No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC. AND AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California in case no. 3:14-cv-04741, Judge Richard Seeborg

RESPONSE OF SANDOZ INC. TO PETITION FOR REHEARING EN BANC BY AMGEN INC. AND AMGEN MANUFACTURING LIMITED

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SEPTEMBER 8, 2015

CERTIFICATE OF INTEREST

Counsel for defendant-appellee Sandoz Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Sandoz Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or are expected to appear in this court are:

Morrison & Foerster LLP: Rachel Krevans, Deanne E. Maynard, Grant J. Esposito, Joseph R. Palmore, Erik J. Olson, David C. Doyle, Marc A. Hearron, Anders T. Aannestad, Eric C. Pai, Stephen D. Keane, Julie Y. Park. Kirkland & Ellis LLP: James F. Hurst, Michael D. Shumsky, John K. Crisham, Reid P. Huefner.

Dated: September 8, 2015 /s/ Deanne E. Maynard

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INTRODUCTION

Properly interpreting the BPCIA as a whole, the panel concluded that a biosimilar applicant does "not violate the BPCIA by not disclosing its [application] and the manufacturing information" to a biologics sponsor under 42 U.S.C. § 262(*l*)(2)(A), and that Congress made a declaratory judgment action by the sponsor for "artificial" infringement the exclusive consequence for an applicant's non-disclosure. Slip Op. 15. That ruling is a correct application of established statutory construction principles. It warrants no further review.

As the panel concluded, subsection (*l*)(2)(A) must be read as part of the BPCIA's integrated "patent-dispute-resolution regime," which includes amendments to Titles 28, 35, and 42 of the U.S. Code. *Id.* at 5. These amendments create artificial acts of infringement, enabling declaratory judgment actions before actual infringement is imminent. 35 U.S.C. § 271(e)(2)(C). Who can bring such an action, when, and for what relief depends on the actions or inactions of the applicant and the sponsor at each step of a multi-step patent-exchange process regarding the sponsor's possible patent claims. 35 U.S.C. § 271(e)(2)(C), (4), (6); 28 U.S.C. § 2201(b); 42 U.S.C. § 262(*l*)(2)-(9). Congress carefully spelled out both the action the applicant or sponsor "shall" take as a condition precedent to continue the process, and if that party declines, what follows. Each step has benefits and burdens for both parties. Critically, the

BPCIA provides no means to force either participant to take any of those steps. Instead, each step is simply a procedural means to a substantive goal: resolving patent disputes so that biosimilars can be available to patients as soon as possible.

As the panel concluded, the BPCIA "explicitly contemplates" that an applicant might not disclose its application under subsection (*l*)(2)(A). Slip Op. 12. In that event, the BPCIA lays out a separate path for resolving any patent disputes: infringement litigation, with the scope and timing at the sponsor's sole discretion. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). The panel correctly concluded that taking this "path expressly contemplated by the BPCIA" cannot violate the Act. Slip Op. 15.

Indeed, as the panel also correctly concluded, the BPCIA expressly sets forth the exclusive consequence for an applicant's non-disclosure of its application. *Id.* at 13. As the panel explained, the non-disclosure about which Amgen complains "is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the '*only* remedies.'" *Id.* at 15 (emphasis added). The plain text of the BPCIA thus expressly forecloses the state-law remedies Amgen seeks, as well as any implied federal right of action to compel compliance with subsection (*l*)(2)(A). Amgen in fact already brought the artificial-infringement declaratory judgment action provided by Congress. *Id.* at 14.

Amgen's en banc petition should be denied.

BACKGROUND

Factual Background. For 24 years, Amgen has marketed its biological filgrastim product called Neupogen®. A5. Beginning in February 2014, and as recently as February 2015, Amgen publicly stated that its "material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013." A915; A960.

On July 7, 2014, the FDA accepted Sandoz's application for biosimilar filgrastim. A5. The next day, Sandoz notified Amgen of its application, advised Amgen that FDA approval was expected in the first half of 2015, and informed Amgen that Sandoz intended to launch immediately upon FDA approval. A1472-73. Sandoz also offered to provide its application subject to confidentiality terms that were more protective than the BPCIA's default terms. A1472-79; *see* 42 U.S.C. § 262(*l*)(1)(A). Amgen declined Sandoz's offer. A1481-82.

Concerned about sharing its application with a direct competitor, and in light of Amgen's public statements about its expired patents, Sandoz determined that subjecting itself to an immediate patent suit was the most expeditious path to resolution of any patent claims. A1495-97. On July 25, 2014, Sandoz informed Amgen that "Amgen [was] entitled to start a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(C)," and that Amgen could then "obtain access to the biosimilar application" under court-ordered confidentiality protections. A1495-96. Thus, as early as July 28, 2014, Amgen could have brought a declaratory judgment action

for artificial infringement and sought a patent-based preliminary injunction. 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Instead, Amgen waited.

District Court Proceedings. Months later, on October 24, 2014, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and a state-law conversion claim. A74. In addition, expressly invoking Section 262(*l*)(9)(C), Amgen brought an artificial-infringement claim under Section 271(e)(2)(C)(ii) of U.S. Patent No. 6,162,427, but still sought no preliminary injunction. Sandoz answered and counterclaimed. A271-88.

The parties cross-moved for partial judgment on the pleadings. Amgen's motion was limited to the "unlawful" element of its California UCL claim, seeking (as relevant to Amgen's en banc petition) a ruling that Sandoz's "failure" to provide its application violated the BPCIA. A305. Sandoz cross-moved on Amgen's state-law claims and Sandoz's first through fifth counterclaims. A351-79; A633-50. On February 5, 2015, more than three months after filing suit, Amgen at last moved for a preliminary injunction – but only on state-law claims.

On February 9, 2015, after months of Sandoz offering to produce its application under an interim protective order, Amgen finally accepted it. A734; A1353. On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar approved under the BPCIA. A1774-82.

District Court Decision. As relevant to Amgen's en banc petition, the district court held it was lawful for Sandoz not to provide its application under subsection (*l*)(2)(A). The court explained that the BPCIA "reflect[s] an integrated scheme that provides consequences for the choice either party makes at each step" of the patent-exchange process. A4-5. Rather than allowing the sponsor to compel compliance with subsection (*l*)(2)(A), the BPCIA "allow[s] the reference product sponsor to commence patent litigation immediately." A10. "Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion." A14.

This Court's Decision. A panel of this Court affirmed that ruling, holding that "[b]ecause Sandoz took a path expressly contemplated by the BPCIA, it did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline." Slip Op. 15. The BPCIA "specifically sets forth the consequence" in that event: the sponsor "may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." *Id.* at 12-13. Those provisions "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id.* at 14. Instead, not disclosing the application and information "is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the 'only remedies.'" *Id.* at 15. The panel thus affirmed

dismissal of Amgen's state-law claims, *id.* at 21-24, with Judge Newman dissenting.

ARGUMENT

The only causes of action on appeal arise under state law, and Amgen has acknowledged that its claims fail unless Sandoz acted unlawfully. Amgen Merits Br. 59-61. Thus, for further review of Amgen's petition to affect this Court's judgment, Amgen would have to demonstrate *both* that Sandoz acted "unlawfully" by taking procedural actions the BPCIA expressly contemplates *and* that Amgen is entitled to have courts provide relief the BPCIA expressly forecloses. The panel's ruling rejecting both contentions is correct and properly enforces the consequences chosen by Congress. Amgen's petition should be denied.

A. The Panel Correctly Concluded That It Was Lawful For Sandoz Not To Provide Its Application Under Section 262(*l*)(2)(A)

1. The BPCIA's carefully reticulated regime expressly contemplates the patent-resolution path taken by Sandoz

The panel correctly concluded that "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Slip Op. 22. "Sandoz took a path expressly contemplated" by the BPCIA: withholding its application and subjecting itself to patent litigation at a time and scope of the sponsor's choosing – a suit that Amgen already has brought. *Id.* Although that consequence may not be to Amgen's liking, it is the one chosen

by Congress. The panel properly refused to create additional ones.

The BPCIA created a carefully reticulated regime to allow patent disputes to commence before FDA approval, facilitating their resolution as quickly as possible. One route to the pre-approval artificial-infringement action created by the BPCIA is to complete its patent-exchange process. As a condition precedent to starting the process, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But as the panel correctly concluded (Slip Op. 12-13), the BPCIA expressly contemplates that an applicant might not provide its application under subsection (*l*)(2)(A). 42 U.S.C. § 262(*l*)(9)(C). In that event, the BPCIA authorizes the sponsor to file suit based on that act of artificial infringement, as Amgen has done. *See* 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). As the panel recognized, "[o]nce the [sponsor] brings an infringement suit under those two provisions, it can access the required information through discovery," as Amgen also has done. Slip Op. 14.

Rather than allowing either party to compel compliance with any particular step in the patent-exchange process, the BPCIA provides incentives to participate. The applicant that does not trigger the patent-exchange process loses its ability to impact the timing of such an artificial-infringement suit by the sponsor, 42 U.S.C. § 262(*l*)(9)(A), and it loses the control it otherwise would have over which patents,

or how many, the sponsor can assert. *Compare* 42 U.S.C. § 262(*l*)(9)(C), *with id.* § 262(*l*)(3)-(5). The sponsor also decides whether to delay suit until after FDA approval, forcing the applicant to launch at risk. An applicant may nevertheless choose this path if the applicant seeks a quick resolution, believes that no unexpired, relevant patents will remain after the exclusivity period expires, and/or has concerns about turning over its application without a court protective order.

In light of the BPCIA's integrated patent-resolution regime, the panel correctly concluded that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Slip Op. 12; *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (internal quotation omitted)). Despite many instances of "shall," the BPCIA provides multiple points at which the sponsor or the applicant may exit the patent-exchange process, and the statute delineates the effect of that choice on the scope and timing of a patent suit. In particular, as the panel correctly concluded, it "specifically sets forth the consequence" when an applicant does not provide its application under subsection (*l*)(2)(A): "the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." Slip Op. 12-13. Those provisions "indicate that 'shall' in paragraph (*l*)(2)(A) does not mean 'must'" in all circumstances. *Id.* at 13. "[M]andating compliance with paragraph (*l*)(2)(A) in all

circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." *Id.* at 14. The panel correctly concluded that taking "a path expressly contemplated by the BPCIA" cannot violate the Act. *Id.* at 15.

2. The panel correctly rejected Amgen's arguments

Amgen's theory depends on the word "shall" in subsection (*l*)(2)(A). But read in its proper context, the "shall" here creates a mandatory condition precedent. It specifies an action that an applicant *must* take to proceed to the next step of the patent-exchange process: *if* an applicant wishes to engage in the patent-exchange process, it "shall" timely provide its application to the sponsor. 42 U.S.C. § 262(*l*)(2)(A). But when the applicant does not satisfy that condition, the statute shifts the parties to a different patent-resolution track: "[*i*]*f* a subsection (k) applicant fails to provide [its] application," *id.* § 262(*l*)(9)(C) (emphasis added), that provides the sponsor with immediate standing to commence a declaratory judgment action under the BPCIA's amendments to the Patent Act, which make that precise failure an act of artificial infringement. Slip Op. 12-13.

Section 262(*l*)(6) confirms that the word "shall" as used in subsection (*l*) does not denote a requirement that is mandatory in all circumstances. Subsection (*l*)(6) provides that at the end of the patent-exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). If

Amgen were correct that "shall" in subsection (*l*) means mandatory in all circumstances, then a sponsor who failed to file an immediate suit for artificial infringement would be "violating" subsection (*l*)(6). *See Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007). It is not rational to believe that Congress made it "unlawful" for a private party to opt not to sue another private party.

Instead, the BPCIA provides incentives for the sponsor to bring an immediate suit, paired with consequences if it does not. Thus, just as with the "shall" provision in subsection (*l*)(2), the requirement that a sponsor "shall" sue within a specified time frame is a condition precedent to other statutory benefits, namely, the availability of the full patent-law remedies provided in Section 271(e). 35 U.S.C. § 271(e)(4), (6)(B). Just as in subsection (*l*)(2), the BPCIA expressly envisions that a sponsor might not sue until "*after* the expiration of the 30-day period" and provides consequences in that event. *Id.* § 271(e)(6)(A)(ii)(I) (emphasis added). That same "if/then" structure is present throughout subsection (*l*).

Contrary to Amgen's contention (Reh'g Pet. 9-10), the panel's interpretation is consistent with subsection (*l*)'s use of "shall," "may," "required," and "fails." Subsection (*l*)(2) uses "shall" and "may" to distinguish between (A) the information that "shall" be turned over as a condition precedent to participating in

the patent-exchange process, 42 U.S.C. § 262(*l*)(2)(A), and (B) the additional information that "may" be provided to the sponsor but is not a condition precedent to proceeding to the next step of the patent-exchange process, *id.* § 262(*l*)(2)(B). Similarly, the statute uses the word "required" to distinguish between the two types of information – the information required by the condition precedent in subsection (*l*)(2)(A) versus any additional information that might be disclosed under subsection (*l*)(2)(B). *See id.* § 262(*l*)(1)(B)(i); *id.* § 262(*l*)(9)(A), (C). The word "required" carries no additional meaning here.

Moreover, the BPCIA's description of the non-provision of the subsection (*l*)(2)(A) information as a "fail[ure]" does not mean that providing that information is mandatory in all circumstances. *See id.* § 262(*l*)(9)(C). The BPCIA elsewhere uses "fail[]" when there plainly is no such duty. Subsection (*l*)(4)(B) is titled "Failure to reach agreement" and discusses what happens if the parties "fail to agree on a final and complete list" of patents to litigate. *Id.* § 262(*l*)(4)(B). Yet despite the use of "fail," there is no obligation to agree and certainly no means to compel agreement.

B. The Panel Correctly Held That Amgen's Sole Recourse Is The BPCIA's Exclusive Patent-Law Remedies

1. The panel correctly concluded that the BPCIA expressly forecloses the relief Amgen seeks

Even if Amgen could convince a majority of the en banc Court of its reading

of subsection (*l*)(2)(A), that would have no effect on the ultimate judgment. The panel correctly held that the BPCIA makes its patent-law remedies the exclusive remedies for an applicant's non-disclosure under subsection (*l*)(2)(A). Slip Op. 14. The BPCIA thus expressly precludes state-law remedies as well as any implied federal remedy. As the panel explained, "Amgen alleged that Sandoz violated the BPCIA, but the alleged violation is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the 'only remedies.'" *Id.* at 15.

Specifically, Section 271(e)(2)(C)(ii) makes the very conduct about which Amgen complains – an applicant *both* submitting a biosimilar application *and* failing to provide the application and manufacturing information to the sponsor under subsection (*l*)(2)(A) – an act of artificial infringement under paragraph (2). 35 U.S.C. § 271(e)(2)(C)(ii). As the panel further explained, "35 U.S.C. § 271(e)(4) provides 'the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2).'" Slip Op. 14 (emphasis by panel). Those remedies are patent-specific, and the BPCIA does not include "any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id.*

2. The panel correctly rejected Amgen's arguments

To try to avoid the exclusivity of the remedies in Section 271(e)(4), Amgen suggests (Reh'g Pet. 11-13) that the declaratory judgment actions referred to in subsection (*l*)(9) are separate from the artificial-infringement actions created in

Section 271(e)(2)(C)(ii). They are not. Absent the BPCIA's amendments to the Patent Act, the sponsor would have no action under the Declaratory Judgment Act (or any other statute) based on an applicant's withholding of its application. That act of artificial infringement is what enables the sponsor to bring a declaratory judgment suit. *See Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004). In focusing on whether subsection (*l*)(9)(C), standing alone, is remedial, Amgen wrongly ignores the interaction between Section 262(*l*) and these other amendments. If the "Subsection (k) application" is "not provided," subsection (*l*)(9)(C) deprives the applicant of the ability to bring certain declaratory judgment actions while authorizing the sponsor to commence immediately a declaratory judgment action for artificial infringement. 42 U.S.C. § 262(*l*)(9)(C).

Amgen next asserts that "[f]ailing to provide the [application] and manufacturing information is not an act of infringement," asserting that the panel "read[] a limitation into infringement under section 271(e)(2)(C)(ii)." Reh'g Pet. 13-14. But that limitation is in the text of the provision itself:

> It shall be an act of infringement to submit— . . . if the applicant for the application fails to provide the application and information required under section [262](*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section [262](*l*)(3)(A)(i) of such Act.

35 U.S.C. § 271(e)(2)(C)(ii). If there is no such failure, there is no artificial infringement under Section 271(e)(2)(C)(ii). If, as Amgen argues, submission of a

biosimilar application alone were an act of infringement, that would render Congress's carefully reticulated scheme essentially irrelevant; either party could commence a declaratory judgment action as soon as an application was filed.[1]

Amgen also suggests that an applicant's non-disclosure of its application will cause the sponsor vague non-patent-infringement harms that courts have "broad powers under federal and state laws to remediate." Reh'g Pet. 15. To the extent Amgen suggests the creation of an implied federal right of action to enforce the BPCIA's procedural steps, the district court correctly held Amgen waived that claim. A8 n.4; A73-80. This case thus would not be a good vehicle for en banc review of that question. In any event, courts are not free to fashion additional remedies not provided by Congress, even if the statute does not "'affirmatively' preclude the availability of a judge-made action at equity." *Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1386 (2015).

In short, Amgen asks this Court to create consequences that Congress chose not to provide. As the majority concluded, the BPCIA contains no provision "that grants a procedural right to compel compliance with the disclosure requirement of

[1] The scope of the artificial infringement under Section 271(e)(2)(C)(ii) likewise is determined by its text. *See* Slip Op. 13 & n.3. Amgen's analogy (Reh'g Pet. 14) to the Hatch-Waxman Act is inapt, both because the BPCIA text is fundamentally different, and because in Hatch-Waxman the submission of an ANDA and a paragraph IV certification *together* constitute the artificial infringement and determine the scope of the infringement. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

paragraph (*l*)(2)(A)." Slip Op. 13. The only provision in subsection (*l*) that Congress chose to make enforceable by an injunction is the confidentiality provision. 42 U.S.C. § 262(*l*)(1)(H). Moreover, contrary to Amgen's suggestion (Reh'g Pet. 3), Congress did not link compliance with any of the patent-exchange provisions to FDA approval. Rather, Congress provided sponsors with 12 years of exclusivity, regardless of patent protection, in exchange for their innovation. 42 U.S.C. § 262(k)(7)(A).

In any event, patent rights are the only substantive interests implicated by the patent-exchange procedures that Amgen invokes. After all, subsection (*l*) is titled "Patents." Even if Sandoz had followed the subsection (*l*) procedures, that process ultimately would have resulted only in Amgen's ability to file a patent-infringement suit – *which Amgen already has done*. Slip Op. 14; *see* 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A).

CONCLUSION

Amgen's en banc petition should be denied. If the Court were to grant Amgen's petition, however, it also should grant Sandoz's petition. Notably, although several amici support granting Sandoz's petition, none supports Amgen's.

Respectfully submitted,

/s/ Deanne E. Maynard

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Dated: September 8, 2015

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on September 8, 2015.

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