ Thus, Painter established the necessity rule, whereby inventions could be protected through process terms, but only if process terms were the most accurate manner in which to describe the invention.⁵¹

Over the next century, the necessity rule experienced constant broadening and narrowing by federal courts. The cases describe a tension not unlike the *Scripps-Atlantic Thermoplastics* debate over the proper scope of protection for product-by-process claims—as both controversies inquire into the amount of patent protection that is necessary to promote invention.

As noted in *Painter*, the CCPA initially adopted and applied the necessity rule,⁵² permitting product-by-process claims only where the

^{44.} In re Pilkington, 411 F.2d 1345, 1348 (C.C.P.A. 1969); see also In re Lifton, 189 F.2d 261, 263 (C.C.P.A. 1951); In re Shortell, 173 F.2d 993 (C.C.P.A. 1949); In re Moeller, 117 F.2d 565, 567 (C.C.P.A. 1941).

^{45. 2} DONALD S. CHISUM, PATENTS § 8.05, at 8-81 (1991).

^{46.} See In re Pilkington, 411 F.2d 1345 (C.C.P.A. 1969).

^{47. 1891} C.D. 200 (Comm'r of Pats. 1891).

^{48.} Id.

^{49.} Id. at 200-01.

^{50.} *Id*

^{51.} As recently as 1974, the CCPA approved the *Painter* ruling, noting that it has been permissible to claim a new product through process terms since at least 1891. *In re* Hughes, 496 F.2d 1216, 1218 (C.C.P.A. 1974).

^{52.} In South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc), the Federal Circuit adopted as precedent the law of the CCPA and the Court of Claims.

invention could not otherwise be defined.⁵³ Application of the rule changed in *In re Bridgeford*,⁵⁴ where the patent examiner rejected a patent application for composite polymeric material consisting of wood fibers or cellulose fibers isolated from wood.⁵⁵ The *Bridgeford* court determined that it was appropriate to examine simply whether the product-by-process claim is patentable and whether the application meets the requirements of 35 U.S.C. § 112, which provides: "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."⁵⁶ Because section 112 places no limitations on how an invention may be claimed, as long as the specification concludes with claims which distinctly claim the invention, ⁵⁷ *Bridgeford* afforded protection to a product-by-process claim even if the applicant could have defined the invention in terms of its structure or novel physical characteristics.⁵⁸

Three years later, in *In re Pilkington*,⁵⁹ the CCPA endorsed protection for product-by-process claims where the claims distinguish the product from prior art.⁶⁰ This case involved the patent examiner's rejection of a claim for a "float glass" process for making sheet glass.⁶¹ The *Pilkington* court held that product-by-process claims are proper where the difference between the applicant's invention and the prior art are not definable by structure.⁶² The *Pilkington* court cited *In re Steppan*⁶³ with approval, stating "Congress has placed no limitations on *how* an applicant [may claim] *his invention* "⁶⁴ Although *Pilkington* does not explicitly contradict the necessity rule, it narrows its application by reasoning that product-by-process claims are proper where they are utilized to distinguish the product from the prior art.⁶⁵

In 1974, the Manual of Patent Examining Procedure⁶⁶ rejected the

^{53.} See In re Lifton, 189 F.2d 261, 263 (C.C.P.A. 1951); In re Moeller, 117 F.2d 565, 567 (C.C.P.A. 1941); In re Butler, 37 F.2d 623, 625 (C.C.P.A. 1930).

^{54. 357} F.2d 679 (C.C.P.A. 1966).

^{55.} Id. at 680.

^{56. 35} U.S.C. § 112 (1984).

^{57.} Id.

^{58.} Bridgeford, 357 F.2d at 682-83. The Bridgeford court also recognized that, in patent infringement suits, some courts have construed product-by-process claims as "covering only a product made by the particular process set forth in the claim." Id. at 682 n.5.

^{59. 411} F.2d 1345 (C.C.P.A. 1969).

^{60.} Id. at 1349.

^{61.} Id. at 1346.

^{62.} Id. at 1349.

^{63. 394} F.2d 1013 (C.C.P.A. 1967).

^{64.} Pilkington, 411 F.2d at 1349 (quoting Steppan, 394 F.2d at 1013).

^{65.} Id.

^{66.} Section 706.03(e) reads "[a]n article may be claimed by a process of making it providing it is definite." M.P.E.P. 706.03(e) (1987).

necessity rule, determining that product-by-process terms are permissible as long as the requirements of Section 112 are satisfied.⁶⁷ Two months later, however, in *In re Hughes*, ⁶⁸ the CCPA declined to explicitly reject the necessity rule. Instead, the exception to the rule was altered again.⁶⁹ The *Hughes* claim involved both process and product claims for "shakes." The court decided that it would allow product-by-process claims even where, as here, the invention could be otherwise defined. The court further asserted that:

even if it is shown that the product can be broadly defined solely in terms of structure . . . where [the] product is incapable of description by product claims which are of a different scope, [the inventor] 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 might be invalidated.⁷²

Thus, an inventor is entitled to use a product-by-process claim to describe a novel manufacturing process when he seeks to avoid the possibility that a broader product claim might be invalidated as overbroad.

Clearly, the CCPA has oscillated in its application of the necessity rule. The current viewpoint is that "product-by-process claims should always be allowed where the invention cannot otherwise be adequately described, whether due to the inability of language to keep pace with inventors or the inability of existing technology to determine just what the invention is." Thus, both the PTO and the federal courts tend to find the necessity rule obsolete, and no longer strictly apply it when considering the legitimacy of a claim.

Basic to the tension addressed by the courts in these cases is the axiom that an invention is patentable only if it is useful, novel, and non-obvious, even where the invention is described through process terms.⁷⁴ As the CCPA has acknowledged, product-by-process claims create unique problems in determining the nonobviousness and novelty of the product.⁷⁵ The central problem is the difficultly in determining the patentability of a claimed product, and *not* the patentability of its process steps, without a physical description of the product.⁷⁶ In Application of

^{67.} In making its decision, The Patent Office relied on Pilkington and Steppan.

^{68. 496} F.2d 1216 (C.C.P.A. 1974).

^{69.} Id. at 1219. The Hughes court found a "sound policy reason" for not abandoning the necessity rule. Id. at 1218.

^{70.} A "shake" is a single split from a short log of straight-grained wood. Id. at 1217 n.1.

^{71.} Id. at 1219.

^{72.} Id.

^{73.} See Mirabel, supra note 3, at 3.

^{74.} E.g., In re Pilkington, 411 F.2d 1345, 1348 (C.C.P.A. 1969).

^{75.} See In re Brown, 459 F.2d 531, 535 (C.C.P.A. 1972).

^{76.} See id.

Brown, the court addressed this dilemma and held 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 on either section 102⁷⁷ or section 103⁷⁸ of the statute is eminently fair and acceptable." Thus, the court implied that the PTO has a lower burden of proof in product-by-process proceedings for denying a claim because of obviousness in its process than it would in a claim application that described an invention exclusively through process terms. Moreover, this holding emphasizes that even though product-by-process claims recite only process limitations, courts are charged with determining the patentability of the claimed product, and not solely the process steps used to manufacture the product. 80

IV. ANALYSIS

The tension between encouraging invention and preventing unfair competition is a century-old battle fought in the federal courts. The question of whether product-by-process claims should be limited to the process described in the claims illustrates this ongoing struggle, as the debate over the necessity rule did in the past. If, as *Scripps* suggests, the product is protected notwithstanding a difference in process, improvment in processes will be discouraged. If differences in processes are considered, as *Atlantic Thermoplastics* suggests, then the invention of products may be discouraged. The Constitution is deceptively clear in describing where the battle line must be drawn: the courts must offer as much protection as is necessary to further the promotion of science and the useful arts.

The third Atlantic Thermoplastics dissent, written by the author of the Scripps opinion, placed claims that contain both product and process terms into three categories: (1) products that are new and nonobvious, but are incapable of independent definition; (2) products that are old or obvious, but have a new process; and (3) products that are new and nonobvious, but have a process-based limitation (e.g. a molded product). The dissent suggested that type (1) claims are examined as product claims, requiring their validity to be based on the novelty and

^{77.} Section 102 of the 1952 Patent Act requires that a claimed invention be novel. 35 U.S.C. § 102 (1984).

^{78.} Section 103 of the 1952 Patent Act requires that a claimed invention be nonobvious. 35 U.S.C. § 103 (1984).

^{79.} Brown, 459 F.2d at 535.

^{80.} In re Hirao, 535 F.2d 67, 69 (C.C.P.A. 1976) (quoting Brown, 459 F.2d at 535).

^{81.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279 (Fed. Cir. 1992) (Newman, C.J., dissenting from the court's denial of rehearing en banc) (citing Mirabel, *supra* note 3, at 3).

nonobviousness of the *product*, while type (2) claims are examined as *process* claims, where validity is based on the novelty and nonobviousness of the *process*.⁸² Most importantly, this dissent stated that only type (1) claims are properly characterized as product-by-process claims, terming them "true" product-by-process claims.⁸³ The dissent identified the *Scripps* claim as a type (1) claim, which is infringed regardless of the process used to make the product.⁸⁴ It would distinguish the *Atlantic Thermoplastics* claim as a type (2) claim, which is infringed only when the same process is used.⁸⁵

The conflicting holdings of *Scripps* and *Atlantic* have sparked much interest, without resolving the uncertainty expressed by the court in *Tropix, Inc. v. Lumigen, Inc.*. Some commentators have failed to take a stand on the debate.⁸⁶ Others have attempted to reconcile the two cases, despite a strong opinion by the drafting judge in *Atlantic Thermoplastics* that the cases are irreconcilable.⁸⁷ This leaves the reader, and the courts, with limited guidance. More helpful would be a

In addition, Judge Rader's concurrence to the second denial of rehearing en banc begins by stating that "[i]n Atlantic Thermoplastics, the court reaffirmed, in the case of a product-by-process claim, that claim language defines the bounds of patent protection. The Supreme Court and this court have, without exception, followed this basic principle for all varieties of claims." Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1299, 1300 (Fed. Cir. 1992) (Rader, J., concurring in the denial of rehearing en banc) (emphasis added). Thus, Judge Rader explicitly states that the ruling in Atlantic Thermoplastics should apply to all product-by-process claims, and not just to Atlantic's type of claim, which was a new process for an old product. Id. He also asserts that "[t]he Atlantic Thermoplastics court tried to distinguish Atlantic's claims from those in Scripps Clinic, but could not." Id. at 1302 n.3. As the author of the original Atlantic Thermoplastics opinion, his analysis of the Court's intent in the original Atlantic Thermoplastic's opinion must be given great weight.

By its own rule, the Federal Circuit was obligated to rehear Atlantic Thermoplastics en banc if it improperly overruled Scripps, because the rule mandates that no panel of the Federal Circuit may overrule another panel unless it does so en banc. Fed. Circ. R. 35 (1993). By denying such a rehearing, a majority of the Federal Circuit has implicitly accepted Atlantic Thermoplastics as correct. Because that ruling specifically declares that it applies to all product-by-process claims, it is pointless and incorrect to suggest, as Hymo & Anderson do, that the Federal Circuit will apply the Scripps rule for some product-by-process claims, and the Atlantic Thermoplastics rule for others.

^{82.} Atlantic Thermoplastics, 974 F.2d at 1284.

^{83.} Id.

^{84.} Id.

^{85.} Id.

^{86.} See, e.g., Kendrew H. Colton & Michael W. Haas, Patent Law Developments in the United States Court of Appeals for the Federal Circuit During 1992, 42 Am. U. L. Rev. 909, 1025-32 (1993).

^{87.} See, e.g., Lawrence A. Hymo & Richard A. Anderson, Product-By-Process Claims: Time for Reexamination, 3 Fed. Circuit B.J. 131 (1993). This article concludes that the holdings of Scripps and Atlantic Thermoplastics are reconcilable. While the article is correct in stating that Scripps and Atlantic Thermoplastics were both properly decided on their facts, the authors' "reconciliation" of these cases does not help patent attorneys understand how to advise their clients should a similar situation arise.

resolution of whether Scripps or Atlantic Thermoplastics is correct in light of Supreme Court and other relevant authority. This section engages in that analysis and, necessarily, addresses the overriding question of which case espouses the interests that the Patent Act is designed to further.

It is the conclusion of this Comment that the *Scripps* panel used the proper approach when it determined that product-by-process claims are not limited to the process set forth in the claim, but instead cover the product even if produced by a different process.⁸⁸ More importantly, it is the position of this Comment that those who dissented from the denial of rehearing *Atlantic* en banc correctly determined that this additional protection is necessary to promote invention.

The Supreme Court has held that process claims are infringed only when the same process is used.⁸⁹ Similarly, the Supreme Court has held that product claims are infringed only when the same product is made.⁹⁰ The Court, however, has not spoken with clarity on "true" product-by-process claims. In fact, the only Supreme Court case to mention such claims, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,⁹¹ did so only in a footnote. This is not surprising, however, because "[t]he facts of relatively few cases relate to the class of product-by-process claims at issue in *Scripps*,"⁹² which involved a "true" product-by-process claim.

In Bonito Boats, the Supreme Court stated that "[a]s 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." The Bonito Boats Court's comment was merely a footnote comparison of this type of product-by-process claim with the Florida statute at issue in the case, which granted boat manufacturers substantial control over the use of a particular process. 94

The Supreme Court's guidance on the proper scope of protection for product-by-process claims is limited to this statement. Therefore,

^{88.} Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991).

^{89.} See Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311 (1884) (finding no violation of process claim unless the alleged infringer used the process in the claimant's specification to produce the article); Merrill v. Yeomans, 94 U.S. 568, 573 (1877) (concluding that the plaintiff's invention was only a process and, therefore, the inventor could only claim the particular process used to make the oil).

^{90.} See General Electric Co. v. Wabash Co., 304 U.S. 364, 373 (1938) (holding that a product claim must be distinguished from prior art).

^{91. 489} U.S. 141 (1989).

^{92.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1297 (Newman, J., dissenting from the court's denial of rehearing en banc).

^{93.} Bonito Boats, 489 U.S. at 158 n.*.

^{94.} Id.

most "true" product-by-process claim law is a creation of the CCPA. Prior to both *Scripps* and *Atlantic Thermoplastics*, the Federal Circuit had not addressed whether the process description in a product-by-process claim serves as a limit to the claim. Both the CCPA and the Federal Circuit, however, had held that a product-by-process claim's patentability depends upon the patentability of the product, and not the patentability of the process.⁹⁵

A. The Scripps Panel's Rationale

Scripps held that the scope of a product-by-process claim is not limited to the process described in the claim. In reaching this conclusion, the Scripps panel cited two cases from the CCPA and one from the Federal Circuit which held that the patentability of an invention that uses product-by-process terminology is based on the patentability of the product, and not the validity of the process. The Scripps court then determined that the same method of interpretation must be used for patentability and infringement purposes.

All three of the cases cited by *Scripps* involved "true" product-by-process claims. Further, all of the precedential language used in its opinion came from holdings, and not mere dicta. Most importantly, the rule set forth by the *Scripps* panel fits into the legal landscape that existed prior to its decision. *Scripps* simply used the previous holdings of the CCPA and the Federal Circuit to address an issue that had not been before either of those courts, and applied these holdings in a manner consistent with its own precedent.

B. The Atlantic Thermoplastics Panel's Rationale

The Atlantic Thermoplastics panel was unable to distinguish the Scripps claims from the Atlantic Thermoplastics claims and, thus, determined that the disputed claims "mirrored" each other. 99 It also argued that the Scripps patent discussed "little more than a process." The

^{95.} See In re Thorpe, 777 F.2d 695, 698 (Fed. Cir. 1985) (holding that prior art pertinent only to the product is proper ground for rejecting product-by-process claims); In re Brown, 459 F.2d 531, 535 (C.C.P.A. 1972) (in product-by-process claims, the patentability of the product must be established independent of the process); In re Bridgeford, 357 F.2d 679, 682-83 (C.C.P.A. 1966) (holding that patentability is determined independent of the process).

^{96.} Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991).

^{97.} See id. (citing In re Thorpe, 777 F.2d 695, 697-98 (Fed. Cir. 1985); In re Brown, 459 F.2d 531, 535 (C.C.P.A. 1972); and In re Bridgeford, 357 F.2d 679, 682-83 (C.C.P.A. 1966)).

^{98.} Scripps, 927 F.2d at 1583.

^{99.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1299, 1302 n.3 (Fed. Cir. 1992) (Rader, J., concurring in the denial of rehearing en banc). 100. *Id.*

panel concluded that the *Scripps* claim must be limited to the process in its claim because there would otherwise be no limitations in the *Atlantic Thermoplastics* claim. ¹⁰¹

The Atlantic Thermoplastics judges grounded their opinion in an analysis of Supreme Court and CCPA precedent.¹⁰² The panel cited a line of Supreme Court cases¹⁰³ to establish the proposition that the process described in a product-by-process claim is the limit of the claim. The panel relied on Supreme Court dicta to support its position, claiming "nothing can be held to infringe the patent which is not made by that process."¹⁰⁴

Atlantic Thermoplastics concluded that Atlantic's product claim is properly interpreted to include the process limitation stated in the claim, ¹⁰⁵ asserting that if the process limitations of the claim were ignored, there would be no limit to the claim and, thus, no way to determine infringement. ¹⁰⁶ Additionally, the court stated that the prosecution history of Atlantic's patent did not show that the claim was intended to be limited to a process. ¹⁰⁷

C. Supreme Court and CCPA Precedent

The Atlantic Thermoplastics panel's analysis is problematic from the start, beginning with its discussion of General Electric and Plummer. Importantly, these two cases involved product claims, not product-by-process claims.

In General Electric, 108 a case revolving around a claim for a tungsten filament for incandescent lamps, the Supreme Court held that since the claimant's patents were indistinguishable from prior art, they were invalid. 109 In reasoning that this claim is synonymous with the claim in

^{101.} Id.

^{102.} Atlantic Thermoplastics, 970 F.2d at 838-46.

^{103.} The cases included Smith v. Goodyear Dental Vulcanite Co., 93 U.S. 486 (1877); Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222 (1880) (addressing the same patent which was the subject of litigation in *Smith*); General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364 (1938); Plumer v. Sargent, 120 U.S. 442 (1887); Merill v. Yeomans, 94 U.S. 568 (1877); and Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884).

^{104.} Atlantic Thermoplastics, 974 F.2d at 1302 (quoting Cochrane, 111 U.S. at 310 (Rader, J., concurring in the denial of rehearing en banc)). A concurring opinion to the second denial of rehearing en banc mocked the dissenting argument's classification of product-by-process claims. Atlantic Thermoplastics, 974 F.2d at 1302. First, it stated that no court has ever categorized some product-by-process claims as "true." Id. at 1303. Second, it implied that type (2) claims, which encompass products that are old or obvious but have a new process, are simply invalid. Id.

^{105.} Id.

^{106.} Id.

^{107.} Id. at 1301.

^{108. 304} U.S. 364 (1938).

^{109.} Id. at 373. See also 2 Donald S. Chisum, Patents § 8.05 (1991). Chisum writes that

Scripps, the Atlantic Thermoplastics court quotes General Electric: "[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." This statement cannot rationally be applied to Scripps. First, it is mere dictum. Additionally, the claim in Scripps was a product-by-process claim, and the claim in General Electric was a product claim. Finally, unlike the claim in General Electric, the Scripps claim was for a complex protein that was clearly new and nonobvious. Thus, the Atlantic Thermoplastics analysis of Supreme Court precedent was erroneous. As the next section will show, it was also unnecessary and, thus, inappropriate.

The panel also utilized *Plummer v. Sargeant*¹¹¹ to support its proposition that the process described in a product-by-process claim serves to limit the scope of the claim. In *Plummer*, the Supreme Court was unable to distinguish the claimant's end product from the alleged infringer's end product, and was forced to compare the processes. After determining that the processes were indeed different, the Court upheld the lower court's noninfringement ruling. Plummer did not involve a "true" product-by-process claim and is therefore not applicable to *Scripps*.

Next, the Atlantice Thermoplastics panel addressed a series of Supreme Court cases which involved process claims, and not product-by-process claims. The panel misinterpreted Smith v. Goodyear Dental Vulcanite Co., 115 where the defendant Smith argued that it had not infringed Goodyear's patent because it had not used Goodyear's process to make its celluloid dental plate. 116 Goodyear's process had distinguished its claim from prior art, because the claimed product, a plate for

most courts have held that a product-by-process claim is infringed "only by a product made through a substantially identical process." *Id.* § 8.05 at 8-81 (citing Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884)). The *Atlantic Thermoplastics* panel found, however, that the cases which Chisum cites as holding in the alternative were patentability cases, and not patent infringement cases. Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 842 n.8 (Fed. Cir. 1992). *See also* 3 Ernest Bainbridge Lipscomb III, Lipscomb's Walker on Patents § 11:19 (3d ed. 1985); 1 Iver P. Cooper, Biotechnology and the Law § 5B.05[2] (1991); 2 Martin J. Adelman et al., Patent Law Perspectives § 2.6[10] (2d ed. 1991).

^{110.} Atlantic Thermoplastics, 974 F.2d at 1292 (quoting General Electric, 304 U.S. at 373) (alteration in original).

^{111. 120} U.S. 442 (1877).

^{112.} Id. at 449-50.

^{113.} Id. at 450.

^{114.} See discussion, supra notes 81-85 and accompanying text.

^{115. 93} U.S. 486 (1877).

^{116.} Id. at 493-94.

holding artificial teeth, was previously known (i.e., not novel).¹¹⁷ The Supreme Court determined that Goodyear's claim was merely a process claim, and that there was therefore no infringement because Smith had used a different process.¹¹⁸ Thus, the claim in *Smith* was a process claim and not a product-by-process claim, and is substantially different from *Scripps's* claim.

The Atlantic Thermoplastics court next cited Goodyear Vulcanite Co. v. Davis¹¹⁹ for the proposition that a product-by-process patent infringement only occurs where both the product and the process are infringed.¹²⁰ The court interpreted this statement to mean that if patent infringement defendants use a different process to make a product than the process described in a plaintiff's product-by-process claim, no infringement has occurred.¹²¹ This reasoning is flawed, however, because the Atlantic Thermoplastics court misread Davis. The Davis Court held that the claim was for a process, and that there was no infringement because the defendant employed a different process.¹²² The same process was required for a finding of infringement in Davis because the claim was a process claim. The Supreme Court did not determine that product-by-process claims are only protected if the same process is used; it simply held that a process claim is not infringed unless an accused infringer uses a claimant's process.

The Atlantic Thermoplastics panel cited Merrill v. Yeomans, ¹²³ yet another case which does not support its position. There, the Court held that the inventor had claimed only a process, and not a product. ¹²⁴ The Court therefore concluded that the patent at issue did not involve a product-by-process claim. ¹²⁵ Merrill, therefore, is easily distinguishable on its facts: Merrill did not involve a product-by-process claim.

Finally, the Atlantic Thermoplastic panel buttressed its analysis of Supreme Court precedent by referencing the Court's statement in Cochrane 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

^{117.} Id. at 493.

^{118.} Id. at 494-95.

^{119. 102} U.S. 222 (1881).

^{120.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 839 (Fed. Cir. 1992) (citing Davis, 102 U.S. at 224).

^{121.} Atlantic Thermoplastics, 970 F.2d at 839.

^{122.} Davis, 102 U.S. at 229.

^{123. 94} U.S. 568 (1877).

^{124.} Id. at 573-74.

^{125.} Id. at 571.

which is not made by that process."¹²⁶ Standing alone, this statement is quite persuasive. A proper interpretation of the statement, however, requires that it be placed in its correct context.

In Cochrane, the claim was for an artificial alizarine made through "either of the methods described, or by any other method, equivalent or not, which will produce anything called artificial alizarine." The Supreme Court determined the product to be an old article of manufacture. The Court limited the holding to its facts, determining that this new process for producing the product was patentable, but the product itself was not. No infringement occurred because the accused product was not made by the claimed process.

The Atlantic Thermoplastics court correctly analogized the Cochrane claim to Atlantic's claim, as they both fit into the type (2) category of products that are old or obvious but have a new process. That panel, however, failed to recognize an important distinction. Although the claims in both Cochrane and Atlantic Thermoplastics were old or obvious but had a new process, not all product-by-process claims may properly be described as such. The Scripps claim clearly illustrates this point, as that claim was new and nonobvious.

Additionally, the Atlantic Thermoplastics panel addressed a series of cases from the CCPA, and made the same mistakes it made in its analysis of Supreme Court precedent. It determined that, as a whole, CCPA precedent regards the process language in product-by-process claims as a limitation on that patent claim. The panel's errors lie in that it examined CCPA cases that involved product claims or process claims, but not product-by-process claims.

The court cited *In re Hughes*, ¹³¹ a case which only addressed the issue of patentability. There, the CCPA held that where it is impossible to describe an invention through structural or physical characteristics, the claimant could use a product-by-process claim. ¹³² Atlantic Thermoplastics interpreted this holding as stating that "the process defines and limits the scope of the claim." ¹³³ In a case addressing infringement issues, *In re Moeller*, ¹³⁴ the CCPA stated that infringement protection for product-by-process claimants is limited to articles pro-

^{126.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 840-41 (Fed. Cir. 1992) (quoting Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884)).

^{127.} Cochrane, 111 U.S. at 312.

^{128.} Id. at 311.

^{129.} Id.

^{130.} Id. at 311-12.

^{131. 496} F.2d 1216 (C.C.P.A. 1974).

^{132.} Id. at 1219.

^{133.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 845 (Fed. Cir. 1992).

^{134. 117} F.2d 565 (C.C.P.A. 1941).

duced by the methods referred to in the claims. In its conclusion, the *Atlantic Thermoplastics* panel improperly extended the *Hughes* and *Moeller* holdings beyond their appropriate application.¹³⁵ Moreover, the panel erroneously determined that ignoring the process limitations in Atlantic's product-by-process claim would amount to a blatant disregard of the doctrine of equivalents.¹³⁶

In sum, the Atlantic Thermoplastics panel determined that Supreme Court dicta supported the position that the process described in a product-by-process claim limits the claim, whether the product was new or old. Furthermore, it interpreted CCPA authority to conclude that the process in a product-by-process patent is a limitation on the patent claim. The Supreme Court and CCPA authority on which the Atlantic Thermoplastics court chose to rely is suspect, however, because it involved product claims or process claims, and not product-by-process claims.

D. The Real Issue in Atlantic Thermoplastics

At issue before the *Atlantic Thermoplastics* court was whether Atlantic's claim was limited to its process.¹³⁷ It was not, as the court's opinion suggests, whether all product-by-process claims are limited to the process in those claims. Atlantic admitted that its claim was limited to the process by which it is made.¹³⁸ Specifically, claim 24 of the patent states "[t]he molded innersole produced by the method of claim 1."¹³⁹ Thus, the claim explicitly accepted a limitation.

Judge Lourie noted that "[i]f the inventor said his claim was limited to the process and if the accused infringer didn't use that process, then the issue is decided." Because this is exactly what occurred, the

^{135.} The Atlantic Thermoplastics panel had no reason to examine Hughes or Moeller because the claims at issue in Atlantic Thermoplastics contained process limitations.

^{136.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 846 (Fed. Cir. 1992). For a discussion on the doctrine of equivalents, see generally Arthur R. Miller & Michael H. Davis, Intellectual Property: Patents, Trademarks, and Copyrights in a Nutshell 126-28 (1990). The doctrine of equivalents states that if an accused invention is substantially equivalent to the claimant's invention, infringement will be found to exist. Id. at 127. An invention is substantially equivalent if "the skilled practitioner would know of the practical interchangeability of the accused infringement's elements with those specifically identified in the patent specification." Id. The purpose of this doctrine is to prevent individuals from making minor changes to an invention, and claiming the new invention as their own. Id. at 127-28. The Atlantic Thermoplastics panel held that the Sorbothane dam and liquid elastomer were substantially different from Atlantic's solid elastomer with inherent tack and, therefore, there was no infringement. Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 838 (Fed. Cir. 1992).

^{137.} Atlantic Thermoplastics, 970 F.2d at 838.

^{138.} See id. at 838-39, 838 n.2.

^{139.} Id. at 836.

^{140.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1299 (Fed. Cir. 1992) (Lourie, J., dissenting from the court's denial of rehearing en banc). Judge Lourie asserted that

proper action by the *Atlantic Thermoplastics* panel would have been to simply state that claim 24 of Atlantic's U.S. Patent No. 4,674,204 *alone* is limited to its process because the claim so concedes.

Instead, the panel journeyed through the history of product-by-process claims and formulated a ruling that applies to all such claims.¹⁴¹ A reinterpretation of Supreme Court and CCPA precedent was not only unnecessary, it amounts to either a declaratory judgment or improper review of an issue that was not before the court.

E. The Atlantic Thermoplastics Approach vs. the Scripps Approach

Even though it is inconsistent with precedent, the Atlantic Thermoplastics holding is not without merit. Under its narrow view, the process in the product-by-process claim is the claim's limitation when determining infringement. A complex biological or chemical claim would be limited to the exact process by which the claimant described it, permitting other inventors to develop new, and possibly more economical, processes for making the same product. The limitation provides greater incentive to create more efficient processes because the discoverer of the new process can profit from both the process and the end product. Clearly, the right to market the end product of drug and chemical research is more valuable to an inventor than having to sell the new process to the patent holder of the end product. This reasoning is endorsed by all of the active Federal Circuit judges who do not have any experience practicing or studying patent law.

Under the *Scripps* approach, a product-by-process patent covers a product no matter how it is produced. This method affords the inventor greater protection from infringement than the *Atlantic Thermoplastics*

the Atlantic panel wrote an overbroad holding, and found that the issue could have been decided without an analysis of precedent. Id. at 1298-99. A second basis for this dissent was that Atlantic Thermoplastics's overruling of Scripps violated Federal Circuit local rules, which state that a prior panel's decision may only be overruled en banc. Fed. Cir. R. 35. When Congress created the Federal Circuit in 1982, one of its goals was to create uniform patent opinions. DeBenedictis, supra note 3, at 36. Since the court's creation, all of the patent appeals from the district courts have been heard before the Federal Circuit. Atlantic Thermoplastics, 974 F.2d at 1280. Moreover, until Atlantic Thermoplastics, no panel had ever overruled another without en banc review. Id. at 1281. The dissent argued that Atlantic Thermoplastics's ruling amounted to blatant disregard of well-established procedure and Congressional mandate. Id. at 1299.

Judge Rich's dissent addressed this issue as well, emphatically stating another local rule: "where there are conflicting precedents, the earlier precedent controls." Id. at 1281. Judge Rich's dissent noted that the parties agreed that the claim was limited to the process by which the innersoles were made. Id. at 1280. He further argued it was improper to establish a rule of law affecting complex drug and chemical cases when the parties briefed the issue only with respect to innersoles. Id.

^{141.} Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 838-46 (Fed. Cir. 1992). 142. *Id.* at 846-47.

approach. Arguably, this method provides less incentive for inventors to improve the efficiency of the processes claimed in their product-by-process claim because anyone who discovers a new process can market only that new process. It is equally true, however, that the *Scripps* rule, which supports a broad scope of protection, provides greater incentive to create new products.

All of the active Federal Circuit judges who have spent their careers as scientists and/or patent attorneys vigorously support the Scripps approach. Judge Rich co-authored the 1952 Patent Act, practiced patent law for twenty-five years, taught patent law for twenty-seven years, and has heard patent appeals since 1956. Judge Lourie practiced patent law for twenty-six years and has published several patent law articles. Chief Judge Nies practiced patent law for twenty-eight years, has served in several editorial capacities, and has published numerous articles. Judge Newman, the Scripps author, has worked as a research chemist, practiced patent law, and directed several national chemical and patent organizations. Their knowledge and understanding of patent law is surpassed by few, if any. It is also extremely likely that their similar academic backgrounds resulted in similar interpretations of product-by-process claims.

The split between the patent and non-patent panels raises the question of who is the most desirable proponent of patent law policy? It is possible that judges who lack patent backgrounds are likely to be more concerned with preventing unfair competition than encouraging invention. It is also possible that former patent attorneys will be markedly pro-patent and favor rules which protect claimants from infringement. On the other hand, it also is likely that the judges with patent experience will be in a better position than the other members of the Federal Circuit judiciary to analyze the effects of policies and interpret the Patent Act.

Those judges who dissented from the court's denial of rehearing en banc did not disagree with the result in *Atlantic Thermoplastics*; they agreed that Faytex did not infringe Atlantic's claim by manufacturing Sorbothane process innersoles. Their discordance came from the overruling of *Scripps* through an analysis of an issue which was not properly before the *Atlantic Thermoplastics* panel and should not have been undertaken. An overbroad holding in a case involving innersoles, which was argued only with respect to innersoles, may affect the entire chemical industry. The *Scripps* method is more appropriate for fostering the purpose of the Patent Act.

Had the Atlantic Thermoplastics panel distinguished type (1) claims from type (2) claims, its holding would be acceptable. But Judge Rader made it clear in his concurrence to the second denial of rehearing

en banc that he did not intend for the Atlantic Thermoplastics holding to be limited to type (2) claims. In fact, he specifically declared that the Atlantic Thermoplastics ruling applies to all product-by-process claims. 143

The correct approach is to apply Atlantic Thermoplastics's rule only to type (2) claims—those which are for products that are old or obvious, but have a new process. The rule is completely improper for type (1) claims—those which are for products that are new and unobvious, but are not capable of independent definition. If a new process is created to manufacture an existing product, patent protection should only be permitted for the new process. This rule may indeed prevent those who develop new processes from being able to market their new processes without cooperating with the product patent holders, but it would ensure the product inventor of full protection for his product, and the process inventor of full protection for his process.

V. CONCLUSION

The Federal Circuit's conflicting opinions have left biotechnology law, as it relates to the proper scope of protection for patent claims, in a state of disarray. It is unfortunate that other district courts may agree with the decision in *Tropix, Inc. v. Lumigen, Inc.* and choose to follow the *Atlantic Thermoplastics* holding, because this approach inhibits pharmaceutical and chemical research and development. Limiting the scope of protection for the few new products that actually reach the marketplace will further retard investment. The *Atlantic Thermoplastics* court's narrow view of infringement protection discourages new research and development ventures.

The proper scope of protection from infringement for product-by-process claims is an issue which cuts to the heart of the purpose of Article I, Section 8, Clause 8 of the United States Constitution. The extent to which product-by-process claims are protected is clearly analogous to one's vision of the scope of protection afforded to inventors through the Constitution. Moreover, the United States Patent Act was created to promote the progress of science and useful arts. 144 Its intention is to encourage inventors by providing a reward, in the form of a patent claim, as incentive for developing new products. 145

If one believes that science is better promoted by permitting inventors to market inventions which contain novel processes for a product

^{143.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1299, 1300 (Fed. Cir. 1992) (Rader, J., concurring in the denial of rehearing en banc).

^{144.} See, e.g., Graham v. John Deere Co., 383 U.S. 1, 5 (1966).

^{145.} Id.

which exists in prior art, and allowing these inventors to receive royalties on both the product and the process even though they had nothing to do with inventing the actual product, then the *Atlantic Thermoplastics* view is correct. If, on the other hand, one looks straight to the text of the Patent Clause of the United States Constitution, where *new products* and useful arts are temporarily protected by *securing exclusive rights*, it is apparent that the *Scripps* approach is proper.

The necessity rule's requirement that product-by-process terminology be permitted only in claims that cannot be otherwise described is now obsolete. Similarly, the end product described in a product-by-process claim should be protected, regardless of the process that is used to create that product.

Judge Rich's dissent mentions a procedural rule of the Federal Circuit which states that where there are conflicting precedents, the earlier precedent controls. ¹⁴⁶ This rule is fortunate because in order to effectively promote invention *exclusive* rights to inventions must be secured, and exclusive protection is what the *Scripps* holding advocates.

MARK D. PASSLER*

^{146.} Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1281 (Rich, J., dissenting from the second denial of rehearing en banc).

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