

09-335 SEP 16 2009

No. OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

ASTELLAS PHARMA, INC.

Petitioner,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.

Respondents.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit erred in ignoring the Court's binding precedent and finding product-by-process claims are not infringed by an identical product made by a different process?

**PARTIES TO THE PROCEEDINGS AND
CORPORATE DISCLOSURE STATEMENT**

The parties to this proceeding are:
Petitioner/Appellant Astellas Pharma, Inc. and
Respondents/ Appellees Lupin Ltd. and Lupin
Pharmaceuticals, Inc. Although Abbott Laboratories
was an appellant below, it has not joined in this
petition for *certiorari*.

The Federal Circuit's decision in 2007-1446
(this case) was a final decision disposing of all issues
between the parties. On appeal, the Federal Circuit
heard this case with 2007-1400, which involved the
same patent and the same plaintiffs. That case was
an appeal of a denial of a preliminary injunction to
plaintiffs Astellas Pharma, Inc. and Abbott
Laboratories and against defendants Sandoz, Inc.,
Sandoz GMBH, Teva Pharmaceuticals USA, Inc.,
Teva Pharmaceutical Industries, Ltd., Ranbaxy
Laboratories, Ltd., Ranbaxy, Inc., Par
Pharmaceutical Companies, Inc., and Par
Pharmaceutical. After remand, that case is
currently stayed pending the outcome of this petition
for *certiorari*. Astellas has provided a courtesy copy
of this petition to the defendants in that case.

As required by the Court's Rule 29.6, Astellas
Pharma, Inc. states that there is no parent
corporation and no publicly held company owns 10%
or more of its stock.

TABLE OF CONTENTS

QUESTION PRESENTED i

PARTIES TO THE PROCEEDINGS AND
CORPORATE DISCLOSURE STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES v

PETITION FOR *CERTIORARI*..... 1

OPINION BELOW 1

JURISDICTION 1

CONSTITUTIONAL PROVISION INVOLVED 1

STATEMENT OF THE CASE..... 2

I. Introduction 2

II. Proceedings Below..... 3

REASONS FOR GRANTING THE PETITION 7

I. By Failing to Follow Its Own Procedures, the
En Banc Majority Took Away an Entire Class
of Patents without Receiving Any Input from
the Public..... 8

II. The En Banc Majority Erred in Deciding that Product-by-Process Claims Are to Be Interpreted Differently for Validity than for Infringement	11
III. The En Banc Majority Erred in Deciding that There Should Be a Single Rule for Product-by-Process Claims Regardless of Whether the Product Claimed Was Old or New.....	15
IV. The En Banc Majority Erred in Its Analysis of the Precedent of This Court and Other Courts	17
V. The En Banc Decision Necessitated that the Panel Improperly Rewrite the Claims	27
VI. Product-by-Process Patents Promote the Progress of Science.....	29
CONCLUSION.....	33
APPENDIX	
<i>Abbott Laboratories v. Sandoz, Inc.</i> , 566 F.3d 1282 (Fed. Cir. 2009).	App. 1
<i>Lupin Limited v. Abbott Laboratories</i> , 491 F. Supp. 2d 563 (E.D. Va. 2007)	App. 89

TABLE OF AUTHORITIES

Cases

<i>Abbott Labs. v. Sandoz, Inc.</i> , 566 F.3d 1282 (Fed. Cir. 2009)	passim
<i>Amazon.com, Inc. v. Barnesandnoble.com, Inc.</i> , 239 F.3d 1343 (Fed. Cir. 2001)	12
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003)	12
<i>Astra-Sjuco A.B. v. Int’l Trade Comm’n</i> , 629 F.2d 682 (C.C.P.A. 1980).....	22
<i>Atlantic Thermoplastics Co., Inc. v. Faytex Corp.</i> , 970 F.2d 834 (Fed. Cir. 1992)	4, 13
<i>Atlantic Thermoplastics Co., Inc. v. Faytex Corp.</i> , 974 F.2d 1279 (Fed. Cir. 1992) (Newman, J., dissenting)	24
<i>Atlantic Thermoplastics Co., Inc. v. Faytex Corp.</i> , 974 F.2d 1299 (Fed. Cir. 1992) (Rader, J., concurring)	13, 15, 16
<i>Aventis Pharms., Inc. v. Barr Labs., Inc.</i> , 372 F. Supp. 2d 430 (D. N.J. 2005).....	5
<i>Bonito Boats v. Thunder Craft Boats</i> , 489 U.S. 141 (1989)	16, 17, 21, 23, 25

<i>Cochrane v. Badische Anilin & Soda Fabrik</i> , 111 U.S. 293 (1884)	17, 18
<i>Coleco Indus., Inc. v. Int'l Trade Comm'n</i> , 573 F.2d 1247 (C.C.P.A. 1978)	22
<i>DSU Medical Corp. v. JMS Co., Ltd.</i> , 471 F.3d 1293 (Fed. Cir. 2006)	9, 10
<i>Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.</i> , 259 F. 258 (6th Cir. 1919)	19, 23
<i>Ex parte Painter</i> , 1891 C.D. 200 (Comm'r Pat. 1891)	3, 16
<i>Gen. Elec. Co. v. Wabash Appliance Corp.</i> , 304 U.S. 364 (1938)	17, 19, 20
<i>Gomez-Astorga v. United States</i> , 2008 U.S. Dist. LEXIS 15808 (D. Utah Feb. 29, 2008)	6
<i>Goodyear Dental Vulcanite Co. v. Davis</i> 102 U.S. 222 (1880)	17, 18
<i>Helmsderfer v. Bobrick Washroom Equip., Inc.</i> , 527 F.3d 1379 (Fed. Cir. 2008)	28
<i>In re Bridgeford</i> , 357 F.2d 679 (C.C.P.A. 1966)	21-23
<i>In re Freeman</i> , 166 F.2d 178 (C.C.P.A. 1948)	21

<i>In re The Orion Co.</i> , 71 F.2d 458 (C.C.P.A. 1934)	22
<i>In re Thorpe</i> , 777 F.2d 695 (Fed. Cir. 1985)	23
<i>In re Violation of Rule 50</i> , 78 F.3d 574 (Fed. Cir. 1996)	9
<i>In re Von Clemm</i> , 229 F.2d 441 (C.C.P.A. 1955).....	22
<i>Lewmar Marine, Inc. v. Bariant, Inc.</i> , 827 F.2d 744 (Fed. Cir. 1987)	13, 14
<i>Lupin Ltd. v. Abbott Labs.</i> , 491 F. Supp. 2d 563 (E.D. Va. 2007)	1
<i>Mannington Mills, Inc. v. Armstrong World Inds., Inc.</i> , 218 F. Supp. 2d 594 (D. Del. 2002)	5
<i>Merrill v. Yeomans</i> , 94 U.S. 568 (1877)	17
<i>Midwest Industries, Inc. v. Karavan Trailers, Inc.</i> , 175 F.3d 1356 (Fed. Cir. 1999)	9, 10
<i>Newell Cos. v. Kenney Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988)	5
<i>O.I. Corp. v. Tekmar Co.</i> , 115 F.3d 1576 (Fed. Cir. 1997)	29
<i>Peters v. Active Mfg. Co.</i> , 129 U.S. 530 (U.S. 1889)	2, 12, 13

<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	10, 28
<i>Pickhardt v. Packard</i> , 22 F. 530 (C.C.D.N.Y. 1884)	18
<i>Plummer v. Sargent</i> , 120 U.S. 442 (1887)	17
<i>Scripps Clinic & Research Foundation v. Genentech, Inc.</i> , 927 F.2d 1565 (Fed. Cir. 1991).....	4, 24
<i>Sealed Air Corp. v. Int’l Trade Comm’n</i> , 645 F.2d 976 (C.C.P.A. 1981).....	22
<i>Smith v. Goodyear Dental Vulcanite Co.</i> , 93 U.S. 486 (1877)	17, 18
<i>SmithKline Beecham Corp. v. Geneva Pharms., Inc.</i> , 2002 U.S. Dist. LEXIS 25275 (E.D. Pa., Dec. 20, 2002)	5
<i>South Corp. v. United States</i> , 690 F.2d 1368 (Fed. Cir. 1982)	22
<i>Takeda Pharm. Co. v. Doll</i> , 561 F.3d 1372 (Fed. Cir. 2009)	16
<i>The Wood-Paper Patent</i> , 90 U.S. 566 (1874)	17
<i>Tropix, Inc. v. Lumigen, Inc.</i> , 825 F. Supp. 7 (D. Mass. 1993)	5

<i>Trs. of Columbia University v. Roche Diagnostics GmbH</i> , 126 F. Supp. 2d 16 (D. Mass. 2000)	4, 5
<i>Trussell Mfg. Co. v. Wilson-Jones Co.</i> , 50 F.2d 1027 (2d Cir. 1931)	20, 23
<i>White v. Dunbar</i> , 119 U.S. 47 (U.S. 1886)	14
<i>Yunus v. Dept. of Veterans Affairs</i> , 242 F.3d 1367 (Fed. Cir. 2001)	5

Constitutional Provisions

United States Constitution, Art. I, Sec. 8	1, 33
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Statutes, Rules and Regulations

28 U.S.C. § 1331	4
28 U.S.C. § 1338	4
28 U.S.C. § 1254(1).....	1
28 U.S.C. § 1295(a)(1).....	1
Fed. R. Civ. P. 11(b)(2)	6
Fed. R. App. P. 35(a)(2).....	8
21 C.F.R. § 314.53(c)(2)(i)(L).....	31
37 C.F.R. § 1.131	14

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 Treatment of Product-By-Process Patent
 Infringement*,
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 Waxman Context*,
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 Accelerated Market Entry of Generic Drugs: Is
 Faster Necessarily Better?*,
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49 U. Miami L. Rev. 233 (Fall, 1994) 3, 19, 26
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PETITION FOR *CERTIORARI*

Petitioner Astellas Pharma, Inc. (“Astellas”) respectfully seeks a writ of *certiorari* to the United States Court of Appeals for the Federal Circuit.

OPINION BELOW

The judgment of the Federal Circuit (en banc as to Section III(A)(2)) was entered on May 18, 2009. Due to an extension granted by the Chief Justice, this petition is due by September 16, 2009. The opinion of the court of appeals was reported at *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). App. 1-88. The opinion of the district court granting summary judgment was entered on June 14, 2007 and was reported at *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007). App. 89-103.

JURISDICTION

The judgment of the court of appeals, en banc as to Section III(A)(2), was entered on May 18, 2009. App. 1. On July 24, 2009, in Application 09A97, the Chief Justice extended the time to file the petition for *certiorari* until September 16, 2009. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1). The jurisdiction of the Federal Circuit was invoked under 28 U.S.C. § 1295(a)(1).

CONSTITUTIONAL PROVISION INVOLVED

The United States Constitution, Art. I, Sec. 8, states that “The Congress shall have 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.”

STATEMENT OF THE CASE

I. Introduction

This case is without precedent. Here, the Federal Circuit *sua sponte* and over dissenting opinions went en banc and decided an important patent law issue with no notice to the public. In deciding that product-by-process “claims are treated as process claims for infringement,” App. 81 (Newman, J., dissenting), the Federal Circuit devalued thousands of active patent claims and overturned 110 years of direct precedent that held that product-by-process claims do cover the product, regardless of how made. Worse still, the Federal Circuit violated the Court’s precedent, which requires claims to be interpreted the same way for both infringement and invalidity. As the Court held 120 years ago, “[t]hat which infringes, if later, would anticipate, if earlier.” *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). The holding put forward by the en banc court here violates that rule, in that now a product described in a product-by-process claim will anticipate if earlier (even if the process used to create it is different from the process in the claim), but will *not* infringe if later (if the process used to create it is different from the process in the claim). Accordingly, the Court should grant the petition for *certiorari* and decide if it was proper for the Federal

Circuit to decide that this Court's binding precedent does not apply to an entire class of claims.

“In a product-by-process claim, a product is protected, even though the product is described by the process that produces it.” Mark D. Passler, Comment, *Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. Miami L. Rev. 233, 234 (Fall, 1994). By no later than 1891, the United States Patent Office had officially recognized that a product may be claimed by the process that makes that product (a “product-by-process” claim). *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm’r Pat. 1891). Nevertheless, the Federal Circuit ignored that precedent, along with the Court’s precedent, and decided to take away an inventor’s right to claim a product by the process that makes that product (unless the product is made by the exact process described). In addition, its decision to go en banc with no notice to the public that it was overturning its own precedent on this issue violated its own procedural rules by not giving interested third parties a chance to comment. Thus, third parties lost the opportunity to demonstrate that product-by-process claims are even more important in the 21st century than they were in the 19th century, when they were first allowed.

II. Proceedings Below

Astellas is the assignee of U.S. Patent No. 4,935,507 (“the ‘507 patent”). The claims of the ‘507 patent are directed to certain crystalline forms of a compound known generically as cefdinir.

On June 14, 2007, the United States District Court for the Eastern District of Virginia granted summary judgment of non-infringement to Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”). The bases for that court’s jurisdiction were 28 U.S.C. §§ 1331 and 1338.

The lower court found that Lupin did not infringe claims 2-5 (the only claims at issue) because Astellas did not present evidence that Lupin’s product was made by practicing the processes set forth in claims 2-5. App. 96, 101-102. The lower court based its holding on *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), which held that a product-by-process claim is only infringed by a product that is made by the process described in the claim. *Id.* at 846-47. In so ruling, the *Atlantic* panel attempted to overrule *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), which had held just one year previously that a product-by-process claim is infringed by a product that is the same as the product described in the product-by-process claim, regardless of the process used to make the product. *Id.* at 1583.

Astellas appealed the lower court’s decision to the Federal Circuit, which *sua sponte* went en banc to decide the product-by-process issue and then affirmed the lower court’s decision. The one thing that may be said about the Federal Circuit’s en banc decision is that it finally resolved the intra-circuit split between *Scripps* and *Atlantic*. With conflicting precedent, some district courts correctly followed

Scripps, see, e.g., *Trs. of Columbia University v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 31-32 (D. Mass. 2000); *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 2002 U.S. Dist. LEXIS 25275, *16 (E.D. Pa., Dec. 20, 2002); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 372 F. Supp. 2d 430, 436 (D. N.J. 2005); *Mannington Mills, Inc. v. Armstrong World Indus., Inc.*, 218 F. Supp. 2d 594, 600 (D. Del. 2002); and some district courts (such as the one in this case) incorrectly followed *Atlantic*. See, e.g., *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 10 (D. Mass. 1993). The reason it was correct for the district courts to follow *Scripps* and incorrect for the district courts to follow *Atlantic* is not because *Scripps* was correctly decided and *Atlantic* was incorrectly decided (although they were), but rather because the Federal Circuit follows the well-established rule that “[w]here there is a direct conflict [between decisions of the Federal Circuit], the precedential decision is the first.” *Yunus v. Dept. of Veterans Affairs*, 242 F.3d 1367, 1372 n.2 (Fed. Cir. 2001) (internal quotation omitted). Thus, unless and until overturned by the en banc Federal Circuit, *Scripps* remained “good law.” *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) (“prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned en banc”).

Now, of course, due to the Federal Circuit’s *sua sponte* decision to go en banc and overturn *Scripps*, that case is no longer “good law.” But, as the dissent noted, before overturning 110 years of precedent, at the very least, the Federal Circuit should have followed its own procedures and

publicized the fact that it was considering whether to change the law on product-by-process claims. But it failed to do so. Accordingly, numerous patent holders, including pharmaceutical and biological companies, were precluded from explaining why it is critical to their industries that product-by-process claims cover the product described and not the process used to make that product.

The law is now very clear that a product-by-process claim no longer covers the product, unless that product was made by the process described in the claim. Because the Federal Circuit has spoken clearly on this issue, it would not be proper for a party to even raise in a district court that a product-by-process claim covers a product made by a different process. *See* Fed. R. Civ. P. 11(b)(2). At most, a party could raise this argument before the district court and explain that, while the district court must follow precedent, the party is reserving the issue so that it can ask the Federal Circuit to go en banc again to reconsider the issue it just decided here, or seek a writ of *certiorari* to the Court regarding this issue. *Cf. Gomez-Astorga v. United States*, 2008 U.S. Dist. LEXIS 15808, *7 (D. Utah Feb. 29, 2008) (where issue was “foreclosed by clear precedent,” the appeal was brought “only to preserve the issue on *certiorari* to the United States Supreme Court”). But considering that the Federal Circuit just decided this issue en banc, after letting the clear intra-circuit split fester on this issue for over 17 years, there is virtually no chance that the Federal Circuit would rehear this issue any time in the foreseeable future.

Finally, because the Federal Circuit has turned product-by-process claims into virtually pure process claims (albeit with an additional hurdle to cross because for patentability the patentee must prove the product is new, while for infringement purposes the relevant consideration is the process), there will be little point in patentees seeking product-by-process claims. Therefore, there will likely be few product-by-process claims for any court to review after the current product-by-process claims all expire within the next twenty years. Thus, for all practical purposes, this case will be the last chance for this Court to decide (and the public to comment on) whether the Federal Circuit properly overturned 110 years of precedent to turn product-by-process claims into little more than process claims.¹

REASONS FOR GRANTING THE PETITION

Judge Newman, the author of *Scripps*, had some very specific criticisms of the majority opinion, which was written by Judge Rader, the author of *Atlantic*. These criticisms were in five main categories. As each of Judge Newman's criticisms

¹ In addition, there would be no advantage for the Court to wait to decide this issue in some future case because 1) as the en banc court has clearly spoken on this issue, there should be little or no change to the law of product-by-process claims going forward, and 2) as the district court and a Federal Circuit panel will have no choice but to hold that product-by-process claims do not cover the product, there will probably be much less briefing and discussion on this issue in any future case (assuming *arguendo*, that there is even a future case that addresses this issue).

are correct, the Court should grant this petition and review the Federal Circuit's en banc opinion.²

I. By Failing to Follow Its Own Procedures, the En Banc Majority Took Away an Entire Class of Patents without Receiving Any Input from the Public

Judge Newman's first criticism was the Federal Circuit's failure to follow its own procedures for hearing cases en banc. According to Petitioner's research, in the last twenty years, it appears that the Federal Circuit has decided cases en banc approximately sixty times, about three times per year. En banc cases are heard so infrequently because such cases are reserved for only "question[s] of exceptional importance." Fed. R. App. P. 35(a)(2). Because these cases are so important, the Federal Circuit's Internal Operating Procedures ("IOP") require the court to tell the public the issues it is deciding en banc so that the public may file amicus briefs regarding those issues. IOP 14.3(c).

There appear to be two reasons why the Federal Circuit Internal Operating Procedures require notice to the public. First, as in this case, decisions by the en banc court may affect thousands of currently issued patents, and thus members of the public who could be affected by those decisions should be allowed to comment before any rules change. Second, decisions by the en banc court as they relate to patent law are generally final, due to

² In addition, as discussed *infra* in section VI, there are important public policy reasons for granting the petition.

the Federal Circuit's exclusive appellate jurisdiction over patent law. Indeed, in the last twenty years, it appears that this Court has granted a petition for *certiorari* from an en banc holding of the Federal Circuit only eight times.

Consequently, the Federal Circuit virtually always announces when it is going to rule en banc to give the public a chance to comment on the issue the Federal Circuit is considering. It is true, however, that its internal operating procedures state that the Federal Circuit is not bound by those procedures. IOP 1. It is also true that this is not the first case where the Federal Circuit *sua sponte* and without notice to the public decided a case related to patent law en banc. Petitioner's research appears to show that there have been two such cases out of the approximately sixty cases decided en banc by the Federal Circuit in the last twenty years.³ Those cases are *Midwest Industries, Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (en banc in part, *overruled on other grounds*), and *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc in part). In both cases, there was not a single dissent. Thus, with unanimity on that court, briefs from the public would probably have been an exercise in futility.

³ In the last twenty years there also have been a few other cases not related to patent law where it appears that the Federal Circuit *sua sponte* decided cases en banc without previous notice to the public. *See, e.g., In re Violation of Rule 50*, 78 F.3d 574 (Fed. Cir. 1996) (en banc) (deciding, over one dissenter, whether a former law clerk improperly practiced before the Federal Circuit).

Moreover, the issues decided en banc in those cases did not involve a ruling that would virtually invalidate an entire class of patent claims. In *Midwest*, the Federal Circuit decided the limited question that it would use its own law “in resolving questions involving the relationship between patent law and other federal and state law rights.” *Midwest*, 175 F.3d at 1358-59. In *DSU*, the Federal Circuit merely clarified that to prove inducement of infringement “[t]he plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts and that he knew or should have known his actions would induce actual infringements.” *DSU*, 471 F.3d at 1304.

Thus, there appears to have been exactly *one case* (this case) where the Federal Circuit *sua sponte* decided an important issue of patent law over dissenting judges and did not give the public a chance to brief the issue. Such a procedure, in violation of its own rules, especially in a case where it made thousands of patent claims virtually worthless, was improper. The Court should grant the petition and hear this case so that the holders of those now virtually worthless patent claims will have a chance to comment on this issue.

In addition, not only was the public at large precluded from commenting on this issue, but so was Petitioner. In its briefing to the Federal Circuit, Astellas’ main focus was not on whether *Atlantic* was correctly decided because *Scripps* remained “good law.” Instead, Astellas focused its main argument on the fact that *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), “sets forth

the proper analysis for interpretation of *all* claims, without making any special exception for product-by-process claims and, thus, there was never any need to choose between *Scripps* and *Atlantic*.” Astellas Opening Brief at 3 (emphasis in original).

If the Federal Circuit had followed its own procedures and informed Astellas that it was deciding this issue en banc, Astellas would have never stated that “there was never any need to choose between *Scripps* and *Atlantic*” because obviously the new en banc opinion would, in fact, “choose between *Scripps* and *Atlantic*.” Therefore, because the Federal Circuit failed to follow its own procedures, Astellas lost its right to focus its argument on why the en banc court should follow *Scripps* and not *Atlantic*.

II. The En Banc Majority Erred in Deciding that Product-by-Process Claims Are to Be Interpreted Differently for Validity than for Infringement

The most important error in the majority’s analysis is the fact that claims are now interpreted differently for validity purposes than for infringement purposes. As Judge Newman explained, a product-by-process claim is now a *product claim* when the Patent Office is deciding whether it is patentable, and is “subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made.” App. 82. But a product-by-process claim is now a “*process claim*[] for infringement.” *Id.* 82 (emphasis added). Thus,

“[f]or the first time, claims are construed differently for validity and for infringement.” *Id.* at 81.

It is one of the oldest maxims in patent law, however, that claims are to be interpreted the same for infringement as for validity. As the Court explained 120 years ago: “That which infringes, if later, would anticipate, if earlier.” *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). This maxim has been followed repeatedly by the Federal Circuit. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (“claims are construed the same way for both invalidity and infringement”); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (“the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses”); *see also* Donald S. Chisum, *5A Chisum on Patents §18.01* (2007) (“A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity”). Indeed, one law professor commenting on the majority opinion stated that “[i]t doesn’t make sense to have the same claim language mean different things for infringement and validity purposes.” Steven Seidenberg, *Process Perils: Ruling Narrows the Protection for Product-by-Process Patents*, Inside Counsel at 23 (Aug. 2009) (“*Process Perils*”) (quoting University of Michigan Law professor, Rebecca Eisenberg).

Judge Rader’s majority opinion ignores the dissent’s argument. But, in his original *Atlantic* opinion, Judge Rader freely admitted that the

Federal Circuit's new rule led to one claim interpretation for validity and another for infringement when he stated that "even though product-by-process claims are limited by and defined by the *process* [for infringement], determination of patentability [validity] is based on the *product* itself." *Atlantic*, 970 F.2d at 845 (emphasis added). He further expounded on this issue in his concurrence to the denial of rehearing en banc in *Atlantic* when he stated that the Supreme Court cases he discussed were not limited to old products because "[i]n its infringement rule, the [Supreme] Court did not presume to address patentability concerns like those in 35 U.S.C. §§ 102 [anticipation], 103 [obviousness]." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1299, 1303 (Fed. Cir. 1992) (Rader, J., concurring) ("*Atlantic Concurrence*"). That is an incorrect statement of patent law.

The Court does not treat infringement separate from anticipation and obviousness. As the Court held, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters*, 129 U.S. at 537. The majority's new standard for product-by-process claims violates that binding precedent. Now, a product that "anticipate[s], if earlier" because it is the same product described by the product-by-process claims *does not* "infringe if later," if it is made by a different process.⁴ Thus, the majority's

⁴ Based on a statutory change, the "classic test" put forth in *Peters* has now changed slightly. The Federal Circuit has explained that the "classic test" must be modified to: That which would *literally* infringe if later in time anticipates if earlier than the date of invention." *Lewmar Marine, Inc. v.*

new rule for product-by-process claims can lead to absurd results. For example, in some cases, juries must decide whether a defendant's product was made (regardless of the process used) before the critical date of a patent. Under the Court's binding precedent, if the jury decides the product was made before, it anticipates; and if the product was made after, it infringes.⁵ But that simple rule has been turned on its head by the rule put forward by the en banc majority. Now, if the product was made by a different process than claimed in the patent, and the jury found the product was made before the critical date, it must also find that the product *anticipates* the patented claim. On the other hand, if the jury found the product was made after the critical date, it must also find that the product *does not infringe* the product-by-process claim.

Long ago, the Court explained that a patent claim is not "a nose of wax which may be turned and twisted in any direction," to be interpreted different ways. *White v. Dunbar*, 119 U.S. 47, 51 (U.S. 1886). Here, the majority opinion renders a patent claim as "a nose of wax," twisting and turning the language of the claim to give it one meaning for infringement and an entirely different meaning for validity. Thus,

Bariant, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added).

⁵ This example assumes that the patentee conceived of the invention by the critical date and diligently worked on reducing the invention to practice. *Cf.* 37 C.F.R. § 1.131 (discussing prerequisites for swearing behind a reference that is less than one year before the priority date).

Professor Eisenberg stated that the majority's decision here will not "fly in the long run" due to the fact that claim language now "mean[s] different things for infringement and validity purposes." *Process Perils* at 23. But unfortunately the decision of the en banc court will "fly in the long run" unless the Court grants this petition for *certiorari*. Consequently, the Court should grant the petition for *certiorari* to decide whether it was proper for the Federal Circuit to contradict its binding precedent with its new product-by-process rule.

III. The En Banc Majority Erred in Deciding that There Should Be a Single Rule for Product-by-Process Claims Regardless of Whether the Product Claimed Was Old or New

Judge Newman explained that this Court's precedent firmly recognized "that when the product was old and only the process was a patentable invention, a claim for the 'product of that process' could not cover the old product made by a different process." App. 65. She noted, however, that the majority opinion ignored the difference between old products and new products. *See id.* at 53-54, 67.

Although the majority opinion was also silent on this issue, Judge Rader did address this exact issue in his *Atlantic Concurrence*. In that concurrence, Judge Rader correctly stated that "[a patentee] could not acquire product patent rights under [a claim] by merely adding new process limitations to an old product." *Atlantic Concurrence*,

974 F.2d at 1302. Such a claim would merely be a process claim, not a product-by-process claim.⁶

Where Judge Rader went astray, however, is when he claimed that “any attempt to limit the Supreme Court’s rule to cases involving old products fails.” *Id.* at 1303. But as discussed *infra*, every case where the Court found that a patented claim was not infringed because the process was not used was either a process claim or involved an old product. There is not a single Supreme Court case that involved a product-by-process claim on a new product. Moreover, Judge Rader’s statement ignores over 110 years of precedent. In 1891, the Patent Office explicitly explained that when “an article of manufacture is a *new thing*, . . . 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” that “an article of manufacture should not be defined by the process of producing [it].” *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm’r Pat. 1891) (emphasis added).

In addition, Judge Rader’s claim that whether a product is new or old is irrelevant ignores this Court’s guidance. Judge Rader did not mention *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141 (1989), the *only* case from the Court that uses the term “product-by-process.” The Court stated that

⁶ A process claim may be granted on a process for making an existing product as long as “the product as claimed can be made by another materially different process.” *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (internal quotation omitted).

“[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*.” *Id.* at 159 n.* (emphasis added). Thus, this Court’s precedent clearly demonstrates that Judge Rader was wrong when he claimed that whether a product is new or old is irrelevant.

IV. The En Banc Majority Erred in Its Analysis of the Precedent of This Court and Other Courts

Although Judge Rader ignored the most relevant binding precedent from this Court, he claimed that other opinions of this Court compel the holding of the majority. In particular he pointed to *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) (“BASF”); *The Wood-Paper Patent*, 90 U.S. 566 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938). Although Judge Rader claimed that in each of “these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations,” App. at 19, he only provided analysis regarding the *BASF* case. *Id.* at 21.

But Judge Rader’s analysis is flawed because *BASF* did *not* involve a product-by-process claim. Judge Rader stated that the product at issue in that case was “artificial alizarine,” *id.*, and that “artificial alizarines were known in the prior art.” *Id.* at 20.

Thus, the product at issue in *BASF* was not a new product; therefore, the only possible patentable invention would be a new process for making that product.⁷ But a “process” patent is not a “product-by-process” patent. In addition, the process claim at issue was found not infringed because “it does not satisfactorily appear that the process . . . will produce the defendants’ article to any useful extent, if at all.” *BASF*, 111 U.S. at 306. Therefore, *BASF* provides no guidance on the correct interpretation of “product-by-process” claims.⁸

Two other cases that the majority mentioned in passing as supporting its holding are the *Goodyear* cases: *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880). But as the dissent explains, neither case supports the majority because they were not product-by-process claims, but rather process claims. App. 70.

⁷ Indeed, that was the holding in *BASF*. The product at issue “was an old article. While a new process for producing it was patentable, the product itself could not be patented.” *BASF*, 111 U.S. at 311.

⁸ Interestingly, *BASF* was involved in a true product-by-process case the same year that the Court decided *BASF*. *Pickhardt v. Packard*, 22 F. 530 (C.C.S.D.N.Y. 1884). The claim in *Pickhardt* was: “As a new manufacture, the coloring matter . . . obtained from [a process] . . . or by any other method which will produce a like result.” *Id.* at 531. The *Pickhardt* court properly found that the defendant infringed that claim because even though there was no evidence regarding the process used by the defendant, any process that “produce[d] like results” to the patented product infringed the claim. *Id.* at 531.

Although the majority's analysis of the *Goodyear* cases is wrong, it is not unprecedented. Apparently, one of the defendants in *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), made the exact same argument. In *Dunn*, the circuit court used the same reasoning as the *Scripps* court, albeit 62 years earlier, and held that a product-by-process claim is infringed based only on the product being identical, even if the process used is different. That court held that it was irrelevant that "[t]he defendants' product is the result of a two-step wire-cutting process[, even though] plaintiff's patent describes a one-step process for making his product." *Id.* at 263. Moreover, that court explicitly rejected the majority's argument here that the *Goodyear* cases stand for the proposition "that a patent for a product is to be confined to the result of the described process." *Id.* at 261 n.2. Instead that court correctly held (as the dissent explained here) that infringement was not found in the *Goodyear* cases because "[n]othing which was not made by the process of vulcanization could be the equivalent of the 'hard rubber or vulcanite' of the claim." *Id.* (emphasis added).

The majority also cited to *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938) as support for its holding. But that case is also irrelevant because, as Judge Newman explained, it "involved no product-by-process claims, but rather claims that recite the properties of the product." App. 75; accord Passler, 49 U. Miami L. Rev. at 248 ("the claim in *General Electric* was a product claim").

Moreover, that case actually demonstrates that the majority opinion is directly contrary to the Court's precedent because the Court explicitly stated that "a claim may validly describe a new product with some reference to the method of production." *General Electric*, 304 U.S. at 373. In support of that statement it approvingly cited to two circuit cases, *Dunn* (discussed *supra*) and *Trussell Mfg. Co. v. Wilson-Jones Co.*, 50 F.2d 1027 (2d Cir. 1931), which both had held that product-by-process claims cover the product, and not the process.

In *Trussell*, the defendant argued that the claims were invalid due to "the claims [] being of a hybrid character, neither for a product nor for a process, but an attempt to define the article by the method of its manufacture." *Id.* at 1029. That court rejected the defendant's argument because while "an old article cannot be patented by claiming it as the product of a new process . . . if the article is new, it may be patented, and the claim will not be invalidated merely because it describes the article with some reference to the method of producing it." *Id.*

As stated *supra*, the majority opinion included a "laundry-list" of other Supreme Court cases, albeit with no analysis of why those cases are relevant.⁹ App. 18-19. The majority did not, however, mention the *only* case from the Court that uses the term

⁹ Judge Newman, in her dissent, ably explains why none of these other Supreme Court cases support the majority's decision, *see* App. 68-77; therefore, Astellas will not repeat her analysis here.

“product-by-process.” *Bonito*, 489 U.S. at 159 n.*. In *Bonito*, the Court analogized the Florida statute at issue in that case to a “product-by-process patent.” *Id.* It noted that 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.* (quoting Donald S. Chisum, *Chisum on Patents* §8.05, 8-67 (1988)). The Court then 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.” *Id.* Thus, when there is “a patent in the resulting product,” one who makes such a product (regardless of the process used for making that product), would infringe that product claim. Thus, the majority’s opinion cannot be squared with this Court’s only direct statement on product-by-process claims.

In addition to Supreme Court cases, the majority also included a few cases from the Court of Customs and Patent Appeals and circuit court cases. Once again, the dissent ably explains why these other cases do not support the majority’s opinion, and Astellas will not repeat that analysis here. *See* App. 50-57, 77-80. But Astellas will briefly discuss *In re Bridgeford*, 357 F.2d 679, 683 n.5 (C.C.P.A. 1966). Although cited by the majority, *Bridgeford* directly contradicts the majority’s opinion. That court explained that for a product-by-process claim “the invention so defined is a product and not a process.” *Id.* at 682. In so holding, that court overruled the suggestion in *In re Freeman*, 166 F.2d 178, 181 (C.C.P.A. 1948), that product-by-process

claims are actually process claims. *Bridgefords*, 357 F.2d at 683 n.6.

Apparently because it did not agree with the holding of *Bridgefords*, the majority found it necessary to belittle the Court of Customs and Patent Appeals by claiming that it was “a court with virtually no jurisdiction to address infringement litigation.”¹⁰ App. 23. That statement is incorrect because the C.C.P.A. regularly heard appeals of infringement cases coming from the International Trade Commission and its predecessor tribunals. *See, e.g., In re The Orion Co.*, 71 F.2d 458, 460-65 (C.C.P.A. 1934) (affirming the Tariff Commission’s decision to embargo certain products for infringing a U.S. patent); *In re Von Clemm*, 229 F.2d 441, 445 (C.C.P.A. 1955) (affirming “the findings and recommendation of the Tariff Commission” after performing a detailed infringement analysis); *Coleco Indus., Inc. v. Int’l Trade Comm’n*, 573 F.2d 1247, 1257-58 (C.C.P.A. 1978) (affirming the decision of the ITC after performing a detailed infringement analysis); *Astra-Sjuco, A.B. v. Int’l Trade Comm’n*, 629 F.2d 682, 686-88 (C.C.P.A. 1980) (same); *Sealed Air Corp. v. Int’l Trade Comm’n*, 645 F.2d 976, 983-85 (C.C.P.A. 1981) (same).

The majority then claimed to find “ambivalence” in *Bridgefords*’s holding because that court stated that “some courts have construed such

¹⁰ It is ironic that the majority belittled the Court of Customs and Patent Appeals because the Federal Circuit voluntarily chose to make that court’s precedent binding on the Federal Circuit. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc).

claims as covering only a product made by the particular process set forth in the claim and not to the product per se.” App. 24 (quoting *Bridgeford*, 357 F.2d at 683 n.5). The majority then made the incorrect claim that the term “some courts’ . . . as this court notes en banc, includes the United States Supreme Court and *every circuit* court to consider the question.” App. 24 (emphasis added). Not only has the United States Supreme Court not addressed this question but, as shown by *Dunn* and *Trussell*, at least the second and sixth circuits did *not* “construe such claims as covering only a product made by the particular process set forth in the claim.” *See Dunn*, 259 F. at 265; *Trussell*, 50 F.2d at 1029.

The majority also quotes *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) for the proposition that “product-by-process claims are limited by and defined by the process.” App. 20. But again, although the language used was not as precise as it might have been, *Thorpe* was addressing an old product made by an allegedly new process and its holding was that “[i]f the *product* in the product-by-process claim *is the same* as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *Id.* at 697 (emphasis added). Indeed, this Court rejected the majority’s interpretation of *Thorpe*, when it explained that, in *Thorpe*, the “product-by-process patent [was] properly denied where [the] *end result* was indistinguishable from prior art.” *Bonito*, 489 U.S. at 159 n.* (emphasis added). Thus, whether the process in the product-by-process claim was a claim limitation was never at issue in *Thorpe*.

As shown above, the case law that the majority cited not only does not support the majority, but instead, it actually supports the dissent. Moreover, this case is much more than the typical disagreements that occur in contested opinions, where the majority describes cases one way, the dissent describes cases the other way, and the petitioner agrees with the dissent. While that is certainly true here, there is an additional factor.

The arguments made by Judge Rader in his majority opinion are virtually identical to the arguments he made in both his *Atlantic* and *Atlantic Concurrence* opinions. See App. 17-20 (citing *Atlantic* for its “discuss[ion] of each of the [Supreme Court] cases” listed in the en banc opinion and stating that it would “adopt[] the rule in *Atlantic*”). Similarly, the arguments that Judge Newman made in her dissent are virtually identical to the arguments in her opinion in *Scripps* and in her dissent from the denial of granting rehearing en banc in *Atlantic*. Compare App. 50-60, 66-80 (explaining that the majority’s holding is not supported by the Supreme Court cases, the circuit court cases and the C.C.P.A. cases that the majority cites and further explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) with *Scripps*, 927 F.2d at 1583 (explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) and *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279, 1285-93 (Fed. Cir. 1992) (Newman, J., dissenting) (explaining that *Atlantic*’s holding is not supported by the Supreme Court cases, the circuit

court cases and the C.C.P.A. cases that *Atlantic* cites and further explaining that *Bridgford* and *Thorpe* demonstrate that product-by-process claims cover the product).

In the seventeen years since the *Atlantic* opinions, dozens of law review articles have been written about product-by-process claims and the different interpretations of those claims by Judge Rader and Judge Newman. As one commentator explained:

The *Atlantic* opinion is *problematic* in several respects. First, the *Atlantic* panel took language from Supreme Court and C.C.P.A. opinions *out of context*. . . . [In addition o]ften, the courts have made broad assertions in dicta that are not entirely accurate. The *Atlantic* decision relies heavily on this dicta in concluding that product-by-process claims are limited by the process described therein in all cases. The dicta relied on by the *Atlantic* panel, however, primarily involved claims in which a new process was applied to an old or obvious product. Most of the Supreme Court cases on this issue involved old products which could only be distinguished from the prior art by the method used to create the product. In these situations, the invention is the process, not the product.

Michael J. Schutte, *Patent Law: Controversy in the Federal Circuit Over Product-By-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp. . . .*, 19 Dayton L. Rev. 283, 307-8 (Fall, 1993) (emphasis added).

Indeed, the majority of commentators agree with Mr. Schutte and find that Judge Newman's analysis is much more accurate, especially when it comes to reviewing the Supreme Court precedent, than is Judge Rader's analysis.¹¹ Thus, this is not merely a case of "he said/she said" (with the petitioner joining in with "she said"), but rather numerous independent third parties have already

¹¹ See, e.g., Passler, 49 U. Miami L. Rev. at 248 ("The Atlantic Thermoplastics analysis of Supreme Court precedent was erroneous."); Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693, 1726 (Winter, 1995) ("The Supreme Court precedent gathered by Judge Rader does not support the proposition that the Court intended to limit a product-by-process claim's scope to the process and the product made by that process."); Alan I. Cohen, Note, *A Prescription for the Treatment of Product-By-Process Patent Infringement*, 67 St. John's L. Rev. 923, 932 (Fall, 1993) ("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"); William E. McGowan, Comment, *Patent Law – Limiting Infringement Protection for Product-by-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), 27 Suffolk U. L. Rev. 300, 307 (Spring, 1993) ("By failing to make a distinction between [cases discussing old and new products], the *Atlantic* court may have erroneously narrowed the scope of infringement protection of product-by-process claims for novel and non-obvious products.").

weighed in that the majority opinion here is wrong as a matter of law because that opinion is virtually identical to the opinion in *Atlantic*. Consequently, the Court should grant the petition for *certiorari* to decide whether the en banc opinion conflicts with the Court's precedent.

V. The En Banc Decision Necessitated that the Panel Improperly Rewrite the Claims

As both of the dissenting opinions noted, the error in the majority's opinion is further demonstrated by its treatment of the phrase "obtainable by."¹² The two independent claims at issue in this petition are claims 2 and 5, which state:

2. Crystalline [cefdinir] which is *obtainable by* acidifying a solution containing [cefdinir] at room temperature or under warming.
5. Crystalline [cefdinir] which is *obtainable by* dissolving [cefdinir] in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room

¹² This section of the opinion is not part of the en banc section, but it directly flows from the en banc's ruling, which is why both of the dissents discussed this issue. *See* App. 83-84 (Newman, J., dissenting); App. 88 (Lourie, J., dissenting).

temperature and allowing the solution to stand.

App. 7 (emphasis added).

The majority opinion simply ignored that the patent claimed cefdinir “which is *obtainable* [by a process],” and instead improperly redefined the claim to cover cefdinir “which is *obtained* [by a process].” *See* App. 29. Here, the “plain import” of the claims could not be more clear. The starting point for claim construction is the words of the claim. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). “Obtainable” has a well-known plain meaning. It is defined, according to Webster’s, as “capable of being obtained.” Webster’s Third New International Dictionary at 1559 (1993). It does not mean “obtained by.” The majority, however, contended that it was proper to rewrite “obtainable by” to “obtained by,” because otherwise claims 2 through 5 would be duplicative of each other. *See* App. 28. But the majority is incorrect for two reasons. First, “[c]ourts cannot rewrite claim language.” *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008). Second, inventors have the right to define their invention how they choose. As the majority noted, it can be difficult to prove infringement for product-by-process claims. Therefore, Astellas chose to claim multiple processes because if a defendant’s product was made by any of the claimed processes, there would be few, if any, evidentiary issues regarding infringement. If, on the other hand, the defendant’s product was made by a different process, Astellas could still prove infringement if it could show that

the product was the same as the product described in its product-by-process claims. In any event, even if the panel was right that claims 2 and 5 are duplicative of each other, the clear language of the claims “trumps the doctrine of claim differentiation.” *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997).

Moreover, the Federal Circuit’s unilateral decision to decide that “obtainable by” actually means “obtained by” puts thousands of current patents at risk. Indeed, in the last twenty years, Petitioner’s research demonstrates that over 11,000 patents have claims that include the phrase “obtainable by.”¹³ The Court should grant the petition to decide whether it was proper for the Federal Circuit to emasculate product-by-process claims.

VI. Product-by-Process Patents Promote the Progress of Science

The majority opinion claimed that, due to increasingly sophisticated technology, product-by-process claims may no longer be necessary because few structures will be “too complex to analyze.” App. 25. That statement is incorrect. Indeed, product-by-

¹³ A search in the Lexis “Utility, Design and Plant Patents” database using the search term “obtainable by” in the segment “claims” for patents issued between August 26, 1989, and August 26, 2009, identified over 11,000 patents with claims including the term “obtainable by.” As patent terms are generally twenty years from the date of filing, the vast majority of those patents are still in effect.

process claims are more important now than they have ever been because the “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.” Cohen, 67 St. John’s L. Rev. at 936.

Many of the latest chemical claims and biotechnology claims such as “recombinant DNA and molecular purification” can only be patented “by reference to the process used to manufacture [them]-i.e., by using [] product-by-process claim[s].” Tomko, 60 Brooklyn L. Rev. at 1698; *see also* Kevin J. McGough and Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology Inventions*, 6 Harv. J. Law & Tec. 85, 101 (Fall, 1992) (“Since further innovation will require great expense and laborious research, investors need reasonable assurances that expansive product or product-by-process patent protection will facilitate attractive returns on investment. This is particularly true regarding . . . DNA sequence claims and claims to host cells.”). Biotechnology companies may be particularly affected by the majority’s holding:

Given the exorbitant expense incurred in researching and developing new products, the biotechnology industry depends upon patent protection for newly developed pharmaceuticals. Because some products of biotechnology are incapable of independent structural definitions, patentees often opt to claim these products using product-by-process

language. In *Atlantic* [and by extension the majority's holding here], the Federal Circuit impairs the biotechnology industry's ability to obtain patent protection by narrowly construing the scope of infringement protection of product-by-process claims as applying only to the specific manufacturing process of the drug.

McGowan, 27 Suffolk U. L. Rev. at 308.

Moreover, product-by-process claims have become so important that the FDA now allows product-by-process claims to be listed in the Orange Book for new drugs.¹⁴ Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 Duke L. & Tech. Rev. 18 (Aug. 2003) ("Product-by-process patents are listable in the Orange Book; . . . [provided] that the patent being submitted is a product-by-process patent in which the product claimed is novel, as opposed to the process being novel . . . [because] process patents . . . cannot be submitted for listing"); see 21 C.F.R. § 314.53(c)(2)(i)(L) (a product-by-process patent may be listed if "the product claimed is novel").

But the Federal Circuit's decision here contradicts the FDA's decision. The FDA allowed

¹⁴ The "Orange Book" is the colloquial name given to the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 631, 634 (Fall, 2007).

product-by-process claims explicitly because they are claims for products, not processes, as process patents can not be included in the Orange Book. *Id.* Thus, if the Court does not review the decision here, numerous product-by-process patent claims may lose their protection of being listed in the Orange Book.

Finally, Judge Rader's contention that inventors may still "stake claims in product-by-process terms," App. 23, will bring cold comfort to pharmaceutical or biological researchers who have uncovered a new important product, but are not able to accurately describe the structure of that important product. Because the only part of the claim the Federal Circuit will protect is the process, the researchers would most likely file a process claim, rather than what one commentator called "a glorified process patent."¹⁵ *See Tomko*, 60 Brooklyn L. Rev. at 1696 ("the *Atlantic* panel pared the scope of a product-by-process patent to that of a glorified process patent"). Thus, the researchers may lose the fruits of their valuable research when "a competing biotechnology company [] pirate[s the] pharmaceutical product patented by a product-by-process claim by slightly altering the method of manufacturing the drug." McGowan, 27 Suffolk U. L. Rev. at 308.

The United States Constitution, Art. I, Sec. 8, Clause 8 maintains that patents "promote the

¹⁵ Indeed, in some respects, product-by-process claims are less than "glorified process patents" because not only must the patentee prove that the alleged infringer practices the process claimed, but then must also prove that the resulting product is, in fact, the product claimed.

progress of science . . . by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.” (Initial Capitalization omitted).
“Product-by-process claims fill an important gap in patent law by furnishing an inventor who cannot describe her invention in terms precise enough to gain a conventional product patent with the means to gain the same protection.” Tomko, 60 Brooklyn L. Rev. at 1738. Thus, product-by-process patents that provide strong protection for the product described are an important part of “promot[ing] the progress of science.” As such, the Court should grant the petition for *certiorari* to decide whether the Federal Circuit’s weakening to the point of destroying product-by-process claims complies with the Court’s precedent and is in the nation’s interest.

CONCLUSION

For the foregoing reasons, the petition for *certiorari* should be granted.

Respectfully submitted,

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