No. 09-335

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

RESPONDENTS' BRIEF IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit correctly concluded that Lupin did not infringe Astellas' patent claims, when (1) the lower courts held, and Astellas does not dispute here, that by its terms, the patent did not encompass the product produced by Lupin, and (2) Astellas conceded that Lupin's products were never made using the process steps that the patent claims required?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

The parties to this proceeding are: Petitioner/ Appellant Astellas Pharma, Inc. and Respondents/ Appellees Lupin Limited and Lupin Pharmaceuticals, Inc. Abbott Laboratories, an appellant below, to date has neither joined Astellas' petition nor filed its own petition.

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 and was an appeal of a denial of a preliminary injunction to plaintiffs Astellas Pharma, Inc. and Abbott Laboratories 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.

Respondent/Appellee Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Respondent/Appellee Lupin Limited. There is no public corporation that owns 10% or more of the stock of respondent Lupin Limited.

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STATEMENT OF THE CASE

I. Introduction

Petitioner holds a patent for a crystalline form of the antibiotic cefdinir ("the '507 patent"). As relevant here, there are two forms of crystalline cefdinir, commonly known as "Crystal A" and "Crystal B." Petitioner's licensee, Abbott, markets Crystal A under the brand-name "Omnicef." Respondent's generic version is almost exclusively Crystal B. Pet. App. 32. The question in this case is whether respondent's use of Crystal B violates petitioner's patent.

The district court held, and the Federal Circuit affirmed without dissent, that the first claim of the patent—which described the claimed invention by chemical name and x-ray signature—covered only Crystal A. Petitioner nonetheless argued that its second through fifth claims, so-called "product-by-process" claims, were broader and encompassed both Crystal A and the Crystal B used in respondent's generic drug.

The Federal Circuit rejected this argument on two independent grounds. First, it affirmed the district court's conclusion—based on the "language of the claims themselves, the specification, and the prosecution history," Pet. App. 13—that all of the patent claims (including the product-by-process claims) claimed only Crystal A, and not Crystal B. *Id.* at 13-17, 31. That fact-bound determination presents no question of general legal significance, is not challenged (or even acknowledged) by petitioner, and wholly resolves the case.

Second, using this case to clarify the proper treatment of product-by-process claims, the court also held en banc that product-by-process claims are not infringed except by a product produced by the same process. *See* Pet. App. 22. Because there was no dispute that respondent produced Crystal B by a method materially different from that described in the product-by-process claims, the court held there could be no infringement even if those claims had purported to patent Crystal B. *Id.* at 17-26. Three judges dissented from one product-by-process aspect of the en banc ruling, but took no position on the ultimate disposition of the case. *Id.* at 37-88.

The petition seeks review of this second alternative holding. In addition to having no relevance to the

outcome of this case, the dispute between the majority and dissenting judges below centers not on the proper general rule for product-by-process claims, but rather on whether the courts should recognize what the dissenters described as a "rarely invoked exception" for products that cannot be described in non-process terms. Pet. App. 59. Petitioner does not claim that this "rarely invoked exception" applies here, and indeed it would not. Instead, petitioner asks this Court to grant certiorari to adopt a novel rule embraced by none of the judges of the Federal Circuit and inconsistent with more than a century of this Court's precedent. That request should be denied.

II. Factual and Procedural History

1. Petitioner originally patented cefdinir in 1985. *Lupin Ltd. v. Abbott Laboratories*, 484 F. Supp. 2d 448, 451 (E.D. Va. 2007) (discussing origins of U.S. Patent No. 4,559,334, the "'334 patent"). Two years later, it filed a patent application in Japan for cefdinir "Crystal A" and "Crystal B". *Id.* Petitioner then applied in the United States for the '507 patent at issue in this case.

While petitioner's Japanese application separately distinguished "Crystal A" and "Crystal B" as distinct compounds and inventions, the U.S. application used the term "Crystalline" to describe cefdinir. Pet. App. 6-8.[1] The first claim in the '507 patent is a traditional product claim, which further characterizes the product by reference to its unique x-ray fingerprint from a "powder X-ray diffraction" test. *Id.* at 6.

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[1] The chemical name of "7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cepham-4-carboxylic acid (syn isomer)" identifies cefdinir whether or not in crystalline form.

Claims 2-5 are petitioner's product-by-process claims. Like Claim 1, they claim as their invention "Crystalline [cefdinir]"; they differ by incorporating a description of, and requiring, a particular process for making crystals, which varies in each of the claims.[2]

2. When petitioner's original '334 patent expired, respondents planned to introduce a generic form of cefdinir, composed almost entirely of Crystal B, to compete with Omnicef, which is composed of Crystal A. *See Lupin*, 484 F. Supp. 2d at 451. Prior to introducing the drug to market, respondents filed an action in the Eastern District of Virginia seeking a declaration that their generic did not infringe petitioner's '507 patent. Pet. App. 4.

The district court found no infringement. It first determined that the cefdinir described in Claim 1 was Crystal A, and Crystal A alone. *Lupin*, 484 F. Supp. 2d at 458. Moreover, the court held that no reasonable jury could find that Crystal B was sufficiently identical to Crystal A as to constitute infringement under the doctrine of equivalents. Pet. App. 98. Petitioner challenges neither finding in this Court.[3]

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[2] The independent claims within claims 2-5 read:

> "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 under warming, then cooling the solution to room temperature and allowing the solution to stand."

Pet. App. 7.

[3] Petitioner originally claimed that respondents' generic literally infringed its patents because it contained material amounts

The district court further construed the product-by-process claims to refer to multiple processes for making the same crystal as in Claim 1—namely, Crystal A. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17.

In particular, the court concluded that the word "crystalline," as used in each of the claims, was intended to refer to Crystal A, and not as petitioner claimed, generically to any crystal form of cefdinir. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17. The specification, the court noted, expressly described the invention to be Crystal A. *Lupin*, 484 F. Supp. 2d at 456. Moreover, the process steps in Claims 2-5 corresponded with the steps set forth in the specification for creating Crystal A. *Id.* at 457. And when petitioner intended to claim both Crystals A and B in its Japanese application, it did so expressly, specifically identifying each form separately and by name. *Id.* at 458.

Even if claims 2-5 had not been expressly limited to the Crystal A form of cefdinir, the district court held that respondents' generic would not infringe the product-by-process claims (2-5) because admittedly it is made by a different process. Relying on the Federal Circuit's decision in *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), the court explained that the process steps in a product-by-process claim "serve as limitations in determining infringement." Pet. App. 96 (quoting *Atl. Thermoplastics*, 970 F.2d at 846-47). Because petitioner had presented "no evidence that Lupin is practicing the process steps set forth in Claims 2-5,"

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of Crystal A, but subsequently abandoned that theory in the district court. Pet. App. 93.

the court held, there could be no literal infringement of those claims. Pet. App. 96.[4]

3. The Federal Circuit affirmed. A three-judge panel initially heard the case and issued a decision that wholly disposed of petitioner's claims on appeal. In addition, the Circuit used the case to clarify the scope of product-by-process claims. That portion of the opinion—circulated among the full court and issued en banc—provided an alternative ground for rejecting petitioner's claims in this particular case.

a. The three-judge panel first affirmed the district court's conclusion that the term "crystalline," in both the product and product-by-process claims, refers solely to Crystal A. Pointing to the Japanese application, the court observed that "[petitioner] knew exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, [petitioner] chose to claim only the A form in the '507 patent." Pet. App. 14. Moreover, the court noted that the process steps were described in the specification as the "Process for Preparing Crystal A" and that the Japanese application had "recited these steps to distinguish between preparations for Crystal A and Crystal B." *Id.* 15 (citation and quotation marks omitted). In addition, the court concluded, "the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A." *Id.* at 16.

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[4] The court further held there was no infringement of Claims 2-5 by equivalents, Pet. App. 96-102, a conclusion upheld on appeal and not challenged in this Court. Pet. App. 34 ("Because Crystal B is not an equivalent of Crystal A, the [district court] did not err in granting summary judgment of noninfringement . . . .").

That conclusion, the panel recognized, was outcome determinative. *See* Pet. App. 36-37 (explaining that the court "correctly construed the '507 patent's recitation of 'crystalline' in each of the asserted claims as limited to Crystal A," and "therefore properly concluded on summary judgment that [respondents'] cefdinir product did not infringe claims 1-5").

b. Although the panel's construction of the term "crystalline" was sufficient to resolve the case, the court affirmed on an alternate ground as well, going en banc to resolve an issue that had persisted for 17 years over the scope of product-by-process claims. *See* Pet. App. 18 (discussing *Atl. Thermoplastics* and *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991)). The full court concluded that, when an applicant chooses to describe its invention in process terms, those terms limit the scope of the patent, such that an identical product made through a different process will not infringe the product-by-process claims. Pet. App. 17-26.

The court explained that this "rule finds extensive support in Supreme Court opinions" stretching back more than 100 years. Pet. App. 18. As early as 1884, this Court had established the general rule that "[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process." *Cochrane v. BASF*, 111 U.S. 293, 310 (1884). The rule arises in part, the Federal Circuit explained, from the fundamental requirement that patent protection extend no further than what the inventor has "particularly point[ed] out and distinctly claim[ed]" in his patent as his invention. Pet. App. 26 (quoting 35 U.S.C. § 112). "If

the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed." *Id.* Moreover, even when limitations on technology or knowledge prevent an inventor from describing a new substance in terms other than the process by which it is created, the court explained, those same impediments prevent a court from knowing whether a similar-seeming product produced by other means is, in fact, the same product. *Id.* at 25-26.

c. Three judges dissented from the en banc portion of the opinion, which they viewed as stating too sweeping a rule.

The principal dissent by Judge Newman did not dispute that, historically, product-by-process claims generally either were not allowed or were limited by their process terms. *See, e.g.*, Pet. App. 67-68 (acknowledging "the general rule" that "nothing can be held to infringe" a product-by-process claim "which is not made by that process") (quoting *BASF*, 111 U.S. at 310); *id.* at 45 (recognizing that "*as a rule* a claim for an article of manufacture should not be defined by the process of producing that article") (quoting *Ex parte Painter*, 1891 C.D. 200, 200 (Comm'r Pat. 1981) (emphasis in original)); *id.* at 54 (acknowledging "general rule against product-by-process claiming"). Instead, the dissent insisted that the there has long been a "rarely invoked" exception, Pet. App. 59, recognized in the case law of the Federal Circuit and its predecessors, for cases in which "the product is new and its structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made," *id.* at 45.

Although it argued that the cases of this Court cited by the majority were distinguishable, the dissent

did not claim that this Court had ever recognized a "rule of necessity" exception. Instead, Judge Newman simply argued that none of this Court's prior cases "discussed the problems of complexity and structural analysis that warrant this expedient, or created a legal solution to these problems." Pet. App. 77. Writing separately, Judge Lourie acknowledged that "there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement," but he faulted those decisions for using "overly broad" language in cases that may not have involved new patentable products. *Id.* at 87.

Their criticisms of this Court's decisions aside, the dissenters recognized that their disagreement with the majority might affect very few cases as a practical matter. Judge Newman conceded that the majority's rule "accommodates most inventions," but speculated that identifying products in non-process terms might prove difficult "in emerging aspects of biotechnology." Pet. App. 59. Judge Lourie's dissent, however, acknowledged that advances in *other* forms of technology, like the powder X-ray diffraction technique used by petitioner in this case, may mean that "there is little need for product-by-process claims." *Id.* at 88.

In any event, none of the dissenters claimed that the exception they advocated applied here, where petitioner admittedly was able to identify in non-process terms Crystal A in Claim 1 of the '507 patent, and Crystal B in its Japanese application. Pet. App. 8. Indeed, none took issue with the panel's ultimate disposition of this particular case, including its alternative holding that the term "crystalline" limited the patent to Crystal A separate and apart from any

effect of the process terms. *See id.* at 37 (Newman, J., "dissenting from en banc Section III.A.2" only); *id.* at 86 (Lourie, J., same).

REASONS FOR DENYING THE PETITION

Petitioner asks this Court to decide whether product-by-process claims are "infringed by an identical product made by a different process." Pet. i. That question does not arise in this case, because the district court found that respondents produce a different product (Crystal B) than the one petitioner patented (Crystal A). That conclusion was based on the language of the patent and its prosecution history; did not depend on the legal limits of product-by-process claims; and is not challenged by petitioner in this Court. As a result, reversing the separate product-by-process holding would have no effect on the outcome of this litigation.

Moreover, even if the question raised by the petition were presented in this case, it would not be worthy of this Court's review. All of the judges below agreed that, as a general rule, product-by-process claims are limited by their process terms. They simply disagreed whether an exception should be permitted in the rare case that an applicant cannot describe his invention in non-process terms. Petitioner has presented no evidence that inventions qualifying for that exception are common. To the contrary, there is every reason to expect that, given advances in analytical technology, the number of affected patents is small and will diminish in the future. Moreover, this case is a particularly poor vehicle for deciding whether a "rule of necessity" is needed, as it is undisputed that petitioner's patent would not qualify for the exception even if this Court were to recognize it.

For that reason, petitioner is forced to argue for an even broader rule than was advocated by the dissenters below, one that would dispense entirely with what all the judges of the Federal Circuit agree has been the general rule for more than a century. With nary a single member of that specialized court advocating petitioner's view of patent law, petitioner's plea for review by this Court should be rejected.

I. The Question Presented Does Not Arise On the Facts of this Case.

Petitioner asks this Court to determine whether "product-by-process claims are . . . infringed by an identical product made by a different process." Pet. i. That question does not arise on the facts of this case because respondents' Crystal B generic drug is not "an identical product" to the Crystal A compound claimed in the '507 patent. Pet. App. 34. Consequently, deciding the question presented would not affect the disposition of this case.

Petitioner does not dispute in this Court that the two crystalline forms of cedfinir are distinct substances and that respondents' use of Crystal B would not infringe a patent for Crystal A, either literally or by equivalence. *See Lupin*, 484 F. Supp. 2d at 458; Pet. App. 93-102. In addition, the district court found, and petitioner does not dispute here, that the compound described by the Claim 1 x-ray fingerprint is Crystal A. *Lupin*, 484 F. Supp. 2d at 458. As a result, petitioner's only hope of prevailing was to convince the court that its product-by-process claims encompass both Crystal A and Crystal B, even though its traditional product claim does not.

The district court, however, found the product-by-process claims were no broader than the product

claim and are likewise limited to Crystal A. *Lupin*, 484 F. Supp. 2d at 454-59; Pet. App. 13-17. The court observed that all of the claims in the patent claim "Crystalline [cefdinir]," which Claim 1 identified as consisting of a compound with the x-ray signature of Crystal A. *Lupin*, 484 F. Supp. 2d at 454. Petitioner knew how to claim Crystal B as well, having done so by name and x-ray signature in its Japanese application. Pet. App. 8-9, 14-15. Petitioner intentionally chose to abandon Crystal B in its U.S. patent.[5] *Id.* The patent's "specification and prosecution history, read carefully together with the claims," the court held, "announce 'Crystal A' as the '507 patent's invention." *Lupin*, 484 F. Supp. 2d at 459.

The Federal Circuit's affirmance of that holding constituted an entirely independent ground for rejecting petitioner's infringement claims. *See* Pet. App. 36-37 (holding that district court "properly concluded on summary judgment that Lupin's cefdinir product did not infringe claims 1-5 literally or claims 2-5 by equivalency"). No member of the en banc court challenged that conclusion, and petitioner does not challenge (or even mention) it here. Moreover, even if it did, any such challenge would fall outside the scope of the question presented and pose no certworthy question of broader legal significance. *See* Pet. i; *Matsushita Elec. Indus. Co. v. Epstein*, 516 U.S. 367, 379 n.5 (1996).

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[5] The expired cefdinir prior art patent, the '334 patent, described in Example 14 the final product as "obtained crystals" of cefdinir; since this cefdinir shared the same characteristics as Crystal B in the Japanese application, respondent could not patent the identical crystal twice in the U.S. *See, e.g.*, 35 U.S.C. § 102(b) (novelty requirement).

II. The Petition Does Not Present a Question of Recurring Importance.

Petitioner has also failed to demonstrate that the dispute among the members of the Federal Circuit involved a question of recurring and lasting importance.

1. All of the judges agreed that, as a general rule, "[e]very patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process." *BASF*, 111 U.S. at 310; *see also* Pet. App. 21-22 (en banc majority) (quoting *BASF* as establishing standard); *id.* at 68 (Newman, J., dissenting) (acknowledging that statement in *BASF* "is indeed the general rule").[6] Three judges, however, argued that there should be "an exception to the general rule," Pet. App. 45 (Newman, J., dissenting), which would apply "only" when a "product is new and its structure is not fully or readily known," *id.*

But there is no reason to believe that many patents would fall within this "rule of necessity," which the dissent itself described as "narrow." Pet. App. 86 (Newman, J., dissenting). Indeed, Judge Newman conceded that, historically, "the rule of necessity was seldom applied," Pet. App. 48-49, and remains "rarely invoked" today, *id.* at 59. It thus would, at most, apply to a "small . . . class of inventions," *id.* at 40, incapable of non-process description despite advances in analytical technology that Judge Lourie recognized may have already rendered the exception unneces-

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[6] *See also* Pet. App. 54 (Newman, J., dissenting) (acknowledging "general rule").

sary, *see id.* at 88 (Lourie, J., dissenting) ("It may be that with today's analytical techniques there is little need for product-by-process claims.").

Petitioner stands alone before this Court insisting that the question presented by its petition is of general importance to the patent-holding community. Although its licensee sold a profitable brand-name drug under the '507 patent, and was a party to this action below, it has not joined in the petition. Nor has a single patent-holder or organization come forward to file an amicus brief in support of the petition.[7] And perhaps most tellingly, although a purported intracircuit conflict over the scope of product-by-process claims endured within the Federal Circuit for more than 17 years prior to the decision in this case, petitioner has not identified a single prior petition to this Court arguing that the conflict created an untenable practical burden on patent-holders. That the Federal Circuit now applies only a single, consistent rule provides even greater reason to think that the question presented has little practical impact.

Unsurprisingly, in the vast majority of cases, an inventor can fully protect its invention by describing it in non-process terms, as petitioner did here in claiming Crystal A, and as it did in its Japanese application attempting to claim Crystal B. If there are, indeed, inventions that, despite advances in technology, can only be described in process terms, the decision in this case still affords them considerable patent protection. If experience shows that the

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[7] The patent bar has not hesitated in the past to inform the Court when it views a decision of the Federal Circuit as addressing a question of recurring importance worthy of this Court's attention. *See, e.g.*, Docket for *Bilski v. Kappos*, No. 08-964 (nine cert-stage *amicus* briefs filed).

Federal Circuit's rule provides inadequate protection in a significant number of applications, this Court will have ample opportunity to review it in a future case where, unlike here, it might actually be dispositive.

2. Petitioner's various complaints about other aspects of the decision below, and the process by which it was reached, do not render an otherwise uncertworthy question suitable for this Court's attention.

First, petitioner complains that the Federal Circuit decided the product-by-process question *sua sponte* without ordering supplemental briefing or holding oral argument on the question. Pet. 8-11. But petitioner's Question Presented does not ask this Court to decide whether the procedures followed here were lawful, *see* Pet. i, and they plainly were. Petitioner does not dispute that en banc review was appropriate to resolve any intracircuit split. And while it alleges that the Court did not follow its self-imposed Internal Operating Procedures (IOP), it acknowledges that the IOP itself states that departures from it are permitted. Pet. 9; *see also* Fed. Cir. IOP 1 ("The court reserves the right to depart from a provision in the IOPs when circumstances require."). Nor does petitioner point to any other source of law precluding courts from circulating opinions prior to publication for en banc consideration,[8] a routine practice in other

[8] Although petitioner makes no mention of it, Judge Newman suggested that the court had violated Rules 34 and 35, Fed. R. App. P. *See* Pet. App. 40-42. But Rule 35 simply states *when* en banc review is appropriate and says nothing about *how* it shall be conducted. And Rule 34 simply addresses oral argument (not briefing) before the three-judge panel, not the procedures for rehearing cases or issues en banc. The en banc court is no more

circuits. *See, e.g.*, 7th Cir. R. 40(e); *Ionics, Inc. v. Elmwood Sensors, Inc.*, 110 F.3d 184, 187 n.3 (1st Cir. 1997); *United States v. Coffin*, 76 F.3d 494, 496 n.1 (2d Cir. 1996). Nor has petitioner shown any real prejudice from the court's procedures. While petitioner hypothesizes that the court would have benefited from additional briefing from the parties, it offers no arguments in its petition that were not thoroughly considered. Likewise, although petitioner asserts that the Federal Circuit's actions prevented *amici* representing the holders of "thousands of patent claims" to participate in the case, Pet. 10, none has come forward in support of the petition to this Court despite ample opportunity to do so. *Cf. supra* n.7.

Second, petitioner also criticizes the panel's construction of the term "obtainable by" in the patent. *See* Pet. § V. But, again, petitioner does not ask this Court to review that holding. *See id.* at i. Nor is the proper construction of "obtainable by" certworthy in its own right. Petitioner claims that the panel's construction of that term "puts thousands of current patents at risk," Pet. 29, because the phrase "obtainable by" has been included in "over 11,000 patents" over the past twenty years, *id.* at n.13. That figure is incorrect,[9] as is the conclusion

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required by Rule 34 to hold additional oral argument upon rehearing en banc than is the original three-judge panel required to hold a second oral argument when it grants panel rehearing.

[9] Respondent conducted the same search, using the same database, and found only 2,600 patents issued between August 26, 1989, and August 26, 2009, containing the phrase "obtainable by" in the "claims." It appears that petitioner's count includes not only issued patents, but also applications. To put

drawn from it. The panel did not hold that "obtainable by" automatically signals a product-by-process claim. To the contrary, the panel reached its conclusion in this case based on the language of the claim, the text of the specification, the relationship among different claims, and the prosecution history which showed petitioner's "acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims." Pet. App. 28. Whether that patent-specific determination was correct does not warrant this Court's review.

III. The Decision Below Was Correct.

Review is further unwarranted because the decision below was correct, and because the rule proposed by petitioner is unprecedented and inconsistent with both this Court's decisions and longstanding principles of patent law.

As noted above, petitioner does not ask this Court to adopt the limited "rule of necessity" advanced by the dissent below. Instead, petitioner claims, as it must, that patent applicants are free in all cases to describe their inventions solely in terms of the process that produces the product and, if they do, are entitled to a monopoly over any new product that they can later show would be produced by such a process. Petitioner does not claim that this Court has ever adopted such a sweeping rule, arguing instead only that the cases cited by the majority below do not preclude petitioner's expansive view of product-by-process claims. But even the dissenters below recognized that this is not so, and that for more than a century, this Court has adhered to the general prin-

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both numbers in context, during the same period, the PTO issued more than 2.7 million utility and reissue patents.

ciple that product-by-process claims are limited to products produced by the process described in the patent. Pet. App. 67-68, 87. Petitioner provides no convincing reason for this Court to revisit that precedent now.

A. This Court Has Long Held That the Process Terms of Product-By-Process Claims Limit the Patent.

For more than a hundred years, this Court has consistently taught that product-by-process claims are limited by their process requirements.

As the Federal Circuit explained, this Court's *BASF* decision set forth the standard for infringement of product-by-process claims in clear and unequivocal terms:

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

BASF, 111 U.S. at 310. The question arose in *BASF* with respect to a patent claim that read:

> "Artificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result."

Id. at 296. This Court held that the accused product did not infringe because it was prepared by a different process. *Id.* at 310.

Petitioner argues that the decision in *BASF* is limited to cases in which process terms are used to described an old, and therefore unpatentable, prod-

uct, pointing to a later passage in the opinion that suggests that the product described in the patent in *BASF* was not new. Pet. 18. But the language in the Court's opinion, quoted above, makes no such distinction. And, in fact, the portion of the opinion upon which petitioner relies provided an entirely independent, alternate ground for the decision. *See BASF*, 111 U.S. at 311 (discussing "another view of the case"). The principal ground for the decision was written on the assumption that the product claimed was in fact new. *See id.* at 310-11.[10]

Moreover, the Court's decision in *BASF* does not stand in isolation. Eight years earlier, in *Smith*, the Court construed a patent directed to artificial teeth, *see Smith*, 93 U.S. at 489-90, with a claim to a "'plate of hard rubber, or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described [in the specification].'" *Id.* at 493. The specification required a very particular process for making the product. *Id.* at 494. This Court interpreted the claim as a product "made in a defined manner," not one "separated from the process by which it is created. . . . The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed." *Id.* at 493.

Three years later, in *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880), this Court considered the question of infringement of this same

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[10] As noted below, the Court has given the same scope to product-by-process claims, both before and after *BASF*, in other cases in which there can be no dispute that the product at issue was new. *See, e.g., Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493-94, 501 (1876); *Plummer v. Sargent*, 120 U.S. 442, 448 (1887).

patent, and affirmed the district court's holding that a celluloid plate for artificial teeth prepared in a manner "wholly unlike that employed in making hard rubber or vulcanite," did not infringe. *Goodyear*, 102 U.S. at 229. To infringe, the Court held, either the stated "process of constructing the plate," or a "process equivalent thereto, must be employed." *Id.* at 226.[11]

The patent in *Merrill v. Yeomans*, 94 U.S. 568 (1876), required heavy hydrocarbon oils deodorized by a specific process. *Merrill*, 94 U.S. at 569-70. Applying "the well-settled rules of construing all instruments," the Court held that the process descriptions "must either refer to the process of making the oils for which the applicant is claming a patent, or they are intended to limit his claim for a patent for the product to that product only, when produced by treating the oils in the manner before described." *Id.* at 571.

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[11] Petitioner and the dissent below argue that the *Goodyear* cases did not involve product-by-process claims because the patent did not include any reference to the process. Pet. 18. This is incorrect. The plate at issue was a specific type of product based on a soft vulcanizable compound which is then hardened to hold the teeth and pins in place. *Smith*, 93 U.S. at 494. This Court interpreted the claim as a modern day product-by-process claim:

> The invention, then, is a product or manufacture made in a defined manner. It is not a product alone separated from the process by which it is created. . . . The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed.

Id. at 493. Contrary to Petitioner's sweeping assertion, the Court concluded both the process and the product were new and patentable. *Id.* at 493-94, 501.

In *Plummer*, the patent claimed the product of an improved process of bronzing or coloring iron. *Plummer*, 120 U.S. at 444-46. Affirming the judgment below, this Court observed that:

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

Id. at 448.[12]

And in *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938), the Court confirmed that "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." *Gen. Elec.*, 304 U.S. at 373 (footnote omitted). Quoting *BASF*, the decision reiterated

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[12] Judge Newman, in dissent, argued that these claims were limited to the process "to sustain validity of the patent in view of the . . . prior art." Pet. App. 74. However, if the product cannot be said to be new or distinguishable from the prior art except by reference to the process by which the product was made, then the resulting product is of the type where Judge Newman seeks to apply the "Rule of Necessity" exception. *Id.* at 37. The en banc majority rule below that, if an inventor chooses to claim the product in terms of its process, then that process "also governs the enforcement of the bounds of the patent right," Pet. App. 25, absolutely follows the logic of *Plummer*, *id.* at 22, mooting Judge Newman's concerns.

that, for a claim trying to distinguish a new product from the prior art by reference to a process, "'nothing can be held to infringe the [claim] which is not made by that process.'" *Id.*[13]

Finally, this Court expressed the same understanding of product-by-process claims in its more recent decision in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989). There, the Court considered whether a state statute was preempted by federal patent law. The state of Florida had made it unlawful for boat manufacturers to:

> use the direct molding process to duplicate for the purpose of sale any manufactured vessel hull or component part of a vessel made by another without the written permission of that other person.

Bonito, 489 U.S. at 144-45 (citation omitted). In the course of its Supremacy Clause decision, this Court likened the state statute to a product-by-process patent. *Id.* at 159. That comparison is apt only because the Florida statute, like federal product-by-process claims, protects against the creation of an identical product through a specified means. In particular, this Court explained, under the state law, "[l]ike the patentee, the beneficiary of the Florida statute may prevent a competitor from 'making' the product [by direct molding] and from 'selling' the product when it is produced in that fashion." *Id.* at 158. This is entirely consistent with the Federal Circuit's approach here, which obligated petitioner to

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[13] While the claim at issue was actually a product claim, the Court nonetheless considered whether an indefiniteness ruling could be avoided by construing the claim with reference to the process described in the specification.

prove the accused product was made by the claimed process.

B. The Federal Circuit's Ruling Does Not Require Construing Claims Differently For Validity and Infringement.

Unable to point to any decision of this Court adopting its view, petitioner instead is reduced to arguing that the decision below conflicts with this Court's authority at a higher level of generality. In particular, petitioner claims that the decision below conflicts with the general proposition of, "[t]hat which infringes, if later, would anticipate, if earlier." Pet. 2 (quoting *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889) (internal quotation marks omitted)). The decision below violates that precept, petitioner argues, because it treats product-by-process claims as a *product* claim for purposes of patentability (since the PTO requires a product-by-process claim to be a new and patentable invention) but as a *process* claim for purposes of infringement (because it requires the use of the process described in the patent). Pet. 11. This argument is misguided as well.

The Federal Circuit's decision is completely consistent with the *Peters* principle: an invention that would infringe a product-by-process patent (*i.e.*, an invention producing the same product by the same process) would anticipate the patent if invented earlier. If the patentee can only distinguish a product by reference to a process, then "that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor." Pet. App. 25.

In this case, for example, if a company other than petitioner produced Crystal A by the process described in the '507 patent before that patent's priority date, the invention would have anticipated petitioner's patent claim; and the same product produced by that same process would infringe the '507 patent if practiced later.[14]

Petitioner nonetheless persists that the basic premise of *Peters* is violated because, it insists, the decision below treats product-by-process claims as product claims for patentability, but as process claims for infringement. This is wrong in two respects.

First, it is wrong to say that the Federal Circuit treats product-by-process claims as product claims for purposes of patentability and validity, but as process claims for infringement. The decision makes abundantly clear that product-by-process claims are product claims at both stages. In deciding patentability, the PTO and the courts apply the "ordinary requirements of patentability." Pet. App. 25. Moreover, the Federal Circuit made equally clear that the resulting patent is for the product, not simply the process, although the product must be made in the way described in the patent. *See id.* The distinction between having a patent for a product made a particular way, and simply having a patent for that process, is of real significance. For example, one who

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[14] This, in fact, is what occurred in *Plummer*; since the accused infringer was practicing a prior art process different from the one in the patent, it "seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described." *Plummer*, 120 U.S. at 449.

has not manufactured a product, but simply sells it, may be sued for violating a product-by-process patent, but not for infringing a pure process patent. *See Joy Tech. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) ("A method claim is directly infringed only by one practicing the patented method."); *Cardiac Pacemakers Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1358-59 (Fed. Cir. 2009).[15]

Second, it is simply untrue that, under the Federal Circuit's interpretation, the PTO gives product-by-process claims a broader construction (unlimited by process terms) than does a court in litigation. As a general matter, the PTO does not construe the scope of the patents it issues. It is solely responsible for determining whether the application meets the criteria for patentability. And, as the Federal Circuit explained, because product-by-process claims are a form of product claim, the PTO must decide whether the product claimed meets the traditional requirements for patentability. Pet. App. 25. The process terms have no bearing on that question and, for that reason, are not the focus of PTO's attention. But that does not mean that the PTO construes a resulting

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[15] Even more significantly, before Congress enacted 35 U.S.C. § 271(g) in 1988, patent-holders could not sue to enforce process patents when the process was practiced outside the U.S. But patent-holders could use product-by-process claims to stop those who made infringing products abroad and then imported them. Congress enacted § 271(g) to prevent competitors from avoiding a process patent by producing products outside the United States and then importing them. *See, e.g.*, S. Rep. No. 100-388, at 33 (1988); H.R. Conf. Rep. No. 100-576, at 1085-87 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1574, 2118-20. This change may explain the diminishing significance of product-by-process claims. The '507 patent here was filed in August 1988, and claims priority to a Japanese patent application filed in 1987.

product-by-process claim as encompassing the product regardless of how it is made (a question that simply does not arise during the course of the PTO's work).[16] Instead, it simply shows that the process restrictions—while limiting the scope of the patent—are generally of lesser practical importance to whether the patent should issue,[17] which is the only question the PTO is charged with deciding.

In any event, as described above, any perceived asymmetry has been accepted by this Court for more than a century. Indeed, although the dissent below complained at length that the decision in this case created an untenable disparity in the treatment of product-by-process claims at the patentability and infringement stages, it did not dispute that the disparity necessarily arises under what it conceded was the "general rule" described in cases like *BASF*. *See* Pet. App. 45, 54.

C. The Federal Circuit's General Rule Is Consistent With General Patent Principles and Policy.

Limiting product-by-process claims in accordance with their process terms is entirely consistent with basic patent principles and the policy underlying federal patent law.

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[16] Nevertheless, the PTO has considered whether process elements were found in the prior art in the context of product-by-process claims. *See In re Hirao*, 535 F.2d 67, 69-70 (C.C.P.A. 1976); *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973).

[17] It has long been recognized that "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535 (C.C.P.A. 1972).

It is a "'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The claims control in the doctrine of equivalents analysis as well. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Thus, a "patent confers the right to exclude others from making, using, or selling the invention defined by the claims." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The courts' focus on claim language ensures that the public receives the benefits of full disclosure of the invention in exchange for the legal monopoly endowed upon the inventor. *See Enzo Biochem., Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 971 (Fed. Cir. 2002).

Freeing product-by-process claims from their process limitations would violate these basic principles.

First, it would undermine the "definitional and public-notice functions of the statutory claiming requirement." *See Warner-Jenkinson*, 520 U.S. at 29. As the court recognized below, it would grant a monopoly in a product that the patent has not, in fact, fully disclosed. *See* Pet. App. 26. Indeed, petitioner's proposed rule would create a substantial disincentive for full disclosure. As at least one commentator has noted, "[b]roadening the scope of product-by-process claims . . . would reduce incentives for inventors to attempt characterization of the claimed invention." Gary Newson, *Product-by-Process Patent Claims: Arguing for a Return to Necessity and a Reduction in the Scope of Protection*, 40 ARIZ. ST. L. J. 327, 338 (2008).

Second, petitioner's proposal would divorce the infringement analysis from the terms of the claim

itself. Under petitioner's view, in order to determine whether a patent claim is infringed, it would never be enough to simply compare the claims in the patent with the allegedly infringing product and process. Instead, one would have to follow the procedures described; produce an actual product; and then compare it to the alleged infringer's wares. But the Federal Circuit has long held that "it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process . . . ." *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994).

Third, allowing patent-holders to substitute an unidentified proxy product or undisclosed product characterizations as claim boundaries, to the exclusion of clearly identified and definite process-based descriptions actually found in the patent claims, would create substantial practical difficulties for the PTO as well as patent-holders and their competitors. The product-by-process format has vexed PTO examiners, because the PTO cannot "manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *Brown*, 459 F.2d at 535.

Those concerned with avoiding patent infringement face the same unnecessary costs and uncertainty. As this Court stated long ago in *Merrill*, "[t]he public should not be deprived of rights supposed to belong to it, without being clearly told what it is that limits these rights." *Merrill*, 94 U.S. at 573; *see also United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942); *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891). But under petitioner's rule, rather than simply examining the text of the patent, a company

concerned about potential infringement must instead follow the process steps (often with significant difficulty and expense) to produce what they hope is the claimed product (and if it is, possibly commit an act of infringement by performing that process), then compare that product through some *other* technique perhaps nowhere mentioned in the patent to determine whether it is the same as the one the company intends to produce. The patent statute has never contemplated such an ordeal, which would discourage the "exploitation of unpatented designs and innovations," upon which our free market depends. *Bonito*, 489 U.S. at 151.

Moreover, the same burdens would be imposed on courts called upon to adjudicate product-by-process claims, the scope of which can be determined only through laboratory experiments rather than through a close reading of the text and history of the patent.

Fourth, as this case illustrates, unmooring patent protection from the disclosures in the patent risks giving patent-holders a protection "wider in its scope than the original actual invention of [the inventors], and wider than anything indicated in the specification of the original patent." *BASF*, 111 U.S. at 313. Here petitioner's traditional product claim was clearly limited by its reference to an x-ray signature to Crystal A. Yet because of the inherent ambiguity in its product-by-process claims, petitioner attempted to assert that Claims 2-5 patented a broader invention. In fact, in the district court, petitioner argued that, after the '507 patent issued, other inventors managed to use (in whole or in part) some of the Crystal A process steps to produce Crystal B. Petitioner thus insisted that its claims must cover Crys-

tal A and Crystal B. *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 769-770, 774 (N.D. Ill. 2007).

The Federal Circuit's approach to interpretation of product-by-process claims, on the other hand, is in accord with the statute (only claims can be infringed, 35 U.S.C. § 271; patentees must use the claims to define the invention, 35 U.S.C. § 112 ¶ 2; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372-4 (1996)); with this Court's guiding principles (each and every claim element is presumptively material: *Warner-Jenkinson*, 520 U.S. at 30); and provides clear guidelines that do not make claim interpretation contingent upon resolving factual disputes about whether a given product is old or new, or an appropriate substitute for the claims or not.

D. Although It Makes No Difference In This Case, The Federal Circuit Properly Refused to Recognize a "Rule of Necessity" Exception.

Whether or not the general rule for product-by-process claims accepted by all the judges below should be subject to an exception for inventions incapable of description through non-process terms ultimately makes no difference in this case. *See supra* at 7, 14-15. But the Federal Circuit nonetheless was correct to refuse to recognize a rule of necessity exception.

The perceived need to protect inventions that cannot be described in non-process terms does nothing to diminish the legal and practical difficulties of divorcing product-by-process claims from the constraints of their process terms. In fact, some of the problems are most acute in precisely the cases in which the rule of necessity would apply, including the

difficulty of deciding whether a similar-seeming product made by a different process is actually identical to the product described in the patent. If the exception applies, it is because the product cannot be identified except by examining the process through which it is made. But if that is true, how could a district court ever ascertain that a product made by process Z is "really the same as the patented compound" made by process Y without looking at the process conditions used to make the product? Pet. App. 25-26.

This Court, in fact, confronted this very issue in *Plummer*, 120 U.S. at 448, for a unique product called "Tucker bronze." The surface of the iron product was described as resulting from a very specific process that leaves a "firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze." *Id.* at 443. The exact composition of the film was unknown and not stated. This Court recognized that the accused product could not be shown to be *identical* to the patented "Tucker bronze" product "unless it is shown that they are made by the same process." *Id.*[18]

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[18] It is at least theoretically possible that advances in analytical technology could permit a patent-holder to show that a product made by a different process is, in fact, the same as that claimed in a product-by-process patent, even though it was impossible to describe the patented product in non-process terms at the time of the patent application. But if and when that happens, the patentee may apply for a broader reissue claim without the limiting process elements, as the patent-holder in *Scripps* eventually did. *See* 35 U.S.C. § 251; *Scripps Clinic & Research Found. v. Genentech, Inc.*, 707 F. Supp. 1547, 1555-56, 1560 (N.D. Cal. 1989); *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1299, 1303 (Fed. Cir. 1992) (Rader, J., concurring). That approach remains open to patent-holders today.

At the same time, limiting the types of cases in which an unrestricted product-by-process claim will be recognized raises difficult line-drawing problems of its own. The dissent suggested no standard for evaluating whether the exception should apply in any particular case, other than to state that it should be available when a product's "structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made." Pet. App. 45. Applying the exception would therefore require extensive satellite litigation over its applicability under an inherently vague standard. Moreover, it would engender substantial uncertainty about the scope of patent monopolies, deterring the introduction of useful products into the market (including, for example, desperately needed, less expensive generic drugs) that benefit the nation and its economy.

As noted above, the Federal Circuit's decision here still allows significant protections for those who might fall within a rule of necessity exception, including pharmaceutical and biotech companies. Pet. App. 25. If more is required, if the needs of emerging technology require rethinking rules that have seen this country through the last century of dramatic innovation and discovery, those arguments are "best addressed to Congress, not this Court." *See Warner-Jenkinson*, 520 U.S. at 28.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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