Appeal No. 2015-1499

United States Court of Appeals

for the

Federal Circuit

AMGEN INC., 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-RS, JUDGE RICHARD SEEBORG

NON-CONFIDENTIAL EMERGENCY MOTION OF PLAINTIFFS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING LIMITED FOR AN INJUNCTION PENDING APPEAL PURSUANT TO FED. R. APP. P. 8(a)

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April 17, 2015

CERTIFICATE OF INTEREST

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

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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:

   AMGEN INC. and AMGEN MANUFACTURING LTD.

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

   AMGEN INC.

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

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STATEMENT OF OPPOSITION

Pursuant to Federal Circuit Rule 27(a)(5), counsel for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") informed counsel for Defendant-Appellee Sandoz Inc. ("Sandoz") of Amgen's intent to file this motion and sought Sandoz's position. Sandoz indicated that it opposes the motion. The parties have agreed to an expedited schedule for this motion, and Amgen is concurrently submitting an unopposed motion reflecting that schedule.

CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 27(m), Amgen has prepared a public version of this motion that omits certain confidential information. Specifically, the material omitted on pages 5 and 17 contains references to Sandoz's confidential information regarding Sandoz's pricing strategy and marketing and sales strategy. The omitted information was designated confidential by Sandoz during discovery under the terms of the Protective Order entered by the district court.

In addition, Amgen has attached public versions of exhibits in support of this motion that omit certain confidential information. Specifically, the material omitted in the exhibits contains Amgen's confidential information regarding market analysis, and sales, pricing, and revenue forecasts, and Sandoz's confidential information regarding pricing strategy and marketing and sales strategy. The omitted information was designated confidential by Amgen and Sandoz under the terms of the Protective Order entered by the district court.

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PRELIMINARY STATEMENT

Sandoz is poised to begin commercial marketing of the first FDA-approved biosimilar, which is a copy of Amgen's innovative NEUPOGEN® biological product. Sandoz has agreed to stay off the market only until May 11, 2015 absent judicial intervention. The commercial marketing and sale of Sandoz's biosimilar product ZARXIO® will be in direct competition with Amgen's NEUPOGEN® and will fundamentally and permanently alter the market, causing irreparable harm to Amgen if this Court ultimately reverses the district court's decision. Accordingly, Amgen respectfully requests that this Court enter an injunction during the appeal, before the status quo is irrevocably changed. Amgen's requested injunction will be short: the merits briefing will be completed by April 28, 2015, and the parties have requested oral argument in June 2015. (Dkt. No. 19.)

This case presents issues of first impression regarding the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 119, 804 (2010). Before 2010, FDA approved biological products under only 42 U.S.C. § 262(a), which typically requires three phases of clinical trials to prove safety, purity, and potency. *Compare* 42 U.S.C. § 262 (2007), *with* 42 U.S.C. § 262 (2010). The BPCIA created a new, abbreviated regulatory pathway, codified in 42 U.S.C. § 262(k), for approval of a biological product as "biosimilar to" a "reference product" that FDA had previously licensed under 42 U.S.C. § 262(a).

Amgen's position is that when a "subsection (k) applicant" (or "Applicant") uses this new regulatory pathway it commits to complying with the mandatory provisions of the BPCIA; it may not follow the provisions it likes and opt out of those it does not. Sandoz's position, which the district court adopted, is that an Applicant may opt in or out of statutory provisions depending on whether it wishes to take advantage of their benefits.

Sandoz submitted an application for ZARXIO® under the abbreviated pathway, referencing Amgen's license for its NEUPOGEN® (filgrastim) product. Ex. 1 at A0005. This lawsuit arose because Sandoz submitted a biologics license application (a "BLA") and pursued FDA approval and threatened to launch its product without complying with the pre- and post-FDA-approval BPCIA provisions that protect the rights of Amgen (the "reference product sponsor" or "RPS"), including the statute's disclosure and patent-dispute process. As the district court stated, "there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process." Ex. 1 at A0002.

Amgen has demonstrated a substantial case on the merits that the statute creates mandatory obligations by the Applicant to the RPS, that Sandoz failed to satisfy those obligations, and that the statute does not foreclose the courts' remedial powers to compel compliance with those obligations. The district court made three fundamental errors of law:

First, § 262(*l*)(2)(A) requires an Applicant to provide a copy of its BLA and information about the manufacture of its proposed biosimilar product to the RPS within 20 days of FDA accepting the BLA for review. Sandoz did not do this. Ex. 1 at A0002. Nevertheless, the district court held that Sandoz was within its rights to elect not to do so. Ex. 1 at A0018. This was error.

Second, § 262(*l*)(8)(A) requires the Applicant to provide at least 180 days' notice before the first commercial marketing of "the biological product licensed under subsection (k)." Sandoz provided this notice when FDA accepted its BLA for review, rather than after FDA approval when its product became "licensed under subsection (k)." Ex. 4 at A0065-66, 71; Ex. 9 at A1472. Nevertheless, the district court held that Sandoz's notice was timely. Ex. 1 at A0014. This too was error.

Third, the district court held that even if Sandoz was required to provide its BLA and manufacturing information and even if Sandoz gave untimely notice of commercial marketing, the BPCIA does not permit the courts to compel compliance with the statute, instead limiting any remedy to the RPS bringing a declaratory judgment of infringement, validity, or enforceability of a patent. Ex. 1 at A0014 n.8, 18. This again was error because the BPCIA forecloses no applicable remedies, and district courts should have a broad range of tools available where an Applicant violates the statute.

From its erroneous reading of the BPCIA, the district court further erred in denying Amgen's motion for a preliminary injunction to compel Sandoz to comply with the terms of the BPCIA as properly construed. After entry of judgment, the district court also declined to enter an injunction pending appeal under Fed. R. Civ. P. 62(c) (Ex. 15 at A2078-80), reasoning that "any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent." Ex. 15 at A2080.

Accordingly, Amgen respectfully requests an injunction pursuant to Fed. R. App. P. 8(a) preventing Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved ZARXIO® biosimilar product until this Court resolves the appeal.

FACTUAL BACKGROUND

A. Amgen's Innovator Product, NEUPOGEN®, and Sandoz's Biosimilar Filgrastim Product, ZARXIO®

In 1991, Amgen obtained regulatory approval for NEUPOGEN® under the traditional biological product regulatory pathway, 42 U.S.C. § 262(a), including demonstrating to the FDA that NEUPOGEN® "is safe, pure, and potent." Ex. 1 at A0005; 42 U.S.C. § 262(a)(2)(C)(i)(I). The active ingredient in NEUPOGEN® is filgrastim, which stimulates the production of white blood cells known as neutrophils. Ex. 4 at A0058.

In 2014, Sandoz filed a BLA under the BPCIA's abbreviated pathway of 42 U.S.C. § 262(k) for approval of its biosimilar filgrastim product, designating Amgen's NEUPOGEN® as the reference product. Ex. 1 at A0005; Ex. 9 at A1472. FDA notified Sandoz that it had accepted its BLA for review on July 7, 2014. Ex. 1 at A0005. FDA approved Sandoz's BLA on March 6, 2015. Ex. 12 at A1775. Sandoz will market its filgrastim product under the name ZARXIO®, *id.*, in direct competition with NEUPOGEN® for each of NEUPOGEN®'s FDA-approved indications. Ex. 12 at A1783. It is undisputed that Sandoz intends to price ZARXIO® [redacted]

B. Sandoz's Refusal to Comply with the BPCIA

Despite availing itself of the benefits of the abbreviated pathway conferred by referencing Amgen's biological license, Sandoz refused to follow the statutory requirements of the BPCIA that protect Amgen's patent rights. Had Sandoz complied with those provisions, Amgen would have been able to identify those patents for which Amgen believes a patent infringement claim could reasonably be asserted, leading to additional exchanges that would have resulted in either a negotiated resolution of the patent disputes or an informed patent-infringement lawsuit under § 262(*l*)(6). Ex. 4 at A0071-72. Without Sandoz's disclosure,

Amgen was materially prejudiced because it was denied the time and information to detect Sandoz's patent infringement and commence an action under the BPCIA before FDA licensure of the biosimilar product. Ex. 4 at A0071-73.

In addition, Sandoz refused to provide Amgen with 180 days' notice of commercial marketing after FDA licensure of the biosimilar product, as required by § 262(*l*)(8)(A). Instead, Sandoz attempted to provide notice prematurely at the same time that FDA accepted its BLA for review, eight months prior to FDA licensure. Ex. 9 at A1472; Ex. 4 at A0071; Ex. 12 at A1774. Had Sandoz given notice after FDA licensure (and not before), Amgen could have had notice of the product that was actually licensed (rather than the biological product that is the subject of the FDA application), and thus used the notice period to commence an orderly preliminary injunction process as contemplated by § 262(*l*)(8)(B).

PROCEDURAL HISTORY

On March 19, 2015, the district court: (1) granted Sandoz's motion for judgment that its reading of the BPCIA is correct, (2) rejected Amgen's motion for judgment on the pleadings that Sandoz's refusal to comply with the BPCIA was a violation of California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 et seq.) (the "UCL"), and (3) denied Amgen's motion for a preliminary injunction that Sandoz comply with the BPCIA's requirements as Amgen understands them. Ex. 1 at A0001-19.

On March 25, 2015, the district court entered final judgment under Rule 54(b) as to the BPCIA claims. Ex. 2 at A0020-23. Amgen timely appealed both the judgment and the district court's denial of Amgen's motion for a preliminary injunction. Ex. 3 at A0024-26. The district court denied Amgen's motion for an injunction pending appeal on April 15, 2015, asserting that Amgen would suffer undue harm only if "Sandoz has infringed an Amgen patent." Ex. 15 at A2080.

ARGUMENT

This Court grants injunctions pending appeal based on a determination of "(1) whether the movant has made a strong showing of likelihood of success on the merits; (2) whether the movant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *See AstraZeneca LP v. Breath Ltd.*, No. 15-1335, Dkt. No. 46, at 2 (Fed. Cir. Mar. 12, 2015) (nonprecedential).

I. Amgen is Likely to Succeed on the Merits

This Court reviews the district court's interpretation of the BPCIA de novo, and reviews the denial of Amgen's preliminary injunction motion for abuse of discretion, reversing if "'the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'" *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*,

686 F.3d 1348, 1352 (Fed. Cir. 2012) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997)). Here, Amgen is likely to succeed on the merits of this appeal because the district court erred in its interpretation of the BPCIA. Specifically, the district court's reading of the BPCIA converts a statute designed to balance the interests of the Applicant and the RPS into one that vitiates the benefits afforded to the RPS. That was not what Congress intended. Congress enacted the BPCIA as part of the Affordable Care Act, because it was "the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

On the one hand, Applicants and the public benefited from the new pathway because it diminished innovators' previous enjoyment of permanent and exclusive rights to their clinical trial data and FDA license. In the BPCIA, Congress advanced the public's interest in price competition by, for example: allowing an Applicant to "reference" the RPS's license and thereby rely on the safety and efficacy of the RPS product, rather than generating its own clinical trial data; limiting an innovator's data exclusivity to twelve years; and allowing the Applicant to enter a market with established demand for the reference product.

On the other hand, Congress protected the RPS and the public's interest in innovation and preserving patents, in part by creating an exchange, negotiation, and patent resolution process in 42 U.S.C. § 262(*l*), "Patents." That subsection

requires the Applicant to provide the RPS with the BLA for the proposed biosimilar and manufacturing information, and requires the parties to identify patents and exchange detailed infringement, validity, and enforceability contentions. The statute then creates a new "Immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6). Subsection 262(*l*)(8) also preserves the status quo for an 180-day period between FDA licensure of a biosimilar product and its first commercial availability so that the RPS may seek injunctive relief on patents that are not listed for the § 262(*l*)(6) litigation.

A. Amgen Will Show that The District Court Erred in Holding that the Requirement of 42 U.S.C. § 262(*l*)(2)(A) Is Not Mandatory

Subsection 262(*l*) creates a detailed, elaborate procedure for patent-dispute resolution. It begins within twenty days of the Applicant being notified by FDA that its BLA has been accepted for review; the Applicant "shall provide" to the RPS a copy of the BLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A).

Following receipt of the BLA and manufacturing information, § 262(*l*)(3) requires the RPS (and the Applicant if it chooses) to provide a list of patents for which "a claim of patent infringement could reasonably be asserted," and to discuss whether the parties are willing to license those patents and whether the Applicant will remain off the market until their expiry. For any other listed

patents—*i.e.*, those for which there is an active dispute—the parties must provide detailed statements describing, claim-by-claim, the factual and legal basis for their contentions regarding infringement, validity, and enforceability. *See* 42 U.S.C. § 262(*l*)(3)(B), (C). Sections (*l*)(4) and (*l*)(5) then require that the Applicant and RPS jointly determine which of the patents identified in the (*l*)(3) exchange shall be the subject of an "[i]mmediate patent infringement action" that the reference product sponsor "shall bring." *Id.* § 262(*l*)(6).

Despite the entire process hinging on the provision of a copy of the BLA and manufacturing information under 42 U.S.C. § 262(*l*)(2)(A), the district court held that an Applicant may "elect" not to provide that information. Ex. 1 at A0009, 18. The court held that an Applicants and RPS "may participate" in the provisions of § 262(*l*), but that "these procedures are 'required'" only "where the parties elect to take advantage of their benefits." Ex. 1 at A0001, 9. The district court erred.

The statute explicitly says that the provision of the BLA and manufacturing information is mandatory. Subsection 262(*l*)(2)(A) says the Applicant "shall provide" its BLA and manufacturing information "[n]ot later than 20 days" after receiving notice that FDA has accepted its BLA for review. "Shall" is generally mandatory language. *See*, *e.g.*, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007); *Lopez v. Davis*, 531 U.S. 230, 241 (2001); *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998).

This is particularly true where, as here, "shall" is juxtaposed with "may." *See, e.g., Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 346 (2005). Under § 262(*l*)(2), the Applicant "shall" provide its BLA and manufacturing information, and "may" provide anything else that the RPS requests. Furthermore, the BPCIA refers to the provision of the Applicant's BLA and manufacturing information as "required" in four separate places. *See* 42 U.S.C. § 262(*l*)(1)(B)(i), (9)(A), (9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). In two, it refers to non-provision of the information as "fail[ure]." *See* 42 U.S.C. § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

The district court based its decision in part on its belief that permitting Sandoz "not to comply" with § 262(*l*) "operates to promote expedient resolution of patent disputes." Ex. 1 at A0011. This turns the statute on its head. In crafting the BPCIA, Congress created a new, "[i]mmediate" patent infringement lawsuit under § 262(*l*)(6). Many other provisions, affecting the rights of the Applicant, the RPS, the public, and even other biosimilar applicants targeting the same reference product, are affected by whether and when a § 262(*l*)(6) lawsuit is filed. *See*, *e.g.*, 42 U.S.C. § 262(k)(6); 35 U.S.C. § 271(e)(4)(D), (e)(6). By allowing the Applicant to prevent a § 262(*l*)(6) lawsuit from ever being filed, the district court toppled the statutory balance in favor of the Applicant and allowed Applicants to game the system.

B. Amgen Will Show that the District Court Erred in Holding that an Applicant May Give Notice of Commercial Marketing Before FDA Licensure of its Biosimilar Product

Subsection 262(*l*) recognizes that there may be patents that read on the biosimilar product and the methods of its manufacture that were initially included in the parties' lists under § 262(*l*)(3) but were not listed for inclusion in the § 262(*l*)(6) lawsuit, as well as "[n]ewly issued or licensed patents" that become part of the RPS's § 262(*l*)(3)(A) list by virtue of § 262(*l*)(7). The BPCIA provides for certain litigation over these patents once FDA licenses the biosimilar product and the Applicant gives the at-least-180-days' notice provided for by § 262(*l*)(8)(A). Provision of that notice triggers preliminary injunction practice for these patents under § 262(*l*)(8)(B), and declaratory judgment actions under § 262(*l*)(9)(A).

Nevertheless, the district court held it was "not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval." Ex. 1 at A0014. The district court erred.

Subsection 262(*l*)(8)(A) requires the Applicant to give notice of commercial marketing of "the biological product licensed under subsection (k)" (emphasis added). Everywhere else § 262(*l*) refers to the product, it uses a variant of "the biological product that is the subject of" the BLA. *See* 42 U.S.C. § 262(i)(2),

(*l*)(1)(D), (*l*)(2)(A), (*l*)(3)(A)(i), (*l*)(3)(B)(i), (*l*)(3)(B)(ii)(I), (*l*)(3)(C), (*l*)(7)(B). The distinction is significant: An Applicant may not give 180 days' notice until the product that was "the subject of the application" becomes a "biological product licensed"—*i.e.*, until after FDA licensure. Everywhere else that 42 U.S.C. § 262 uses the term "product licensed," it refers to a product that FDA has already licensed. *See* 42 U.S.C. § 262(d)(1), (i)(4), (k)(5).

The district court's interpretation—that an Applicant may give notice when FDA accepts its BLA for review—frustrates the purpose of the notice, which is to allow the RPS time to seek a preliminary injunction on the patents not listed for inclusion in the § 262(*l*)(6) lawsuit. *See* 42 U.S.C. § 262(*l*)(8)(B). Providing notice when the BLA is accepted for review means that those patents have not even been identified. That would render the notice meaningless to the RPS.

C. Amgen Will Show that the District Court Erred in Holding that Subsection 262(*l*)(9) Provides the Exclusive Remedy for Failure to Comply with Subsection 262(*l*)(2)(A) or 262(*l*)(8)(A)

The district court held that even if an Applicant is required by § 262(*l*)(2)(A) to provide its BLA and manufacturing information, and even if the Applicant provides untimely notice or no notice at all under § 262(*l*)(8)(A), the only remedy available to the RPS is to bring a declaratory judgment on a patent under § 262(*l*)(9). Ex. 1 at A0014 n. 8, 18. That declaratory judgment is the "exclusive consequence[]," and the RPS may not "obtain injunctive relief, restitution, or

damages against the applicant." Ex. 1 at A0018. That was error.

A declaratory judgment action under § 262(*l*)(9) is not a remedy for a violation of the BPCIA itself, nor is it exclusive, and district courts should have a broad range of tools available, under federal and state law, to compel an Applicant to comply with the BPCIA.

First, § 262(*l*)(9)(C) is limited to a declaration of infringement, validity, or enforceability of "any patent that claims the biological product or a use of the biological product." It is not a remedy for failure to provide the BLA and manufacturing information required by § 262(*l*)(2)(A), without which the RPS often will be unable to tell what patents are infringed, and thus on which patents the RPS should commence litigation. Indeed, § 262(*l*)(9)(C) does not mention patents covering the Applicant's manufacturing processes. It cannot be the case that the consequence for Applicant's failure to provide manufacturing information is that the Applicant may avoid litigation on manufacturing patents altogether.

Second, a declaratory judgment action provides no remedy to the RPS where the Applicant provides untimely notice, or no notice, of commercial marketing under § 262(*l*)(8)(A). If the Applicant starts marketing its product without notice, the RPS can seek emergency relief for infringement under 35 U.S.C. § 271. A declaratory judgment action affords the RPS no way to remedy the harm of a lack of timely notice.

Third, nothing in the BPCIA says declaratory judgment actions under § 262(*l*)(9) are exclusive. If the Applicant fails to take a required action, the RPS "may" bring a declaratory judgment action. The statute does not say "shall bring" a declaratory judgment action, or "may bring only" such an action. When Congress intends remedies to be exclusive, it says so explicitly, as it did in 35 U.S.C. § 271(e)(4), which sets forth "the only remedies which may be granted" for infringement under § 271(e)(2) other than attorneys' fees, and in 35 U.S.C. § 271(e)(6)(B), which provides "the sole and exclusive remedy that may be granted" where an RPS does not timely commence the § 262(*l*)(6) lawsuit on a listed patent. There is no parallel in the statute here. Nothing in the BPCIA says that declaratory judgment actions under § 262(*l*)(9) are an exclusive remedy, or prohibits any remedy where an Applicant fails to comply with the statute's terms.

Further, should this Court hold that Sandoz's conduct is unlawful, then Amgen has stated claims under California state law—for UCL and conversion—that can be based on violations of or the misuse of privileges and rights under federal law. *See*, *e.g.*, *G.S. Rasmussen & Assocs., Inc. v. Kalitta Flying Serv., Inc.*, 958 F.2d 896 (9th Cir. 1992); *Citizens for a Better Env't-California v. Union Oil of California*, 996 F. Supp. 934 (N.D. Cal. 1997); *Farmers Ins. Exch. v. Superior Court*, 2 Cal. 4th 377, 383 (1992).

II. Amgen Faces Irreparable Harm Without an Injunction Pending Appeal

Without an injunction, Sandoz has agreed to stay off the market until only May 11, 2015. Should Sandoz launch in violation of the BPCIA (under Amgen's reading), Amgen will be irreparably harmed. Accordingly, Amgen seeks an injunction during the pendency of this appeal.

In denying Amgen's motion for a preliminary injunction, and then again in denying Amgen's motion for an injunction pending appeal, the district court found Amgen had not shown irreparable harm because Amgen's evidence was "highly speculative" and "based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." Ex. 1 at A0018; *accord* Ex. 15 at A2080. That is error. The harm to Amgen does not depend on Sandoz having infringed an Amgen patent; it arises independently from Sandoz's product entering the market on a biological license it secured without having complied with the *Patents* provision of the BPCIA. By refusing to provide the required BLA and manufacturing information, Sandoz materially prejudiced Amgen, depriving it of the time, which can be up to 230 days, and information needed to detect Sandoz's infringement and commence an § 262(*l*)(6) action under the BPCIA before FDA licensure. By refusing to provide 180-day advance notice after FDA licensure, Sandoz denied Amgen the statutory period to seek a preliminary injunction on the licensed product. And the harms wrought by Sandoz's unlawful competition are

not speculative, they are immediate and real. Amgen will face price erosion, patent uncertainty, and harm to its goodwill and customer relationships, which cannot be remediated by a later-issued injunction or by money damages.

Price Erosion: It is undisputed that Sandoz intends to price ZARXIO® [redacted] Ex. 8 at A1444; Ex. 10 at A1682-83. [redacted] Ex. 6 at A0477-79; Ex. 14 at A1997; Ex. 7 at A0516-17. Amgen will therefore suffer irreparable harm in the form of price erosion immediately upon ZARXIO®'s launch at a lower price. This is particularly true because Sandoz [redacted] and the market for filgrastim is price-sensitive with no unmet clinical need. *See* Ex. 13 at A1992-93; Ex. 6 at A0477-78. Thus, sales of ZARXIO® will come at the expense of NEUPOGEN®, to which it is biosimilar. Ex. 6 at A0477.

If ZARXIO®'s launch is not enjoined but this Court ultimately reverses the district court decision, Amgen would find itself in a situation where "it would be very difficult if not impossible for Amgen to simply raise its prices back to what they were before ZARXIO[®] competition." Ex. 6 at A0479. Under Medicare reimbursement rules, any rapid attempt to rehabilitate NEUPOGEN®'s price would

put customers underwater—that is, their acquisition cost would exceed their reimbursement—and a slower attempt to rehabilitate NEUPOGEN®'s price would mean the effects of price erosion would persist longer. Ex. 6 at A0479-80. Thus, Amgen will face irreparable price erosion, just as any innovative pharmaceutical would suffer harm from unlawful generic competition. *See, e.g.*, *Abbott Labs. v. Sandoz Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (generic Biaxin®); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006) (generic Plavix®).

"Patent Uncertainty": Amgen has approximately 400 patents directed to methods of manufacturing recombinant proteins. Ex. 5 at A0473. By refusing to provide its BLA and manufacturing information as required by § 262(*l*)(2)(A), Sandoz made it impossible for Amgen to determine which of these patents read on the manufacture of Sandoz's biological product. Allowing an Applicant to market its product without complying with the BPCIA procedures that protect the RPS's patent rights undermines the value of those patents irreparably, as well as investors' confidence that such patents will protect the risk-based investments made by innovative companies like Amgen. This is the unrebutted testimony of Amgen's economic expert. *See* Ex. 7 at A0518-19, 21; Ex. 11 at A1749-50.

Loss of Goodwill and Harm to Customer Relationships: If Sandoz launches ZARXIO® before this appeal is resolved, and Amgen lowers its price for NEUPOGEN®, Amgen will suffer irreparable harm to its reputation, consumer

relationships, and goodwill if it later prevails on this appeal and tries to restore pricing. Ex. 7 at A0522-23; Ex. 6 at A0479-80. As noted above, Medicare reimbursement rules would prevent rapid price rehabilitation without significantly harming Amgen's consumer relationships, and a slower rehabilitation would entail lingering price erosion effects. Ex. 6 at A0479-80. Restoring prices, as well as market reaction to Sandoz's entry and withdrawal, could thus unfairly harm Amgen for enforcing its legal rights

III. The Equities and Public Interest Favor Granting an Injunction Pending Appeal

The district court did not reach the balance-of-equities and public-interest prongs of the injunction test. Both favor an injunction here.

Balance of Equities: Postponing the launch of ZARXIO® until after this appeal is unlikely to have a significant impact upon Sandoz. Whatever sales it loses in the brief period of an injunction are not irreparable and can be compensable by money ameliorated by a bond. Amgen will be prepared to address the calculation of a bond if the Court enters an injunction.

While Sandoz also says it could face competition from another, not-yet-approved biosimilar filgrastim product, if true that is a harm of Sandoz's own making: had it timely complied with the BPCIA, it would have been many months ahead of the next biosimilar competitor(s).

Amgen, on the other hand, faces immediate and irreversible price erosion, devastating injury to its consumer relationships and goodwill, and diminution in the value of its patents. As such, the balance of hardships clearly favors a short injunction of Sandoz's sales of ZARXIO® pending this appeal.

Public Interest: The public interest also favors an injunction. There is a strong public interest in encouraging investment in drug development, and the fact that a generic (or, here, a biosimilar) may sell at a lower price does not override that important concern. *See Sanofi-Synthelabo*, 470 F.3d at 1383-84. Moreover, if Sandoz is permitted to launch ZARXIO® before the resolution of this appeal, other biosimilar applicants will be incentivized to behave as Sandoz has done, breaching the clear terms of the BPCIA that serve to preserve incentives to innovators to engage in biologics discovery.

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that the Court enjoin Sandoz from marketing, selling, offering for sale, or importing into the United States its ZARXIO® biosimilar product during this appeal.

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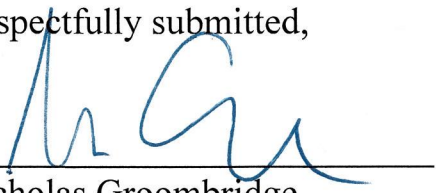
Respectfully submitted,



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