No. 09-335

In The
Supreme Court of the United States

ASTELLAS PHARMA, INC.,

Petitioner,

v.

LUPIN LIMITED, et al.,

Respondents.

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

RESPONDENT SANDOZ INC.'S BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit correctly applied established precedent in construing all claims of the Astellas patent to require the Crystal A form of cefdinir, whose structure was known and described by the patentee?

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

The parties to the proceedings are: Petitioner/ Appellant Astellas Pharma, Inc. and Respondents/ Appellees Lupin Ltd., Lupin Pharmaceuticals, Inc., Sandoz Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical. Abbott Laboratories was an appellant below, but has not joined in the petition for certiorari.

Pursuant to the Court's Rule 29.6, Sandoz Inc. states that Novartis AG is the ultimate parent company of Sandoz Inc., owning 100% of Sandoz Inc. and trading on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

This decision turned on claim construction of the term cefdinir. The Federal Circuit properly construed each of the claims in the Astellas '507 patent to require the Crystal A form of cefdinir, whose structure was known and described by the patentee in the '507 patent and in its earlier Japanese patent application. Based on that ruling alone, the panel affirmed the Northern District of Illinois's denial of a preliminary injunction sought by Astellas against defendants' Crystal B products.

Astellas's petition for a writ of certiorari ignores the dispositive Crystal A holding by the panel, and instead focuses on the Federal Circuit's decision to go en banc to further address its internal product-by-process dispute, which plays out in Section III.A.2 of the opinion and the dissent. Presenting one holding without the other portrays a heavily skewed picture, especially since the en banc court left standing the panel's Crystal A holding. In the end, Astellas's failure to contest the panel's holding for Crystal A in every patent claim means that the outcome here would be the same regardless of how the product-by-process claim issue is resolved. Because of that crucial fact, this case presents a poor vehicle for the Court's review of product-by-process claims.

The Federal Circuit, moreover, properly acted within its authority to take this case *sua sponte* en banc. Its actions are consistent with the rules of

practice and procedure that have been approved by the Court and enacted by Congress. Requiring otherwise rigid procedures would unduly hamper circuit en banc resolution of issues.

Thus, this is not a proper case for grant of certiorari.

STATEMENT OF THE CASE

Astellas Pharma, Inc. ("Astellas") is the assignee of U.S. Patent No. 4,935,507 ("the '507 patent"). Astellas and its licensee, Abbott Laboratories, asserted patent claims 1–5 against numerous defendants in two separate courts. Astellas sued Sandoz Inc. ("Sandoz") and others in the Northern District of Illinois and was a declaratory judgment defendant against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") in the Eastern District of Virginia.

Each of the five claims of the '507 patent is directed to a crystalline form of the pharmaceutical cefdinir. Structure claim 1 recites only the crystalline form of cefdinir while claims 2–5 recite the crystalline form of cefdinir obtainable by certain process steps.

On April 27, 2007, the United States District Court for the Eastern District of Virginia determined that the asserted claims were limited to only one crystalline form of cefdinir, Crystal A. *Lupin Ltd. v. Abbott Labs.*, 484 F. Supp. 2d 448, 466 (E.D. Va.

2007). Based on that claim construction, the court granted Lupin's motion for summary judgment of noninfringement on June 14, 2007. *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563, 571 (E.D. Va. 2007).

In the United States District Court for the Northern District of Illinois, Astellas, Sandoz, and the other defendants agreed to be bound by the Eastern District of Virginia's claim construction, and on May 3, 2007, after a two-day hearing, the court denied Astellas's motion for a preliminary injunction against Sandoz and Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"). *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 770, 776 (N.D. Ill. 2007).

Without relying upon product-by-process claim analyses, and after reviewing evidence of the crystalline structure of both Crystal A and Crystal B, the Illinois district court determined that Astellas's claims, all of which required the Crystal A form of cefdinir, do not cover Sandoz's Crystal B cefdinir product, either literally or under the doctrine of equivalents. *Id.* at 771, 773–76. The district court denied the preliminary injunction because it found that it was unlikely that Astellas would be able to prove that Sandoz would infringe the '507 patent. *Id.* at 776.

Astellas appealed both the Illinois and the Virginia district court decisions to the Federal Circuit. In a single opinion, the Federal Circuit panel

affirmed the lower courts' holdings that each of the claims at issue was limited to Crystal A:

> Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."

Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1291 (Fed. Cir. 2009). Accordingly, the Federal Circuit affirmed the grant of summary judgment of no infringement by Lupin, and affirmed the denial of the preliminary injunction against Sandoz and Teva based on claim construction. *Id.* at 1297–99.

The Federal Circuit then took this case partially en banc to address a unique type of product-by-process claims in Section III.A.2. *Id.* at 1291–95.

REASONS FOR DENYING THE PETITION

I. ASTELLAS DOES NOT DISPUTE THAT THE FEDERAL CIRCUIT PROPERLY FOLLOWED THE COURT'S CLAIM CONSTRUCTION PRECEDENT

The Federal Circuit applied well settled law of claim construction in affirming the finding that the claims of the '507 patent are limited to the Crystal A form of cefdinir. In its petition, Astellas does not dispute that the claim term crystalline cefdinir, which appears in every claim of the '507 patent, is limited

to Crystal A. This concession alone is reason to deny the petition.

A. The '507 Patent Characterizes The Invention As Crystal A, Which Is Determinative Of The Case

According to statute, the claims must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶2 (1975). Indeed, the Court stressed long ago the importance and purpose of patent claims: "[t]he claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." *White v. Dunbar*, 119 U.S. 47, 52 (1886). Hence, it is a fundamental tenet of patent law that the wording of the claims determines the scope of the patent. *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1373 (Fed. Cir. 2008).

Here, all five of the asserted claims contain the term "Crystalline 7-[2-(2-a minothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cepham-4-carboxylic acid (syn isomer)," which is the chemical name for cefdinir. *Abbott Labs.*, 566 F.3d at 1286.

There are at least two forms of cefdinir; one form is known as Crystal A and the other form is known as Crystal B. *Id.* at 1287. The two forms are

distinguished by their infrared ("IR")-absorption wavelengths and powder X-ray diffraction ("PXRD") angles and intensities: Crystal A can be described by three IR wavelengths and sixteen PXRD angles and intensities, while Crystal B can be described by five IR wavelengths and twenty-one PXRD angles and intensities. *Id.*

The disclosure of the '507 patent compels construing "crystalline cefdinir" to mean "Crystal A." The specification refers to Crystal A thirty-four times but notably makes no mention of any other form of crystalline cefdinir. '507 Patent col.2 l.2–col.13 l.67. According to the specification Crystal A is the "present invention":

> After an intensive study, the inventors of the present invention succeeded in obtaining the compound (I) as a special crystalline form, i.e. Crystal A . . . .

Id. at col.1 ll.34–36. Crystal A is described repeatedly in the specification as showing seven distinguishing "peaks" located at specific angles in a PXRD pattern. *See, e.g.*, *id.* at col.1 ll.49–66; col.12 l.48–col.13 l.3; and Fig.1; *see also Abbott Labs.*, 566 F.3d at 1289–90. No other crystal is disclosed. *See* '507 patent; *see also Abbott Labs.*, 566 F.3d at 1289.

The Federal Circuit agreed with the Virginia district court that claim 1 was limited to Crystal A because the specification repeatedly referred to "Crystal A of the compound (I) of the present invention," and it offered no suggestion that the recited processes could produce Crystal B. *Abbott*

Labs., 566 F.3d at 1289. Abbott's disavowal of Crystal B further supported the court's decision to limit the claim to Crystal A. *Id.* Abbott had successfully claimed Crystal B in a Japanese priority application, and thus knew how to claim Crystal B had it so desired. *Id.* Yet, in its U.S. patent application, Abbott removed all support for Crystal B in the specification, only disclosing Crystal A. *Id.*

Regarding the four other asserted claims 2–5, the court concluded that they also were limited to Crystal A because the "intrinsic evidence, including the prosecution history and [the] priority [Japanese] application, evince[d] a clear intention to limit the [asserted] patent to Crystal A." *Id.* at 1290. Because all the claims were limited to Crystal A, the process used to make them and whether that process was further limiting to the claims would not have changed the decision. *Id.* at 1291. *Cf. id.* at 1320 (Lourie, J., dissenting) ("[C]laim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.").

B. Based On Claim Construction, The Federal Circuit Affirmed No Likelihood Of Infringement By Sandoz's Crystal B Product

Because the Federal Circuit found that all five of the asserted claims were limited to Crystal A, *id.* at

1289–90, the court affirmed the Illinois district court's denial of a preliminary injunction against Sandoz and Teva, because Abbott would most likely not be able to prove infringement: "Abbott was not likely to show [that] Sandoz and Teva's products contained any Crystal A at all." *Id.* at 1299. The court also affirmed the summary judgment finding of no infringement by Lupin due to the limiting of the claims to Crystal A. *Id.* at 1298. Therefore, the court found for the respondents on a completely separate basis from the product-by-process issue on which Astellas exclusively focuses in its petition for a writ of certiorari. *Id.* at 1297–99.

By failing to address the Federal Circuit's construction of claims 1–5, the petition paints an incomplete picture of the decision below. (Pet. Br. at 11–27); *Abbott Labs.*, 566 F.3d at 1289–91. Notably, the en banc portion, Section III.A.2, left standing the panel's case-dispositive holding that each of the claims of the '507 patent is limited to the Crystal A form of cefdinir. Astellas has not petitioned the Court on this case-controlling issue.

For these reasons, the case presents a poor vehicle to review product-by-process claims and the Court should deny the petition for a writ of certiorari.

II. ARTICLE III COURTS HAVE THE POWER TO MAKE AND INTERPRET THEIR OWN OPERATING PROCEDURES

Sua sponte resolution of an issue en banc at the circuit level is neither improper nor unusual.[1] Congress enacted 28 U.S.C. § 2071(a) (1988), which states that "all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business." These rules only need to be consistent with the rules of practice and procedure and rules of evidence that the Supreme Court prescribes and submits to Congress. *Id.* at §§ 2071, 2072.

In accordance with 28 U.S.C. § 2071(a), the Federal Circuit promulgated Internal Operating Procedures ("IOPs"). Internal Operating Procedure 14.3 specifically permits that "hearing en banc following hearing by a panel of judges, but before the entry of judgment and opinion(s) by the panel, may be ordered sua sponte." The IOP further states that after a *sua sponte* petition for hearing en banc is granted, the "clerk shall provide notice that a majority of the

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[1] Several circuits may hear cases en banc without providing notice to the public and/or receiving additional briefing from the parties or the public. *See, e.g.*, 2d Cir. L.R. 35 (no notice requirement for hearing a case en banc); 3d Cir. IOP 9.6.3 (notice to parties may be requested but is not necessary); 4th Cir. L.R. 35 (no notice requirement for hearing a case en banc); 9th Cir. Advisory Committee Note to Rules 35–1 to 35–3; D.C. Cir. Internal Procedures XIII(B)(2) ("On occasion, only the original briefs have been considered," and "any active judge of the Court . . . may suggest that a case be reheard en banc.").

judges . . . has acted under 28 U.S.C. § 46 and Fed. R. App. P. 35(a) to order the appeal to be heard en banc, and indicate any questions the court may wish the parties and amici to address." Fed. Cir. IOP 14.3. Further, IOP 14.3 notes that "[a]dditional briefing and oral argument will be ordered as appropriate." *Id.*

The IOP does not contain a timing requirement for notice, and the requirement for briefing is "as appropriate" to the Federal Circuit. *Id.* Hence, where the court does not believe it needs additional briefing or oral argument to further aid in the decision, contemporaneous notice of en banc review with the court's decision is sufficient for compliance with the IOP. *See* Fed. Cir. IOP 14.3(c).

Regardless, the very first IOP states: "[t]he court reserves the right to depart from a provision in the IOPs when circumstances require." Fed. Cir. IOP 1.1. Thus, under any interpretation of the IOPs, the Federal Circuit was operating well within its authority.[2] As noted by Astellas, the Federal Circuit

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[2] Other circuits similarly state that they may depart from their operating procedures. For example, the Sixth Circuit states that its operating procedures "are not rules" and that "[i]n the interest of expediting decision or for other good cause, the Court may suspend the requirements of these [operating procedures]." 6th Cir. L.R. 2. Similarly, the Seventh Circuit asserts that the court may dispense with its operating procedures in particular cases; "[l]itigants acquire no rights under these procedures." 7th Cir. L.R. 2. The Tenth, Eleventh, and District of Columbia Circuits also contain provisions that

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has given contemporaneous notice before under IOP 14.3 (Pet. Br. at 9).

Moreover, the Supreme Court typically does not review whether courts have complied with their own operating procedures. As a general principle, "it is always within the discretion of a court or an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it. . . ." *Am. Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 539 (1970). The Court will not review a court's action with respect to its operating procedures "except upon a showing of substantial prejudice to the complaining party." *Id.* As the Federal Circuit's IOPs are procedural rules that it adopted for the orderly maintenance of its docket, it has the discretion to relax, modify, or circumvent the IOPs. Certainly, there is no abuse of discretion here.

Astellas's only alleged harm is the loss of opportunity for it and third-parties to comment on the product-by-process issue prior to the en banc ruling. However, Astellas's arguments in its petition parrot those of Judge Newman in *Scripps*, her dissent in the denial for rehearing of *Atlantic Thermoplastics*, and her dissent in this case, all of which the en banc court rejected and the Court now has before it. Thus, as Astellas puts it, "briefs from [Astellas and] the

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allow them to suspend their operating procedures or local rules. *See* 10th Cir. L.R. 2.1; 11th Cir. L.R. 2.1; D.C. Cir. R. 2.

public would have been an exercise in futility." (Pet. Br. at 9). Consequently, Astellas fails to allege a substantial prejudice in the Federal Circuit, and its procedural argument fails.

CONCLUSION

For the foregoing reasons, Sandoz Inc. respectfully requests that the Court deny certiorari.

Respectfully submitted,

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