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, Case No. 3:14-cv-04741-RS, Judge Richard Seeborg

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SANDOZ INC.'S OPPOSITION TO EMERGENCY MOTION FOR INJUNCTION PENDING EN BANC CONSIDERATION AND REVIEW

NON-CONFIDENTIAL VERSION

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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: August 31, 2015 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

Materials that were made confidential pursuant to the protective order have been redacted from the non-confidential version of the brief. These materials include confidential business information from documents and exhibits filed in the district court.

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INTRODUCTION

In a perfunctory motion, Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited ("Amgen") ask for an injunction "preventing Defendant-Appellee Sandoz Inc. ("Sandoz") from launching its biosimilar product ZARXIO®—while the Court considers whether to grant Amgen's petition for rehearing en banc, and if granted, while the en banc Court decides this appeal." Mot. 1. Amgen's four-page "Emergency Motion" does not even state, much less attempt to meet, the applicable standard for such an injunction. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 21-22 (2008). That alone is sufficient reason to deny Amgen's extraordinary request.

Moreover, any "emergency" is entirely of Amgen's own making. Over a month ago, on July 21, 2015, a panel of this Court issued its decision in this case. That decision "extend[ed] the injunction pending appeal through September 2, 2015," to allow Amgen "a period of time to assess and act upon its patent rights." Slip Op. 21-22. Yet despite being well aware of the impending September 2 expiration of that injunction as well as its own plans to seek rehearing en banc, Amgen waited until days before the expiration date to file this motion. And, despite having received Sandoz's biosimilar application on February 9, 2015 (A734), Amgen still has not sought an injunction from *any* court based on *any* alleged patent rights. Amgen's own delay precludes the equitable relief it seeks.

Apple, Inc. v. Samsung Elecs. Co., 678 F.3d 1314, 1325 (Fed. Cir. 2012); *High Tech Med. Instrumentation, Inc. v. New Image Indus.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995).

Nevertheless, because of the significant harm that would befall cancer patients, filgrastim purchasers (including taxpayers), and Sandoz if this Court were to grant Amgen's motion, Sandoz responds here in full. As explained below, Amgen did not address the governing standard for good reason: it cannot establish any of the four factors required for an injunction pending appeal – much less all of them. Most significantly, the balance of interests weighs against any further injunction. Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") to make competing biosimilar products available to patients and to reduce prices. The Food and Drug Administration ("FDA") approved Sandoz's filgrastim product Zarxio® on March 6, 2015, and a panel of this Court has determined that, under the BPCIA, Sandoz can commercially market Zarxio® on September 3, 2015. Amgen's motion should be denied.

ARGUMENT

I. AMGEN'S MOTION SHOULD BE DENIED

An injunction is an "extraordinary remedy" requiring "a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22. An injunction pending appeal requires a court to consider:

> (1) whether the . . . applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent [an injunction]; (3) whether issuance of the [injunction] will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776 (1987). Satisfying one factor does not lessen the requirement to establish the others. *See Winter*, 555 U.S. at 21-22.

A. Amgen Cannot Make A Strong Showing Of A Likelihood Of Success On The Merits

Amgen does not try to make any showing of a likelihood of success on its en banc petition – *i.e.*, that the Court will both grant its petition and reverse. Amgen merely states that it "believes that the panel majority erred in its holding." Mot. 2. To say the least, that is not a "strong showing." Even if Amgen's rehearing petition were granted (and it should not be), Amgen cannot prevail on its state-law claims – the only claims on appeal. To do so, Amgen would have to demonstrate *both* that Sandoz acted "unlawfully" when it took procedural actions expressly contemplated by the BPCIA *and* that Amgen is entitled to have courts provide relief expressly foreclosed by the BPCIA. As explained below, Amgen cannot show that it is likely to prevail on either, much less both, of those issues.

1. The panel correctly held that it was lawful for Sandoz not to provide its application under Section 262(l)(2)(A)

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. The BPCIA created a carefully reticulated regime to facilitate early resolution of potential patent disputes. It amended the Patent Act to make submitting a biosimilar application to the FDA an artificial act of infringement under certain circumstances. 35 U.S.C. § 271(e)(2)(C). That enables a declaratory judgment action before any actual infringement is imminent. Who can bring such an action, when, and for what relief depends on the actions or inactions at each step of a multi-step information exchange process between the applicant and the sponsor 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 spelled out both the action the applicant or sponsor "shall" take to continue the process and, if that party declines, what follows. The end result is a possible pre-approval artificial-infringement suit. *Id.*

One route to that pre-approval patent litigation is to complete the BPCIA's patent-exchange process from beginning to end. 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 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), and the BPCIA lays out a separate path for resolving any patent disputes in that event: patent-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).

Contrary to Amgen's suggestion (Mot. 3), an applicant does not "damage" the sponsor when it does not provide its biosimilar application. Rather, the sponsor gains the right to file an immediate, pre-launch 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); *see* Slip Op. 13 & n.3. 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.

By contrast, when an applicant does not trigger the patent-exchange process, the applicant loses its ability to impact the timing of such a suit, *see* 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 alone decides whether and when to sue and can delay suit until after FDA approval, effectively forcing the applicant to launch at risk. An applicant may nevertheless choose to pursue this path when the applicant seeks a quick resolution, believes that no unexpired patents covering the sponsor's product will remain after the 12-year 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," as Amgen seeks to do. 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): "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. Amgen's sole recourse is the BPCIA's exclusive patent-law remedies

Even if Amgen could make a strong showing that it is likely to succeed on its reading of Section 262(*l*)(2)(A) (which it cannot), Amgen cannot make a strong

showing that it would be entitled to have a court "fashion a remedy" for its alleged injury from Sandoz's purported "violation" of subsection (*l*)(2)(A). Mot. 3. The only causes of action at issue in Amgen's en banc petition arise under state law, which Amgen argues entitles it to a state-law injunction. But as the panel correctly held, the BPCIA provides that its patent-law remedies are the exclusive remedies for an applicant's non-disclosure of its application under subsection (*l*)(2). Slip Op. 14. The BPCIA thus forecloses the state-law remedies that Amgen seeks.

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) provides that "if the applicant . . . fails to provide the application" to the sponsor, the submission of the application to FDA constitutes an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii). And, 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 added by panel).

Amgen already has brought such an artificial-infringement suit, and it remains pending in district court. But to be entitled to any relief in that suit, Amgen must prove infringement of a valid patent claim. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365-66 (Fed. Cir. 2003). Amgen has made no

attempt to do so.

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 such a claim. A8 n.4; A73-80. In any event, there is no evidence of the required affirmative congressional intent to create such a private right of action, and Amgen has never tried to establish that Congress did so. *See, e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001). Moreover, the BPCIA's creation of its own exclusive remedies – regardless of whether they are to Amgen's liking – defeats the effort to imply additional ones. *Id.* at 290.

B. Amgen Has Not Shown A Likelihood Of Irreparable Harm

Amgen asserts, without explanation, that it will be irreparably harmed without an injunction beyond September 2, 2015. Mot. 3. Amgen's actions belie its claim. Amgen delayed months before bringing this suit: it could have sued Sandoz as early as July 28, 2014, but it did not do so until October 24, 2014. *See* A74; A1495-96. Amgen then delayed three more months, until February 5, 2015, before finally moving for a preliminary injunction – and then based only on state-law claims, not on alleged patent infringement. A441; A469. It now has waited over five weeks since the panel's July 21, 2015, decision before seeking this injunction. Amgen's unexplained delays negate its claim of harm and preclude its resort to equity. *Apple*, 678 F.3d at 1325; *High Tech*, 49 F.3d at 1557.

Amgen asserts that it needs this injunction due to the "unique interests Amgen seeks to protect, which include, but go beyond its patents," so that, if it ultimately prevails before the en banc Court, the district court can "fashion a remedy." Mot. 3. Amgen does not bother to explain what those non-patent "unique interests" might be, but patent rights are the only substantive interests protected by the BPCIA procedures that Amgen invokes. Even if Sandoz had followed those procedures, they ultimately would have resulted only in Amgen's ability to file a patent-infringement suit, *which Amgen already has done*. Slip Op. 14; 42 U.S.C. § 262(*l*)(6), (8)(B), (9)(A). Yet despite having now had Sandoz's biosimilar application for nearly seven months, Amgen still has not tried to prove any infringement. Indeed, although the majority interpreted the BPCIA to give Amgen an additional 180 days of exclusivity beyond what Congress expressly provided (*see* Dkt. 119 (Sandoz Reh'g Pet.)) to allow Amgen "a period of time to assess and act upon its patent rights" (Slip Op. 21), Amgen still has not sought a patent-based injunction. If Amgen ever proves infringement of a valid patent claim, the district court can fashion an appropriate remedy then.

Amgen also makes passing reference to its previous claims of irreparable harm. Mot. 3. As the district court found as fact, those claimed harms are "at best highly speculative." A18, A2080; *see* Dkt. 84 (Sandoz Opp'n to FRAP 8 Mot.) at 15-19. Although the panel issued an injunction pending appeal, it never expressly

stated that the district court's findings were clearly erroneous. *See* Fed. R. Civ. P. 52(a)(6). They were not. And Amgen's terse references to irreparable harm are insufficient to justify an injunction.

First, Amgen did not establish price erosion. [redacted] Beginning in February 2014, and as recently as February 2015, Amgen's annual and quarterly reports have stated: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States . . . ." A915; A960. [redacted] In any event, any price erosion could be remedied by patent-infringement damages. *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009).

Second, Amgen's claimed harm to goodwill is equally unavailing. Amgen's theory is contingent on Amgen's lowering Neupogen® prices, then forcing removal of Sandoz's product from the market, then rapidly rehabilitating prices. But as explained above, any price reduction by Amgen is speculative. Nor has Amgen established it has any patent rights to remove Sandoz's product from the market.

Third, Amgen argued its 400-patent portfolio is somehow diminished

because, without Sandoz's application, it was "impossible for Amgen to determine which of [its] patents read on the manufacture of Sandoz's biological product." Dkt. 56 at 18. This claim cannot support irreparable harm at this point because Amgen has had Sandoz's application since February 9, 2015, and yet has failed to move for an injunction on *any* of those patents, including the patent asserted in the district court here. In any event, Sandoz's withholding its application put Amgen in a *better* position to enforce its patent rights, permitting it to sue much earlier, in July 2014. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C).

C. The Balance Of Hardships Weighs In Sandoz's Favor

Sandoz invested years of effort and tens of millions of dollars to have the first biosimilar filgrastim in the United States. Through this considerable investment, Sandoz established a significant head start over two competing biosimilar filgrastim applicants expected to receive approval and launch this year or early in 2016. A1063. Any further injunction would seriously jeopardize the first-to-market advantage Sandoz earned. A1060-68. By contrast, Amgen already has enjoyed double the 12-year exclusivity period Congress decided sufficient to reward biologics innovation. 42 U.S.C. § 262(k)(7)(A). If Amgen has any valid patent rights and if Amgen had been diligent, it could have obtained Sandoz's application in discovery, evaluated it, added any allegedly relevant patents to the litigation, and sought an injunction based on them last year. It did not.

D. An Injunction Would Disserve The Public Interest

The requested injunction would disserve the public interest. Congress enacted the BPCIA to provide patients with competing biosimilar products and to tackle the enormous costs of biologics by speeding biosimilars to market. Sandoz's filgrastim product Zarxio® has been approved since March 6, 2015, but Sandoz has not yet been able to make it available to cancer patients. A panel of this Court already has rejected Amgen's claims and determined that Sandoz can commercially market Zarxio® on September 3, 2015. Any further injunction would harm the interests of cancer patients and purchasers – including taxpayers (through Medicare and Medicaid), insurers, and consumers.

II. ANY INJUNCTION MUST BE CONDITIONED ON THE POSTING OF A SIGNIFICANT BOND AND MUST BE LIMITED IN SCOPE

Amgen's motion should be denied. But were an injunction to be issued, it should be conditioned on the posting of a substantial bond. Amgen has never contested a bond requirement. "Normally an injunction bond or equivalent security is essential." *Roche Diagnostics Corp. v. Med. Automation Sys., Inc.*, 646 F.3d 424, 428 (7th Cir. 2011). A bond is essential to protect Sandoz in case it ultimately is concluded that Sandoz "had the right all along to do what it was enjoined from doing." *Nintendo of Am., Inc. v. Lewis Galoob Toys, Inc.*, 16 F.3d 1032, 1036 (9th Cir. 1994). If so, Sandoz will be "entitled to be made whole." *Roche*, 646 F.3d at 428. As Sandoz requested in its petition for rehearing, Amgen

immediately should be required to post a bond sufficient to cover the harm Sandoz has suffered since the panel first issued the injunction on May 5, 2015. Dkt. 119 (Sandoz Reh'g Pet.) at 14-15. If Sandoz is further enjoined, it would be further harmed.

The parties previously submitted briefing on the appropriate amount of a bond. Dkts. 108, 111. For the reasons set forth in its bond brief, Sandoz respectfully requests that any bond be set at $460,000 per day for the period of the injunction. Dkt. 108 (Sandoz Statement Regarding Bond) at 1. The risk of setting a bond that is too low runs only in one direction. Amgen has ample resources ($27 billion in cash and marketable securities, A690) and will not be harmed by posting a bond, even if the bond amount later turns out to be more than necessary. "Judges therefore should take care that the bond is set high enough to cover the losses that their handiwork could cause." *Roche*, 646 F.3d at 428; *see Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000) (courts "should err on the high side"). "A limit of zero – the upshot of an injunction without a bond – is bound to be too low." *Roche*, 646 F.3d at 428.

Finally, Amgen seeks an injunction that would bar Sandoz "from marketing, selling, offering for sale, or importing into the United States its ZARXIO® biosimilar product." Mot. 3-4. For all of the reasons Sandoz already has briefed to this Court, there is no basis in the BPCIA for an injunction that broad. *See* Dkt. 68

(Sandoz Merits Response Br.) at 63; Dkt. 84 (Sandoz Opp'n to FRAP 8 Mot.) at 20; Dkt. 119 (Sandoz Reh'g Pet.) at 14. In addition, any injunction based on Amgen's California-law claims (the only claims it has asserted here) could apply only to conduct occurring within California. Dkt. 68 (Sandoz Merits Response Br.) at 55-56; Dkt. 84 (Sandoz Opp'n to FRAP 8 Mot.) at 20; *see Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1360 (Fed. Cir. 2013) (reversing nationwide injunction), *cert. denied*, 135 S. Ct. 2886 (2015).

CONCLUSION

Amgen's "emergency" motion for injunctive relief should be denied. If it were to be granted, it should be conditioned on the posting of a substantial bond and should be limited in scope.

Respectfully submitted,

/s/ Deanne E. Maynard

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Dated: August 31, 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 August 31, 2015.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: August 31, 2015 /s/ Deanne E. Maynard

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