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)

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
JENNIFER H. WU
JENNIFER GORDON
PETER SANDEL
MICHAEL T. WU
ARIELLE K. LINSEY
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, New York 10019
(212) 373-3000

VERNON M. WINTERS
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, California 94104
(415) 772-1200

WENDY A. WHITEFORD
LOIS M. KWASIGROCH
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

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:

Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
Alexander D. Baxter
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Nicholas Groombridge

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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.

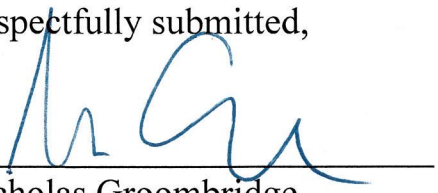
Public Interest: The public interest also favors an injunction. There is a strong public interest in encouraging investment in drug development, and the fact that a generic (or, here, a biosimilar) may sell at a lower price does not override that important concern. *See Sanofi-Synthelabo*, 470 F.3d at 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.

Dated: April 17, 2015

Respectfully submitted,



Nicholas Groombridge
Eric Alan Stone
Jennifer H. Wu
Jennifer Gordon
Peter Sandel
Michael T. Wu
Arielle K. Linsey
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

Vernon M. Winters
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
(415) 772-1200

Wendy A. Whiteford
Lois M. Kwasigroch
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Attorneys for Plaintiffs-Appellants

Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

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

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ORDER

Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") move for an injunction pending appeal pursuant to Fed. R. App. P. 8(a).

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The motion is granted.

(2) Sandoz and all those acting in concert with it or on its behalf, are enjoined from marketing, selling, offering for sale, or importing into the United States any biosimilar filgrastim product until such time that this Court decides Amgen's appeal.

_____, 2015 _____

EXHIBITS IN SUPPORT OF MOTION

INDEX OF EXHIBITS

Ex.	Description	Date Filed	Appendix No.
	Declaration of Jennifer H. Wu in Support of Plaintiffs-Appellants' Motion for an Injunction Pursuant to Fed. R. App. P. 8(a)		
1.	District Court's Order on Cross Motions for Judgment on the Pleadings and Denying Amgen's Motion for Preliminary Injunction [Dkt. No. 105]	3/19/2015	A0001-19
2.	District Court's Judgment Under Rule 54(b) and Order Establishing Schedule for Rule 62(c) Proceedings and Staying All Other Proceedings [Dkt. No. 111]	3/25/2015	A0020-23
3.	Amgen's Notice of Appeal [Dkt. No. 112]	3/25/2015	A0024-26
4.	Amgen's Complaint [Dkt. No. 1]	10/24/2014	A0045-83 (selected pages)
5.	Watt Declaration in Support of Amgen's Motion for a Preliminary Injunction [Dkt. No. 56-1]	2/5/2015	A0471-73
6.	Azelby Declaration in Support of Amgen's Motion for a Preliminary Injunction [Dkt. No. 56-2]	2/5/2015	A0474-81
7.	Philipson Report (Exhibit B to Philipson Declaration in Support of Amgen's Motion for a Preliminary Injunction) [Dkt. No. 56-5]	2/5/2015	A0487-553 (selected pages)
8.	Exhibit C to Baxter Declaration in Support of Amgen's Preliminary Injunction Reply: Business Review with Carol Lynch [Dkt. No. 83-21] [Confidential]	3/6/2015	A1441-45 (selected page)

Ex.	Description	Date Filed	Appendix No.
9.	Exhibit 1 to Wu Declaration in Support of Amgen's Preliminary Injunction Reply: Sandoz's July 8, 2014 Letter [Dkt. No. 83-6]	3/6/2015	A1471-79 (selected page)
10.	Exhibit A to Olson Declaration in Support of Sandoz's Administrative Motion for Leave and Stipulated Request to Supplement the Record: Excerpts from Thole Deposition [Dkt. No. 90-6] [Confidential]	3/11/2015	A1647-84 (selected pages)
11.	Exhibit C to Olson Declaration in Support of Sandoz's Administrative Motion for Leave and Stipulated Request to Supplement the Record: Excerpts from Rausser Deposition [Dkt. No. 93-3]	3/11/2015	A1740-51 (selected pages)
12.	Exhibit 13 to Supplemental Wu Declaration in Support of Amgen's Administrative Motion and Stipulated Request to File Supplementary Exhibit Relating to Amgen's Motion for a Preliminary Injunction: Sandoz's March 6, 2015 Letter [Dkt. No. 97-2]	3/12/2015	A1773-818 (selected pages)
13.	Exhibit A to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal [Dkt. No. 107-8] [Confidential]	3/24/2015	A1990-93 (selected pages)
14.	Exhibit B to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal: OBU Q4 14' QBR Review [Dkt. No. 107-10] [Confidential]	3/24/2015	A1994-97 (selected page)
15.	District Court's Order Denying Amgen's Motion for Injunction Pending Appeal [Dkt. No. 129]	4/15/2015	A2078-80

Appeal No. 2015-1499

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC., AMGEN MANUFACTURING LTD.,

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

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DECLARATION OF JENNIFER H. WU IN SUPPORT OF PLAINTIFFS-APPELLANTS' MOTION FOR AN INJUNCTION PENDING APPEAL PURSUANT TO FED. R. APP. P. 8(a)

I, Jennifer H. Wu, declare and state as follows:

1. I am an attorney admitted to the bar of this Court, and a partner of the law firm, Paul, Weiss, Rifkind, Wharton & Garrison LLP. I am one of the attorneys of record in Appeal No. 2015-1499 for Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"). I have personal knowledge of the facts set forth in this Declaration, and if called upon as a witness, I could and would testify competently as to these facts.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction (Dkt. No. 105) dated March 19, 2015 from *Amgen Inc. v. Sandoz Inc.*, No. 3:14-CV-04741-RS (N.D. Cal.) (the "District Court Action").

3. Attached hereto as Exhibit 2 is a true and correct copy of the Final Judgment Under Rule 54(b) and Order Establishing Schedule for Rule 62(c) Proceedings and Staying All Other Proceedings (Dkt. No. 111) dated March 25, 2015 from the District Court Action.

4. Attached hereto as Exhibit 3 is a true and correct copy of Amgen's Notice of Appeal (Dkt. No. 112) dated March 25, 2015.

5. Attached hereto as Exhibit 4 is a true and correct copy of excerpts of Amgen's Complaint (Dkt. No. 1) dated October 24, 2015 from the District Court Action.

6. Attached hereto as Exhibit 5 is a true and correct copy of the Declaration of Stuart Watt in Support of Amgen's Motion for a Preliminary Injunction (Dkt. No. 56-1) dated February 5, 2015 from the District Court Action.

7. Attached hereto as Exhibit 6 is a true and correct copy of the Declaration of Robert Azelby in Support of Amgen's Motion for a Preliminary Injunction (Dkt. No. 56-2) dated February 5, 2015 from the District Court Action.

8. Attached hereto as Exhibit 7 is a true and correct copy of excerpts of the Expert Report of Tomas J. Philipson, Ph.D. (Dkt. No. 56-5) dated February 5, 2015 from the District Court Action.

9. Attached hereto as Exhibit 8 is a true and correct copy of excerpts of Exhibit C to Baxter Declaration in Support of Amgen's Preliminary Injunction Reply (Dkt. No. 83-21) dated March 6, 2015 from the District Court Action. This contains excerpts of a document produced by Defendant-Appellee Sandoz Inc. ("Sandoz") bearing the production numbers SDZ(56)0200760-838.

10. Attached hereto as Exhibit 9 is a true and correct copy of excerpts of Exhibit 1 to Wu Declaration in Support of Amgen's Reply Supporting Its Preliminary Injunction Motion (Dkt. No. 83-6) dated March 6, 2015 from the District Court Action. This is a letter from Sandoz to Amgen dated July 8, 2014.

11. Attached hereto as Exhibit 10 is a true and correct copy of excerpts of Exhibit A to Olson Declaration in Support of Sandoz's Administrative Motion for Leave and Stipulated Request to Supplement the Record (Dkt. No. 90-6) dated March 11, 2015 from the District Court Action. This contains excerpts from the February 26, 2015 deposition transcript of Alexander Thole.

12. Attached hereto as Exhibit 11 is a true and correct copy of excerpts of Exhibit C to Olson Declaration in Support of Sandoz's Administrative Motion for Leave and Stipulated Request to Supplement the Record (Dkt. No. 93-3) dated

March 11, 2015 from the District Court Action. This contains excerpts from the March 2, 2015 deposition transcript of Gordon Rausser, Ph.D.

13. Attached hereto as Exhibit 12 is a true and correct copy of excerpts of Exhibit 13 to Supplemental Wu Declaration in Support of Amgen's Administrative Motion and Stipulated Request to File Supplementary Exhibit Relating to Amgen's Motion for a Preliminary Injunction (Dkt. No. 97-2) dated March 13, 2015 from the District Court Action. This contains excerpts of a March 6, 2015 letter from Sandoz to Amgen with FDA correspondence regarding BLA approval.

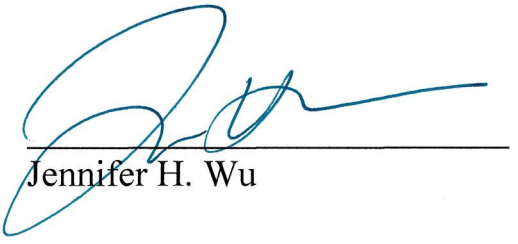
14. Attached hereto as Exhibit 13 is a true and correct copy of excerpts of Exhibit A to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal (Dkt. No. 107-8) dated March 24, 2015 from the District Court Action. This contains excerpts of a document produced by Sandoz bearing the production numbers SDZ(56)0201396-406.

15. Attached hereto as Exhibit 14 is a true and correct copy of excerpts of Exhibit B to Baxter Declaration in Support of Amgen's Motion for an Injunction Pending Appeal (Dkt. No. 107-10) dated March 24, 2015 from the District Court Action. This contains excerpts of a document produced by Amgen bearing the production numbers AMG-NEUP-00002616-38.

16. Attached hereto as Exhibit 15 is a true and correct copy of the Order Denying Amgen's Motion for Injunction Pending Appeal (Dkt. No. 129) dated April 15, 2015 from the District Court Action.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on April 17, 2015 in New York, New York.



Jennifer H. Wu

EXHIBIT 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER ON CROSS MOTIONS FOR JUDGMENT ON THE PLEADINGS AND DENYING MOTION FOR PRELIMINARY INJUNCTION

United States District Court
Northern District of California

I. INTRODUCTION

This dispute arises from conflicting interpretations of the Biologics Price Competition and Innovation Act ("BPCIA"), which established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market ("biosimilars") to receive Food and Drug Administration ("FDA") license approval. *See* 42 U.S.C. § 262(k), (*l*). The BPCIA allows a drug maker who demonstrates the biosimilarity of its product to one which has already received FDA approval (the "reference product") to rely on studies and data completed by the reference product producer ("reference product sponsor"), saving years of research and millions in costs. Through its amendments to both 42 U.S.C. § 262 and 35 U.S.C. § 271, the BPCIA also enabled a process for resolving patent disputes arising from biosimilars, whereby applicants and sponsors may participate in a series of disclosures and negotiations aimed at narrowing or eliminating the prospect of patent litigation. While engagement in the process creates a temporary safe harbor from declaratory judgment actions, a party's failure to participate

permits the opposing party to commence patent litigation.

Plaintiffs Amgen, Inc. and Amgen Manufacturing, Ltd. (collectively "Amgen") have produced and marketed the biologic product filgrastim under the brand-name Neupogen since 1991. They aver that defendants Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH,[1] who in July 2014 applied to the FDA to receive biosimilar status for their filgrastim product in order to begin selling it in the United States, behaved unlawfully under 42 U.S.C. § 262 by failing to comply with its disclosure and negotiation procedures. Amgen alleges these transgressions give rise to claims under California's Unfair Competition Law ("UCL") and for conversion, as well as patent infringement as to U.S. Patent No. 6,162,427 ("'427 patent"). Sandoz counterclaims for declaratory judgment adopting its interpretation of the BPCIA and finding its conduct permissible as to Amgen's UCL and conversion claims; and for noninfringement and invalidity of the '427 patent. The parties each filed cross-motions for partial judgment on the pleadings.[2] Amgen, in addition, requests a preliminary injunction to forestall Sandoz's market entry until a disposition on the merits has issued.[3]

While there is no dispute that Sandoz did not engage in 42 U.S.C. § 262's disclosure and dispute resolution process, its decision not to do so was within its rights. Amgen's motion for partial judgment on the pleadings or partial summary judgment in the alternative is, accordingly, denied, and its UCL and conversion claims are dismissed with prejudice. As the BPCIA does not bar Sandoz's counterclaims for noninfringement and invalidity of the '427 patent, these claims may advance. In addition, Amgen's motion for preliminary injunction is, accordingly, denied.

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[1] Of the named defendants, only Sandoz, Inc. has responded to Amgen's suit thus far. Sandoz, Inc. will be referred to herein simply as "Sandoz."

[2] Amgen notes that, while the standards under these rules are similar, it brings its motion under both Rule 12(c) and Rule 56 to account for conflicting case law as to whether a court may rule only as to certain claims, but not others, on a motion for judgment on the pleadings.

[3] Since then, however, the parties stipulated that Sandoz would not market its product until the earlier of either a partial judgment on the pleadings in its favor, or April 10, 2015. Sandoz further agreed that, should it receive a favorable ruling before April 10, 2015, it will give Amgen five days' notice before launching its product.

II. BACKGROUND

A. Relevant Provisions of the BPCIA

The dispute presented in the pending motions exclusively concerns questions of law—specifically, of statutory interpretation, as to several provisions in 42 U.S.C. § 262 and 35 U.S.C. § 271(e), both amended in 2010 via Congress's enactment of the BPCIA. The Act's stated purpose was to establish a "biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). At issue in particular are two central provisions of 42 U.S.C. § 262: (1) paragraphs (*l*)(2)-(*l*)(6), which lay forth the disclosure and negotiation process that commences with an applicant sharing its Biologic License Application ("BLA") and manufacturing information with the reference product sponsor within twenty days of receiving notice that the FDA has accepted the application for review; and (2) paragraph (*l*)(8), requiring an applicant to give the sponsor at least 180 days' advance notice of the first commercial marketing of its biosimilar. Understanding these particular provisions requires a review of the statutory context.

Subsection (a) of 42 U.S.C. § 262 sets forth standards for FDA approval of biologic products. Among other requirements, applicants must demonstrate that their products are safe, pure, and potent. Subsection 262(k) establishes an abbreviated pathway by which a product "biosimilar" to one previously approved under subsection (a) (a "reference product") may rely on the FDA's prior findings of safety, purity, and potency to receive approval. According to subsection (k), any entity which demonstrates its biologic product is sufficiently similar to a reference product may apply for an FDA license to market its biosimilar product. Applications must include publicly available information as to the FDA's prior determination of the reference product's safety, purity, and potency, and may include additional publicly available information. 42 U.S.C. § 262(k)(2)(A).

The FDA may not approve a biosimilarity application until twelve years after the date on which the reference product was first licensed under subsection (a); in other words, reference products are entitled to twelve years of market exclusivity. Biosimilarity applicants are precluded

from even submitting applications under subsection (k) until four years after the licensing of the reference product. 42 U.S.C. § 262(k)(7)(A), (B).

Subsection 262(*l*) sets forth a process and timeline by which an applicant and reference product sponsor "shall" participate in a series of informational exchanges regarding potential disputes over patent validity and infringement. As long as both parties continue to comply with these disclosure and negotiation steps, neither may bring a declaratory action regarding patent validity, enforceability, or infringement against the other until the applicant provides notice of its upcoming first commercial marketing. 42 U.S.C. § 262(*l*)(9)(A)-(C).

The BPCIA also added to 35 U.S.C. § 271, which governs patent infringement, a provision rendering it "an act of infringement to submit" a subsection (k) application based on a patent the reference product sponsor identified (or could have identified) as infringed by the applicant's biosimilar product under subsection (*l*)'s disclosure and negotiation procedures. 35 U.S.C. § 271(e)(2)(C). In addition to enabling a reference product sponsor to initiate an infringement action for an applicant's reliance on its product, subsection 271(e) sets forth remedies for instances in which liability for infringement is found. Where the sponsor identified or could have identified the infringed patent on its initial disclosure to the applicant under 42 U.S.C. § 262(*l*)(3), injunctive relief may be granted to prevent such infringement, while damages or other monetary relief may only be awarded if there has been commercial manufacture, use, offer to sell, or sale within the United States of an infringing product. Other than attorney fees, these are "the only remedies which may be granted by a court for [infringement of such a patent]." 35 U.S.C. § 271(e)(4)(B)-(D). Where, however, the infringed patent appears on the parties' agreed-upon list of patents that should be subject to an infringement action, 42 U.S.C. § 262(*l*)(4), or their respective lists of such patents, 42 U.S.C. § 262(*l*)(5)—and the sponsor did not sue within the time frame prescribed in subsection (*l*), had its suit dismissed without prejudice, or did not prosecute its suit to judgment in good faith—the "sole and exclusive remedy" for infringement "shall be a reasonable royalty." 35 U.S.C. § 271(e)(6).

Together, 42 U.S.C. § 262(*l*) and 35 U.S.C. § 271(e) reflect an integrated scheme that

provides consequences for the choice either party makes at each step of subsection (*l*)'s information exchange to carry on the process, or end it and allow patent litigation to commence. At one step in this series of tradeoffs, for example, the applicant has sixty days to respond to a list of patents the sponsor flagged in the prior step as potential grounds for an infringement suit. The applicant, according to 42 U.S.C. § 262(*l*)(3)(B)(ii), must provide the factual and legal basis for its beliefs that any patents flagged by the sponsor are invalid, unenforceable, or not infringed by its biosimilar. If the applicant does not complete this step, however, the sponsor may bring a declaratory judgment action for any patents it flagged in the prior step. 42 U.S.C. § 262(*l*)(9)(B). Conclusion of the process yields a list of patents on which a sponsor may bring suit within thirty days. 42 U.S.C. § 262(*l*)(6). Should the sponsor elect not to do so, it may collect only a reasonable royalty. 35 U.S.C. § 271(e)(6)(A). Thus, to continue the process or to terminate it confers advantages and disadvantages the parties must weigh at each step.

B. Procedural Background

Since 1991, Amgen has produced and marketed the biologic product filgrastim under the brand-name Neupogen as a result of the FDA's approval of Amgen's application for a license to market the product pursuant to BLA No. 103353. Neupogen was originally approved for decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA subsequently approved additional therapeutic indications for the drug, such as aiding faster engraftment and recovery for bone marrow transplant patients.

On July 7, 2014, Sandoz received notice that the FDA had accepted for review its BLA for approval of a biosimilar filgrastim product under subsection (k). The next day, it mailed a letter to Amgen offering to share a copy of its BLA under the protection of a proposed Offer of Conditional Access; notifying Amgen that it believed it would receive FDA approval in the first or second quarter of 2015; and stating its intent to market its biosimilar product immediately thereafter. Sandoz sent Amgen a second letter on July 25 again offering conditional access to its

BLA. It also asserted therein that the BPCIA entitled it to opt out of subsection (*l*)'s procedures, and that Amgen could instead procure information via an infringement action. Amgen, it appears, declined both offers to view Sandoz's biosimilarity BLA under Sandoz's proposed terms. Only after a protracted dispute did the parties, on February 9, 2015, enter a stipulated protective order providing Amgen protected access to Sandoz's BLA and related application materials. They did not engage in any further patent information exchanges.

Amgen initiated this action on October 24, 2014, asserting claims of (1) unlawful competition under Cal. Bus. & Prof. Code § 17200 et seq. based on two alleged violations of the BPCIA; (2) conversion; and (3) infringement of Amgen's '427 patent. According to Amgen, failure to comply with subsection (*l*)'s disclosure and negotiation procedures and its interpretation of subparagraph (*l*)(8)(A)'s 180-day notice requirement each comprise an unlawful business practice actionable under the UCL. In addition, Amgen contends, Sandoz's use of Amgen's FDA license for Neupogen in its biosimilarity BLA without abiding by subsection (*l*)'s procedures rises to an act of conversion.

Alongside its answer, the following month Sandoz asserted seven counterclaims seeking declaratory judgments in favor of its interpretation of the BPCIA, as well as non-infringement and invalidity of the '427 patent. Specifically, these counterclaims are for the following declaratory judgments: (1) subsection (k) applicants may elect not to provide their applications to the reference product sponsor, subject to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C); (2) the BPCIA does not provide for injunctive relief, restitution, or damages for failure of a subsection (k) applicant to share its BLA; (3) the BPCIA sets forth exclusive consequences for failure to comply with 42 U.S.C. § 262(*l*)'s disclosure, negotiation, and notification provisions; (4) the BPCIA renders remedies under UCL and conversion claims unlawful and/or preempted; (5) a reference product sponsor does not maintain exclusive possession or control over its biologic product license; (6) noninfringement of the '427 patent; and (7) invalidity of the '427 patent.

Amgen now moves for partial judgment on the pleadings, or partial summary judgment in the alternative, as to the two bases in the BPCIA for its UCL claim, and for declaratory judgment

barring Sandoz's sixth and seventh counterclaims. Sandoz cross-moves for partial judgment on the pleadings granting declaratory judgment in favor of its first through fifth counterclaims, for dismissal with prejudice of Amgen's UCL and conversion claims, and for denial of Amgen's motion.

III. LEGAL STANDARDS

While the Federal Circuit is the court of appeal for all cases raising claims under patent law, it defers to regional circuit courts on non-patent issues. *See* 28 U.S.C. 1338(a); *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002); *Research Corp. Techs. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008). Ninth Circuit law therefore governs the disposition of the parties' cross-motions.

Rule 12(c) of the Federal Rules of Civil Procedure provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Such a motion, like one brought under Rule 12(b)(6), challenges the "the legal sufficiency of the opposing party's pleadings." *Qwest Communications Corp. v. City of Berkeley*, 208 F.R.D. 288, 291 (N.D. Cal. 2002). Accordingly, "a plaintiff is not entitled to judgment on the pleadings when the answer raises issues of fact that, if proved, would defeat recovery." *General Conference Corp. of Seventh–Day Adventists v. Seventh–Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989). A defendant's sufficient pleading of an applicable affirmative defense likewise will defeat a plaintiff's motion. *Id.* Regardless of what facts or affirmative defenses may be raised by an answer, however, a plaintiff's motion may not be granted absent a showing that he or she "is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc.*, 896 F.2d 1542, 1550 (9th Cir. 1989).

Rule 56(a) of the Federal Rules of Civil Procedure provides that a "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The party who seeks summary judgment bears the initial responsibility of identifying the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party satisfies this initial

burden, it shifts to the non-moving party to present specific facts showing that there is a genuine issue for trial. *Celotex*, 477 U.S. at 324. "Only disputes over facts that might affect the outcome of the suit under governing law" are material. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A genuine issue exists if the non-moving party presents evidence from which a reasonable factfinder, viewing the evidence in the light most favorable to that party, could resolve the material issue in his or her favor. *Id.* at 248–49.

IV. DISCUSSION

As noted above, this dispute hinges on the interpretation of two portions of subsection 42 U.S.C. § 262(*l*) of the BCPIA. According to Amgen, Sandoz acted unlawfully because it (1) failed to comply with subsection (*l*)'s disclosure and negotiation procedures; and (2) intends to market its biosimilar immediately upon receiving FDA approval, rather than waiting until at least 180 days thereafter. These actions, Amgen avers, constitute the predicate wrongful behavior to sustain its claims under the UCL. Sandoz also committed conversion, avers Amgen, by making use of Amgen's FDA license for Neupogen in its biosimilarity BLA.[4]

Sandoz contends its actions have comported with the letter and spirit of the BPCIA, necessitating, therefore, the denial of Amgen's motion and dismissal of its UCL and conversion claims. As the analysis below demonstrates, Sandoz's reading of the statute is the more coherent of the two, and merits granting, in part, Sandoz's motion.

The interpretation of a statute is a question of law whose answer begins with an examination of the plain meaning of the statute. *United States v. Gomez–Osorio*, 957 F.2d 636, 639 (9th Cir. 1992). Words not otherwise defined take on their ordinary, common meaning. The court must, however, read a statute's language in context and with regard to its role in the overall

[4] While Amgen contended at oral argument that the BPCIA enables a private right of action from which its suit against Sandoz could, alternatively, have arisen, this set of motions does not properly raise that issue and it, accordingly, will not be addressed. Amgen is left with the untenable argument that Congress intended not a self-contained statutory scheme under the BPCIA, but rather contemplated a hunt by reference product sponsors through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation.

statutory framework, looking to legislative history as appropriate. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Morton*, 467 U.S. 822, 828 (1984). If the statutory language is unambiguous, and the statutory scheme is coherent and consistent, that should mark the end of a court's interpretative inquiry. *Miranda v. Anchondo*, 684 F.3d 844, 849 (9th Cir. 2012).

A. BPCIA: Disclosure and Negotiation Procedures

As noted above, Sandoz elected not to supply Amgen with a copy of its BLA and manufacturing process description within twenty days from notice that the FDA had accepted its application for review,[5] and to engage in subsection (*l*)'s subsequent series of disclosures and negotiations regarding potential patent disputes. These acts, Amgen avers, amount to unlawful transgressions of mandatory requirements for subsection (k) applicants set forth in 42 U.S.C. § 262(*l*)(2)-(8). Indeed, these paragraphs repeatedly use the word "shall" to describe the parties' obligations under its prescribed procedures. Subparagraph (*l*)(9)(B) moreover characterizes lack of compliance as a "fail[ure] to provide the application and information required."

While such phrasing lends support to Amgen's reading, Sandoz's overall interpretation of the statute's plain language is more persuasive. While Amgen correctly notes that subsection (*l*) uses the word "may" in certain paragraphs, thereby suggesting that the use of "shall" in others implies an action is required, several countervailing factors reflect otherwise. First, that an action "shall" be taken does not imply it is mandatory in all contexts. It is fair to read subsection (*l*) to demand that, if both parties wish to take advantage of its disclosure procedures, then they "shall" follow the prescribed procedures; in other words, these procedures are "required" where the parties elect to take advantage of their benefits, and may be taken away when parties "fail."

That compliance allows an applicant to enjoy a temporary safe harbor from litigation and, potentially, to resolve or narrow patent disputes outside court proceedings, bolsters this reading.

[5] Whether Amgen effectively declined access to Sandoz's BLA within these twenty days pursuant to Sandoz's July 2014 letters is a factual matter disputed by the parties, and is not at issue here.

Subparagraphs (*l*) (9)(B) and (C) contemplate the scenario in which an applicant does not comply at all with disclosure procedures, or fails to follow through after having begun the process. They allow the reference product sponsor to commence patent litigation immediately in either instance—removing (or precluding) availability to the applicant of a litigation safe harbor. Congress took the additional step in the BPCIA to amend 35 U.S.C. § 271(e) to add that an applicant's failure to disclose information regarding a potentially infringed patent under subsection (*l*)'s requirements is immediately actionable, making it clear that such a dispute is ripe for adjudication.

Such an interpretation would not be wholly without precedent; other district courts faced with a similar question have found that failure to comply with a provision containing "shall" was not unlawful, where the statute contemplated and provided for such a scenario. See *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff'd*, 776 F.3d 947 (8th Cir. 2014) (finding a statute stating that "[e]very conveyance of real estate shall be recorded" and that "every such conveyance not so recorded shall be void" was not mandatory because the statutory language "specifically contemplate[d] that not all conveyances will be recorded and outlines the consequence of failing to do so.")

Further, while Amgen contends persuasively that use of subsection (*l*)'s procedures can serve important public interests, including potential reduction of patent litigation and protection for innovators, nowhere does the statute evidence Congressional intent to enhance innovators' substantive rights. In contrast to numerous other federal civil statutes which offer a claim for relief and specify remedies, here Congress did more than remain silent—it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's non-compliance. Even in subsection (*l*) itself, subparagraph (*l*)(8)(B) is clear in providing the remedy of a preliminary injunction for failure to give the 180-day notice required in (*l*)(8)(A). It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit. The statute contains no stick to

force compliance in all instances, and Amgen does not identify any basis to impute one.

Indeed Sandoz's decision not to comply with subsection (*l*) reflects how the statute's overall scheme operates to promote expedient resolution of patent disputes. Compliance with the disclosure process affords an applicant many benefits: it allows the applicant to preview which patents the reference product sponsor believes are valid and infringed, assess related factual and legal support, and exercise some control over which patents are litigated and when. An applicant with a high (or unknown) risk of liability for infringement could benefit considerably from this process: it would be able to undergo the information exchange while protected by the statute's safe harbor from litigation, and if necessary, delay its product launch to protect the investment it made in developing its biosimilar.

On the other hand, subsection (*l*) lays out a process that could take up to 230 days—just to commence patent litigation. An applicant who values expedience over risk mitigation may believe that the disclosure and negotiation process would introduce needless communications and delay. Such an applicant may have good reason to believe that no unexpired relevant patents relate to its biosimilar, and that it is likely to prevail if challenged with an infringement suit. The applicant may, in such an instance, opt to forego its ability to bring certain types of declaratory actions and receive information about potentially relevant patents from the reference product sponsor, and instead commence litigation immediately.

Perhaps confident in its limited exposure to liability and eager to resolve patent disputes so as not to face delays to market entry, Sandoz opted to invite a suit from Amgen soon after filing its BLA with the FDA.[6] Had the parties followed subsection (*l*)'s disclosure and negotiation

[6] While Amgen contends that the path chosen by Sandoz enables biosimilar producers to evade liability for patent infringement because biosimilar producers may keep reference product sponsors in the dark about their biosimilarity BLAs and plans to take their products to market, the 180-day notice requirement addressed below mitigates such concerns. With six months' advance notice of a biosimilar producer's intent to commence sales, a reference product sponsor who believes it may have an infringement claim can file suit to access the biosimilarity BLA, manufacturing process, and other relevant information via discovery—as in any other typical instance of potential infringement. While Amgen may have preferred that Sandoz share this information voluntarily, the BPCIA rendered it Sandoz's choice to make.

procedures, it is unlikely the present infringement action—filed in October 2014—would have even commenced until mid-March 2015, given the 230-day timeline over which subsection (*l*)'s procedures are designed to unfold. Sandoz therefore traded in the chance to narrow the scope of potential litigation with Amgen through subsection (*l*)'s steps, in exchange for the expediency of an immediate lawsuit. The BPCIA's plain language and overall statutory scheme support a reading that renders this decision entirely permissible.

B. BPCIA: One Hundred Eighty Days' Notice Prior to First Commercial Marketing

The most reasonable interpretation of paragraph (*l*)(8) of 42 U.S.C. § 262 also favors Sandoz. As noted above, this provision dictates that an applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Upon receiving such notice, the reference product sponsor may seek a court order enjoining such market entry until a court can decide issues of patent validity or infringement. 42 U.S.C. § 262(*l*)(8)(B). It may also initiate a declaratory judgment action. 42 U.S.C. § 262(*l*)(9)(B).

Amgen makes too much of the phrase quoted above from subparagraph (*l*)(8)(A). It argues that the word "licensed," a past tense verb, means an applicant may not give the required 180-day notice to the reference product sponsor until *after* the FDA has granted approval of biosimilarity—resulting in a mandatory 180-day post-FDA approval waiting period prior to biosimilar market entry. Amgen draws support for this reading from Congress's use in other paragraphs of the statute of the phrase "subject of an application under subsection (k)" to refer to biosimilars. *See, e.g.*, 42 U.S.C. § 262(i)(2). Congress employs the distinction between the two phrasings, asserts Amgen, to signal whether it intends a particular provision to refer to a biosimilar before or after it has received FDA approval. Amgen contends that the only logical conclusion, therefore, is that because (*l*)(8)(A) refers not to the "subject of an application," but rather a "licensed" product, FDA approval must be a condition precedent to valid notice.

Amgen's attempt to bolster this interpretation by referencing a prior decision of this district, *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12,

2013), has little effect. In that case, Sandoz sued to obtain a declaratory judgment that two patents were invalid, unenforceable and would not be infringed if Sandoz used, offered to sell, sold, or imported a drug product "biosimilar" to Amgen's etanercept product Enbrel. Finding for Amgen on Article III standing grounds, the court stated merely in passing that, in addition, Sandoz could not obtain a declaratory judgment prior to filing an FDA biosimilarity application according to the procedures set forth in 42 U.S.C. § 262(*l*). While Sandoz contended that its suit complied with section 262(*l*), which permits actions for declaratory judgment once a manufacturer of a licensed biosimilar has provided notice of commercial marketing, the district court—looking only to the language of the statute itself—wrote that "as a matter of law, [Sandoz] cannot have provided a [such notice] because . . . its [biosimilar] product is not 'licensed under subsection (k).'" *Id.* The Federal Circuit affirmed the district court's ruling on standing grounds, but expressly declined to address its BPCIA interpretation, which had not been briefed for the district court and was not dispositive in its ruling. This prior case, therefore, has little persuasive authority over the present dispute.

Indeed the more persuasive interpretation accounts for the fact that FDA approval must precede market entry. It would be nonsensical for subparagraph (*l*)(8)(A) to refer to a biosimilar as the subject of a subsection (k) application because upon its "first commercial marketing" a biosimilar must, in all instances, be a "licensed" product. "Before" modifies "first commercial marketing"; "licensed" refers only to "biological product"—not the appropriate time for notice.

Even more problematic with Amgen's reading is the impact it would have on the overall statutory scheme. Because the FDA cannot license a biosimilar until twelve years after approval of a reference product, Amgen's reading would tack an unconditional extra six months of market exclusivity onto the twelve years reference product sponsors already enjoy under 42 U.S.C. § 262(k)(7)(A).[7] Had Congress intended to make the exclusivity period twelve and one-half years, it

[7] Amgen contends that because the FDA approval process may entail modifications to a biosimilar's properties or manufacturing process, allowing applicants to give 180-day notice prior to FDA approval would burden sponsors with the unfair task of having to aim infringement claims at a moving target. While this statutory construction may indeed disadvantage sponsors in some

could not have chosen a more convoluted method of doing so. Moreover, Congress presumably could have been far more explicit had it intended for infringement suits to commence only once a biosimilar receives FDA approval. It was, therefore, 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.[8]

C. Amgen's State-Law Claims for Unlawful Business Practices and Conversion

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. A plaintiff may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates another law is independently actionable under § 17200. *Cel–Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that defendants' conduct is "unfair" within the meaning of the several standards developed by the courts. *Id.* at 186–87, 83 (finding of unfairness must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that "members of the public are likely to be deceived" by the challenged business acts or practices. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory, averring that Sandoz behaved unlawfully by violating both subsection (*l*)'s disclosure and negotiation procedures and paragraph (*l*)(8)(A)'s 180-day notice requirement. As shown above,

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respects, such policy considerations are for Congress, not the courts, to address.

[8] In addition, had Sandoz failed to do so, it would be subject only to the consequences prescribed in 42 U.S.C. § 262(*l*)(9)(B)—an action for declaratory judgment regarding patent infringement, viability, or enforceability.

however, Sandoz's actions are within its rights and subject only to the consequences contemplated in the BPCIA. Because Amgen has not shown that Sandoz violated any provision of law, its UCL claim fails.

Amgen further alleges that Sandoz's reliance on Amgen's FDA license for Neupogen in its subsection (k) application constitutes conversion. To sustain a claim for conversion, a plaintiff must demonstrate (1) the plaintiff's ownership or right to possession of the property; (2) the defendant's conversion by a wrongful act or disposition of property rights; and (3) damages. *Burlesci v. Petersen*, 68 Cal. App. 4th 1062 (1998).

Sandoz's "wrongful act," alleges Amgen, was making use of Amgen's FDA license for Neupogen without complying with subsection (*l*)'s disclosure and negotiation procedures. Yet the BPCIA expressly contemplates that a subsection (k) applicant will rely on the reference product's license and other publicly available safety and efficacy information about the reference product. Indeed, as Sandoz's decision to forego the benefits of subsection (*l*)'s disclosure and negotiation procedures and instead open itself up to immediate suit for patent infringement was entirely permissible under 42 U.S.C. § 262, Sandoz has committed no wrongful act. The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in addition to exacting the consequences written expressly into the legislation itself—is unworkable. Amgen therefore cannot maintain a claim for either unlawful business practices or conversion, and both claims are dismissed with prejudice pursuant to Sandoz's motion.

D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

Amgen contends that 42 U.S.C. § 262(*l*)(9)(C) bars the counterclaims for declaratory judgment of noninfringement and invalidity Sandoz alleges in response to Amgen's averment that Sandoz infringed its '427 patent. Subparagraph (*l*)(9)(C) states that where, as here, an applicant has not provided its BLA and manufacturing process information to the reference product sponsor, "the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or

enforceability of any patent that claims the biological product or a use of the biological product." According to Amgen, this provision prohibits Sandoz, a subsection (k) applicant who has not provided its BLA and manufacturing process information to its sponsor, from raising its counterclaims for declaratory judgment regarding the '427 patent.

Asserting a counterclaim is not the equivalent of commencing a lawsuit. *See Alexander v. Hillman*, 296 U.S. 222, 241 (1935). The BPCIA addresses only an applicant's ability to "bring an action," not to assert a counterclaim if placed in a position to defend against an infringement suit. Furthermore, as Sandoz's counterclaims arise from the same transaction or occurrence that is the subject of Amgen's claim—the validity and relevance of Amgen's '427 patent—they are compulsory, and would be waived if not asserted. Barring such claims in particular raises "real due process concerns." *See U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 505 F. Supp. 2d 20, 26 (D.D.C. 2007). Sandoz's sixth and seventh counterclaims regarding Amgen's '427 patent are, therefore, not barred by the BPCIA.

E. Amgen's Motion for Preliminary Injunction

Amgen has claimed it is entitled to both preliminary relief in advance of a decision on the merits, and, in the event of a decision in its favor, an injunctive remedy placing the parties where they would have stood had Sandoz fully complied with the BPCIA as Amgen interprets it. To obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits; that he or she is likely to suffer irreparable harm in the absence of preliminary relief; that the balance of equities tips in his or her favor; and that an injunction would serve the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies this standard in reviewing the grant or denial of an injunction where the issues at play are unique to patent law. Where they are not, it applies the law of the regional circuit (here, the Ninth Circuit). *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). The Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after

the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm. *Id.* at 1135.

The parties disagree as to which standard is appropriate here. Yet because it cannot demonstrate serious questions as to the merits, let alone a likelihood of success, Amgen is foreclosed from injunctive relief under either formulation of the test for injunctive relief.

Indeed, the analysis above resolves in Sandoz's favor the merits as to the issues raised in the parties' cross-motions. Neither Sandoz's failure to supply its BLA and manufacturing process information within twenty days of learning the FDA had accepted its application for approval and subsequent decision to forego subsection (*l*)'s disclosure and negotiation procedures,[9] nor its intention to proceed to market by giving 180-day in advance of FDA approval, constitutes wrongful or unlawful behavior. As Amgen has failed to show otherwise, neither Amgen's UCL claim nor its conversion claim is, therefore, viable; and it has yet to proceed on its remaining claim for patent infringement.

Amgen furthermore does not carry its burden to demonstrate that irreparable harm will result in the absence of injunctive relief. Amgen argues market entry of Sandoz's biosimilar filgrastim product will cause it irreparable harm in several respects, specifically by: (1) delaying or precluding Amgen (through its sales of biosimilar filgrastim and diversion of revenue from Amgen) from undertaking research and development for new drugs and potentially causing Amgen to lose staff and scientists; (2) diverting Amgen sales representatives' energy from selling new products to competing with Sandoz for filgrastim market share; (3) causing Amgen to drop

[9] Even were the BPCIA to render unlawful an applicant's failure to supply its BLA and manufacturing process information to the reference product sponsor within twenty days, whether Sandoz made such information available to Amgen in a timely manner is a factual dispute between the parties that need not be reached here.

the price of Neupogen to remain competitive; and (4) damaging Amgen's customer relationships and goodwill in the event that the Court compels Sandoz to remove its product from the market, thereby prompting Amgen to enforce the order or raise its prices to where they were prior to Sandoz's market entry.

Not only are such harms at best highly speculative; they are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen. While Amgen has averred infringement of its '427 patent and argues that Sandoz's biosimilar filgrastim has the potential to infringe some four hundred more, *see* Declaration of Stuart Watt, it has not raised these contentions for a disposition at this juncture. It must, therefore, be assumed that no such infringement has occurred. As the twelve-year exclusivity period for Neupogen long ago expired, there exists no substantive bar to market entry for Sandoz's biosimilar filgrastim—and, consequently, no basis on which Amgen is entitled to injunctive relief or other remedies for disadvantages it may suffer due to market competition from Sandoz.

V. CONCLUSION

For the all of the aforementioned reasons, Amgen's motions for partial judgment on the pleadings or partial summary judgment in the alternative, and for preliminary injunction, are denied. Its claims under the UCL and for conversion are, furthermore, dismissed with prejudice.

Insofar as the above interpretation of the BPCIA is consistent with Sandoz's first through fifth counterclaims, judgment is hereby entered in Sandoz's favor. The BPCIA renders permissible a subsection (k) applicant's decision not to provide its BLA and/or manufacturing information to the reference product sponsor, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C). Such a decision alone does not offer a basis for the sponsor to obtain injunctive relief, restitution, or damages against the applicant; indeed, 42 U.S.C. § 262(*l*)(9) sets out the exclusive consequences for an applicant who elects not to provide its BLA and/or manufacturing information, or participate in any aspect of subsection (*l*)'s disclosure and negotiation process. As the BPCIA contemplates that a subsection (k) applicant will use the reference product sponsor's FDA license, and does not declare it unlawful for the applicant to do

so without participating in subsection (*l*)'s disclosure and negotiation process, there exists no predicate wrongful act on which to base Amgen's conversion claim.[10] In addition, the BPCIA poses no bar to Sandoz's sixth and seventh counterclaims for patent noninfringement and invalidity as to Amgen's '427 patent.

IT IS SO ORDERED.

Dated: March 19, 2015

RICHARD SEEBORG
United States District Judge

[10] Whether a sponsor otherwise maintains some exclusive property rights over an FDA license obtained for a biologic product is beyond the scope of this disposition.

United States District Court
Northern District of California

EXHIBIT 2

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **~~[PROPOSED]~~ FINAL JUDGMENT UNDER RULE 54(B) AND ORDER ESTABLISHING SCHEDULE FOR RULE 62(C) PROCEEDINGS AND STAYING ALL OTHER PROCEEDINGS** The Honorable Richard Seeborg

On March 19, 2015, the Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction. (ECF No. 105.) The Court's Order dismissed with prejudice the first and second causes of action brought by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") and entered judgment in favor of Defendant Sandoz Inc. ("Sandoz") on Sandoz's first, second, third, fourth, and fifth counterclaims insofar as those counterclaims are consistent with the Court's interpretation of the Biologics Price Competition and Innovation Act ("BPCIA"). The Order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for judgment on the pleadings (or alternatively for partial summary judgment) on Sandoz's sixth and seventh counterclaims, allowing those counterclaims to proceed.

Following the Court's March 19, 2015, Order, the only claims remaining before the Court relate to Amgen's '427 patent: Amgen's claim of infringement, and Sandoz's counterclaims of noninfringement and invalidity. These remaining patent claims are distinct and separable from the two claims and five counterclaims that were adjudicated in the March 19, 2015, Order.

Pursuant to the parties' agreement that, should either party appeal the decision of this Court, the parties would jointly seek expedited review in the Federal Circuit, the parties have jointly moved for entry of final judgment under Rule 54(b) of the Federal Rules of Civil Procedure so as to facilitate an immediate appeal of the BPCIA-related claims, all of which were resolved by the Court's March 19, 2015, Order.

Rule 54(b) certification is not available as of right. Rather, it requires that the judgment to be entered be final as to the claims it addresses, and that there be no just reason for delay. *See e.g., W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc.*, 975 F.2d 858, 862 (Fed. Cir. 1991). A judgment is final for Rule 54(b) purposes where it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Id.* at 861-62 (emphasis omitted) (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)). In determining whether there is just reason for delay, the Court considers "such factors as whether the claims under review [are] separable from the others remaining to be adjudicated and whether the nature of the claims already determined [are] such that no appellate court would have to decide the same issue more than once even if there were subsequent appeals." *Id.* at 862 (quoting *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980)).

Having considered the standard for entry of judgment under Rule 54(b), the Court finds that it is appropriate to enter judgment under Rule 54(b) as to Amgen's first and second causes of action and as to Sandoz's first through fifth counterclaims. There is no just reason to delay entry of final judgment on these adjudicated claims and counterclaims. They all relate to the correct interpretation of the BPCIA and do not address the sole subject of the remaining claims and counterclaims (Amgen's third cause of action and Sandoz's sixth and seventh counterclaims), which relate to enforceability, infringement, and validity of the '427 patent. Moreover, the claims and counterclaims decided by the Court's March 19, 2015, Order raise important legal issues that

are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the Food and Drug Administration has now approved Sandoz's application for its biosimilar product (the first biosimilar that the FDA has approved), implicating concerns about prejudice to the parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims. Finally, entry of a Rule 54(b) judgment is especially appropriate here, where Amgen intends to appeal now the denial of the preliminary injunction under 28 U.S.C. § 1292(a), because entry of such judgment will allow the entire March 19, 2015, Order to be appealed together.

The parties have also jointly requested entry of a scheduling order for Amgen's contemplated motion for an injunction under Rule 62(c). Additionally, the parties jointly have requested entry of an order staying all remaining proceedings in this Court (apart from those on the contemplated Rule 62(c) motion) until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order.

Accordingly, it is ORDERED and ADJUDGED:

1. FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Sandoz and against Amgen on Amgen's first and second causes of action, as well as on Sandoz's first, second, third, fourth, and fifth counterclaims in accordance with the Court's March 19, 2015, Order.

2. Amgen will make any motion for an injunction under Rule 62(c) no later than Tuesday, March 24, 2015. Sandoz will file its response to any such motion by March 31, 2015. Amgen will file its optional reply by April 2, 2015.

3. All other proceedings in this Court related to this matter, except for the entry of the jointly requested Rule 54(b) judgment and Amgen's contemplated Rule 62(c) motion, are STAYED until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order. During the period of the stay imposed by this paragraph, Amgen may continue efforts to effect service on Sandoz International GmbH and Sandoz GmbH, provided, however, that the time to move, answer, or otherwise respond to the complaint for either entity so served is tolled until twenty days after the expiration of the stay imposed by this paragraph.

Dated: 3/25, 2015

THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

EXHIBIT 3

SIDLEY AUSTIN LLP
Vernon M. Winters (SBN 130128)
Alexander D. Baxter (SBN 281569)
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice*)
Michael T. Wu (*pro hac vice*)
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

AMGEN INC.
Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **AMGEN PLAINTIFFS' NOTICE OF APPEAL**

NOTICE OF APPEAL

NOTICE IS HEREBY GIVEN that Amgen Inc., and Amgen Manufacturing, Limited, ("Amgen"), Plaintiffs in the above named case, hereby appeal to the United States Court of Appeals for the Federal Circuit from:

1. The district court's denial of Amgen's motion for a preliminary injunction in the March 19, 2015 Order (Dkt. No. 105). Attached as Exhibit A is a true and correct copy of the denial of Amgen's motion for a preliminary injunction.
2. The district court's judgment under Fed. R. Cir. P. 54(b) dismissing Amgen's first and second causes of action with prejudice and entering judgment in favor of Sandoz on Sandoz's first, second, third, fourth, and fifty counterclaims, dated March 25, 2015, (Dkt. No. 111) and all rulings, proceedings, orders, findings, and decisions (whether oral or written) interlocutory thereto or underlying the judgment. Attached as Exhibit B is a true and correct copy of the Rule 54(b) judgment.

Date: March 25, 2015

/s/ Vernon M. Winters

Vernon M. Winters (SBN 130128)
Alexander D. Baxter (SBN 281569)
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

OF COUNSEL:
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice)*
Michael T. Wu (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

EXHIBIT 4

NEUPOGEN® (filgrastim). The biological product license to NEUPOGEN® (filgrastim) is owned by Amgen and exclusively licensed to AML.

46. The active ingredient in NEUPOGEN® is filgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor or "G-CSF." NEUPOGEN® (filgrastim) is also known as recombinant methionyl human granulocyte-colony stimulating factor. By binding to specific receptors on the surface of certain types of cells, NEUPOGEN® (filgrastim) stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEUPOGEN® (filgrastim) counteracts neutropenia. The availability of NEUPOGEN® (filgrastim) represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by thus facilitating more effective chemotherapy regimes.

47. Another major advance provided by NEUPOGEN® (filgrastim) is for patients undergoing peripheral blood progenitor cell collection and transplant. In order to successfully treat certain forms of blood cancer, patients undergo hematopoietic progenitor cell transplants. NEUPOGEN® (filgrastim) is indicated for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Mobilization with NEUPOGEN® (filgrastim) allows for the collection of increased numbers of hematopoietic progenitor cells capable of engraftment compared with collection without the use of NEUPOGEN® (filgrastim) or from bone marrow harvest. Furthermore, transplantation with an increased number of hematopoietic progenitor cells can lead to faster engraftment, which may result in a faster recovery for the patient after transplant.

the United States in the same way that Plaintiffs' NEUPOGEN® (filgrastim) is administered. Upon information and belief, Defendants are seeking FDA approval for one or more indications for which NEUPOGEN® (filgrastim) is already approved.

61. Upon information and belief, Defendants' BLA is the first application that the FDA has accepted under the § 262(k) pathway.

62. Upon information and belief, Defendants have not and do not seek to independently demonstrate to the FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. 262(a), as Amgen did in its BLA for its innovative biological product NEUPOGEN® (filgrastim). Rather, upon information and belief, Defendants have requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen's FDA license for NEUPOGEN® (filgrastim). Accordingly, Defendants submitted to the FDA publicly-available information regarding the FDA's previous licensure determination that NEUPOGEN® (filgrastim) is "safe, pure, and potent." 42 U.S.C. 262(k)(2)(A)(iii)(I).

63. Upon information and belief, Defendants "received notification from the FDA on July 7, 2014" that the FDA had accepted their BLA for the Sandoz biosimilar product. Letter from Robin Adelstein, Vice President, Legal, IP & Compliance, Sandoz Inc., to Wendy A. Whiteford, Vice President Law, Amgen Inc. (July 25, 2014). Pursuant to the Biosimilar Biological Product Authorization Performance Goal and Procedures, which sets forth FDA goals for fiscal years 2013-2017, the FDA is committed to reviewing and acting "on 70 percent of original biosimilar biological product application submissions within 10 months of receipt" for biosimilar biological product applications filed in 2014.[1] Therefore, the FDA will complete its final review of Sandoz's biosimilar product at least by May 2015. Upon information and belief, Defendants believe that they may secure FDA approval of the Sandoz biosimilar product before

[1] FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/%20HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf, attached as Ex. I.

May 2015. *See* Letter from Robin Adelstein, Vice President, Legal, IP & Compliance, to David J. Scott, General Counsel and Secretary, Amgen Inc. (July 8, 2014) (Defendants' "reasoned belief" is that their BLA for the Sandoz biosimilar product "will be approved by the FDA in or around Q1/2 of 2015."); Letter (Oct. 20, 2014), *supra* ¶ 30 (confirming that "Sandoz continues to expect FDA approval in or around Q1/2 of 2015").

64. Defendants' receipt of FDA notification that their BLA had been accepted for review triggered the mandatory obligations set forth in 42 U.S.C. § 262(l). Specifically, the following provisions are required of Defendants, and would have been required of Amgen and FDA but for Defendants' failure to timely comply with their initial disclosure pursuant to 42 U.S.C. § 262(l)(2)(A):

Provision	Date
FDA notifies Defendants that their application for the Sandoz biosimilar product has been accepted for review.	Thursday, July 7, 2014
Subsection (k) application information. Not later than 20 days after Defendants' receipt of FDA notification: • Defendants "shall provide" to Amgen a copy of the application submitted to the FDA under § 262(k), 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).	On or before Monday, July 28, 2014
List and description of patents. Not later than 60 days after Amgen's receipt of Defendants' BLA and manufacturing information: • Amgen "shall provide" to Defendants a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted by Amgen. 42 U.S.C. § 262(l)(3)(A)(i). • Amgen "shall provide" to Defendants an identification of the patents on such list that Amgen would be prepared to license to Defendants. 42 U.S.C. § 262(l)(3)(A)(ii).	On or before Friday, September 26, 2014
List and description by subsection (k) applicant. Not later than 60 days after Defendants' receipt of Amgen's patent list: • Defendants "may provide" to Amgen a list of patents that Defendants believes could reasonably be asserted by	On or before Tuesday, November 25, 2014

compared to that set forth in the statute, and reminded Defendants of their statutory obligation to provide its BLA and manufacturing information to Amgen. Letter from Wendy A. Whiteford, Vice President Law, Amgen Inc., to Robin Adelstein, Vice President, Legal IP & Compliance, Sandoz Inc. (Aug. 22, 2014). After Amgen responded, Defendants sent Amgen another letter dated September 4, 2014, asserting that Defendants had decided "not to disclose our application to Amgen" and chosen not to exercise their "right to use the patent information exchange process of the BPCIA." Letter (Sept. 4, 2014), *supra* ¶ 68. Defendants sent another letter on October 20, 2014, purporting to "remind" Amgen of "our July 8, 2014 letter which provided you with Sandoz's notice of commercial marketing pursuant to 42 U.S.C. 262(l)(8)(A)." Letter (Oct. 20, 2014), *supra* ¶ 30.

71. Upon information and belief, Defendants' violation of 42 U.S.C. § 262(l)(2) is part of a carefully orchestrated scheme to deprive Amgen of the substantive and procedural benefits of the BPCIA.

72. In particular, receipt of the BLA and manufacturing information gives the reference product sponsor the opportunity to evaluate the manufacturing processes used by the biosimilar applicant to determine whether those processes would infringe any patents held by the reference product sponsor, including under 35 U.S.C. § 271(g). The purpose of the statutory provisions of 42 U.S.C. § 262(l)(2) is, *inter alia*, to permit such an evaluation, as in the absence of such a disclosure, the reference product sponsor has no access to the BLA and manufacturing information. Had Defendants provided Amgen with a copy of their BLA and manufacturing information, Amgen would have been in a position: (1) to provide to Defendants a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted as to the Sandoz biosimilar product, and (2) to identify to Defendants whether Amgen would be prepared to grant a license to Defendants under any of the patents included on such a list. *See* 42 U.S.C. § 262(l)(3)(A). Amgen has an extensive portfolio of patents relating to various aspects of the manufacture of biological products. However, because Defendants' manufacturing process for the Sandoz biosimilar product is secret, without the disclosure required under 42 U.S.C. § 262(l)(2) Amgen's ability to

conduct a full and complete evaluation of its patent portfolio with respect to Defendants' specific product, process(es) of manufacture, and uses is undermined and delayed. By unlawfully withholding the information required under 42 U.S.C. § 262(l)(2) Defendants have thereby frustrated the statutory purpose and deprived Plaintiffs of the opportunity to seek redress for potential infringement.

73. One patent which Amgen believes could have been identified on its list pursuant to 42 U.S.C. § 262(l)(3)(A)(i), is U.S. Patent No. 6,162,427 ("the '427 patent"), which covers a method of using NEUPOGEN® (filgrastim) to treat a disease requiring peripheral stem cell transplantation in a patient in need of such treatment. However, Amgen holds numerous other patents directed to processes for manufacturing products such as the Sandoz biosimilar product. As noted above, had Defendants provided Amgen with a copy of their BLA and information necessary to describe the process(es) for manufacturing the Sandoz biosimilar product, Amgen would have complied with its obligations under 42 U.S.C. § 262(l)(3) and identified any patents to which a claim of patent infringement could reasonably be asserted. Amgen therefore reserves the right to seek leave to assert additional patents following eventual receipt of Defendants' BLA and manufacturing information and other relevant information to be produced in discovery in this action under the Federal Rules.

74. Further, had Defendants complied with the statutory requirements, then Amgen could have brought a patent infringement action, if necessary, against Defendants under 42 U.S.C. § 262(l)(6) in February or March 2015. Because Defendants did not comply with the mandatory disclosure requirements of 42 U.S.C. § 262(l)(2), however, Amgen was deprived of any opportunity to review Defendants' BLA and manufacturing information, identify a comprehensive list of infringed patents, and review Defendants' contentions, and, possibly, licensing position, prior to bringing an action. Amgen also lost the benefit of the time provided in 42 U.S.C. § 262(l)(2) for Amgen and Defendants to identify potentially disputed patents, the time to evaluate those patents, the substantive exchange of statements concerning those patents, and the ability to identify more patents after exchanging patent lists prior to Amgen bringing a patent infringement action. Defendants' actions also create the

substantial and continuing risk that Plaintiffs may not be able to obtain manufacturing information regarding Defendants' biosimilar product that would permit Plaintiffs to assert their process patents prior to commercialization of the biosimilar product. Forcing Plaintiffs to assert one or more of their patents (including process patents) after Defendants' commercial entry into the market harms Plaintiffs by diminishing the value of such patents.

75. Additionally, Defendants violated the statute by not providing Amgen with a legally operative notice of commercial marketing. Upon information and belief, Defendants do not intend to provide Amgen with a notice of commercial marketing on or after FDA approval. Therefore, Defendants intend to and/or will violate the BPCIA absent an order of the Court compelling Defendants to comply.

76. Each of Defendants' unlawful acts (violation of 42 U.S.C. § 262(l)(2)(A) and violation of 42 U.S.C. § 262(l)(8)(A)) independently deprive Amgen of the benefits afforded under the statute and which Congress provided to reference product sponsors. Defendants' failure to provide the BLA and manufacturing information to Amgen under 42 U.S.C. § 262(l)(2)(A) deprives Plaintiffs of the opportunity to seek a preliminary injunction enjoining Defendants from engaging in the commercial manufacture or sale of the Sandoz biosimilar product in time to prevent irreparable harm to Plaintiffs, *i.e.,* after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product. In addition, Defendants' failure to provide a legally operative notice of commercial marketing deprives Plaintiffs of the opportunity to seek a court intervention to prevent Plaintiffs from suffering irreparable harm. This too prevents Plaintiffs from enjoining Defendants in time to prevent irreparable harm.

FIRST CAUSE OF ACTION
(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200 et seq.)

77. The allegations of ¶¶ 1-76 are repeated and incorporated herein by reference.

78. Defendants' actions in filing a BLA with the FDA under the § 262(k) pathway for approval to commercially market, manufacture, import and sell a biosimilar version of Plaintiffs' product NEUPOGEN® (filgrastim), and in planning the launch of a biosimilar

EXHIBIT 5

SIDLEY AUSTIN LLP
Vernon M. Winters (SBN 130128)
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice*)
Michael T. Wu (*pro hac vice*)
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

AMGEN INC.
Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **DECLARATION OF STUART WATT IN SUPPORT OF AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION**

I, Stuart Watt, declare and state as follows:

1. I am an attorney and Vice President, Law and Intellectual Property Officer at Amgen, Inc. ("Amgen"). I submit this declaration in support of Amgen's Motion for a Preliminary Injunction against Sandoz, Inc. ("Sandoz"). I am personally knowledgeable about the matters set forth in this Declaration and, if called upon to do so, I could and would competently testify to the following facts set forth below.

2. I understand that Sandoz is poised to enter the oncology market with a biosimilar version of Amgen's Neupogen® (filgrastim) product, which Sandoz has said will be named Zarxio. I further understand that Sandoz has not provided Amgen with a copy of the Biologics License Application ("BLA") and, as set forth in 42 U.S.C. § 262(l)(2)(A), "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."

3. Amgen and its subsidiaries are the owners by assignment of more than 1,400 United States patents that have issued since 1998. A good number of those issued patents are directed to manufacturing and purification processes for recombinant proteins. The United States Patent and Trademark Office classifies and subclassifies patents based on subject matter. Using that classification system, I located several classes and subclasses that could include patents that might be relevant to the recombinant production and purification of filgrastim, including the following:

- 435/69.1 Recombinant DNA technique included in method of making a protein or polypeptide
- 435/243 Micro-organism, … process of propagating, maintaining or preserving micro-organisms or compositions thereof; … culture media therefor
- 435/252.1 Bacteria or actinomycetales; media therefor
- 435/252.3 Transformants (e.g., recombinant DNA or vector or foreign or exogenous gene containing, fused bacteria, etc.)
- 530/412, 416, 417 Separation or purification of protein

4. Amgen has more than 400 patents issued since 1998 that fall within the above-listed USPTO classes and subclasses. While many of those patents would clearly not apply to the production of Zarxio, because they are either specific to proteins or classes of proteins other than filgrastim (including, for example, patents on purification of antibodies) or are specific to recombinant production of proteins in eukaryotic (for example, mammalian) cells as opposed to the bacterial cell production which Amgen uses to produce filgrastim and I suspect is used by Sandoz to produce Zarxio, some of those 400 Amgen patents could cover the recombinant manufacture and purification of filgrastim in bacterial cells.

5. Further, there could be additional Amgen patents in other classes and subclasses that could be relevant to the production of Zarxio or its use.

6. If Sandoz had provided its BLA and manufacturing information required by the statute, Amgen could have made a determination whether a claim of infringement of such patents could reasonably be asserted if Sandoz engaged in making, using, offering to sell, selling or importing into the United States, the filgrastim product that is the subject of its BLA. Without that BLA and manufacturing information, on the other hand, Amgen cannot assess which of its patents may apply in order to assert those patents against Sandoz.

7. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed the 5th day of February, 2015, at Thousand Oaks, California.

Stuart Watt

Stuart Watt

EXHIBIT 6

SIDLEY AUSTIN LLP
Vernon M. Winters (SBN 130128)
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
vwinters@sidley.com

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
Nicholas Groombridge (*pro hac vice*)
Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice*)
Michael T. Wu (*pro hac vice*)
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
ngroombridge@paulweiss.com

AMGEN INC.
Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
wendy@amgen.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **DECLARATION OF ROBERT AZELBY IN SUPPORT OF AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION**

I, Robert Azelby, declare and state as follows:

1. I am Vice President and General Manager Oncology at Amgen Inc. ("Amgen"). I submit this declaration in support of Amgen's Motion for a Preliminary Injunction against Sandoz, Inc. I am personally knowledgeable about the matters set forth in this Declaration and, if called upon to do so, I could and would competently testify to the following facts, below:

Amgen's Filgrastim Products

2. Amgen has two filgrastim products: Neupogen® (filgrastim) and Neulasta® (pegfilgrastim).

3. Generally speaking, Neupogen® is approved by FDA for use to treat patients in five indications: (1) cancer patients receiving myelosuppressive chemotherapy; (2) patients with acute myeloid leukemia receiving induction or consolidation chemotherapy; (3) cancer patients receiving bone marrow transplants; (4) patients undergoing peripheral blood progenitor cell collection and therapy; and (5) patients with severe chronic neutropenia. The current prescriber information for Neupogen® can be found at http://pi.amgen.com/united_states/neupogen/neupogen_pi_hcp_english.pdf

4. Neulasta® is approved by FDA for use in treating cancer patients receiving myelosuppressive chemotherapy. The current prescriber information for Neulasta® can be found at http://pi.amgen.com/united_states/neulasta/neulasta_pi_hcp_english.pdf

5. In my role as Vice President and General Manager Oncology at Amgen, my responsibilities include the sales and marketing of Amgen oncology business unit products and services in the United States. I am therefore familiar with both Neupogen® and Neulasta®, the channels through which they are sold and paid for, the patients they serve, how they are used by health care providers, and considerations that influence purchasing decisions. The same sales force that sell Neupogen® and Neulasta® also sell other of Amgen's oncology products such as Vectibix®. This sales force reports indirectly through to me in my role as Vice President and General Manager Oncology.

6. Both Neulasta® and Neupogen® are administered to patients most commonly by subcutaneous injection. A cancer patient receiving myelosuppressive chemotherapy who is treated with Neupogen® or Neulasta® in accordance with the prescribing information would receive the first dose of Neupogen® or the only dose of Neulasta® no earlier than 24 hours after receiving a dose of chemotherapy. Typically, this has meant that a patient receives a dose of chemotherapy and then must return to the treatment center on the following day to receive an injection of Neupogen® or Neulasta®. Treatment with Neulasta® requires only a single injection, while Neupogen® is generally injected daily for a number of days.

7. Each of Neupogen® and Neulasta® is a highly successful product. Each has achieved "blockbuster" status, an industry term used to denote products with over $1 Billion in total sales, and each has become incorporated into the standard of care for cancer patients receiving certain myelosuppressive chemotherapy regimens. While Amgen does not publicly report the precise profitability of these products, the contribution margins on Neupogen® and Neulasta® are significant.

The Market For Filgrastim Products

8. Healthcare providers have a choice of filgrastim products: Neupogen®, Neulasta®, and Teva's Granix® (tbo-filgrastim), which is not biosimilar to Neupogen®. In my experience, decisions about which product to prescribe are made based on a desire to maximize successful treatment outcomes, ensure safety and efficacy, and address patient convenience, while also being sensitive to the economics of healthcare.

9. Any company selling products or services in the oncology market will strive to understand the details of that market, which is complicated and ever changing. Neupogen® and Neulasta® are each paid for, for example, by both public payers (for example, Medicare/CMS) and private payers (for example, private health insurance). Although there is substantial overlap among them, the medications are generally administered in three principal market "segments": oncology clinics, hospitals, and pharmacy purchasers. How healthcare providers are reimbursed

for their out-of-pocket expense to purchase and administer filgrastim products varies by segment and often by payer.

10. To take an example Medicare in the hospital segment: For many inpatient treatments, hospitals are reimbursed by Medicare based on a patient's Diagnosis-Related Group, or "DRG," which includes a fixed payment amount in return for a bundle of related therapies and pharmaceuticals. Some private insurers similarly reimburse certain types of hospitals for specific inpatient treatments.

11. In the oncology clinic segment, the Medicare reimbursement system is different. Medicare reimburses doctors based on a product's Average Selling Price, or "ASP," which is the pharmaceutical's net selling price in recent quarters including rebates and discounts. In oncology, for example, Medicare reimburses doctors at ASP + 6% (currently lowered to 4.3% because of the federal sequester).

12. A new entrant wishing to sell a filgrastim product in competition with Amgen's Neupogen® and Neulasta® products, like Sandoz, could choose from at least four basic strategies: (1) target the hospital segment; (2) target the clinic segment; (3) target the pharmacy segment; or (4) target all three.

Sandoz's Proposed Entry into the Filgrastim Market and the Potential Harm to Amgen

13. I am aware that Sandoz is poised to launch a biosimilar version of Neupogen®, which it will call Zarxio, upon FDA approval. I also understand that Amgen has asserted through the filing of a lawsuit that Sandoz's anticipated launch is premature and unlawful.

14. I am very concerned that Sandoz's premature launch of its biosimilar filgrastim product in the United States will severely and permanently harm Amgen.

15. As an initial matter, I anticipate that sales of Zarxio will reduce Amgen's revenue from Neupogen® and Neulasta® sales. The market research I have seen suggests that the population of patients who need filgrastim treatment are currently getting it. Therefore, sales of Zarxio will likely and largely come at the expense of Neupogen® and possibly Neulasta® sales.

16. Customers of filgrastim products are fairly price-sensitive. Even though Granix is approved for only one indication, as compared to Neupogen®'s five, Teva gained roughly 8 to 9% of the short-acting filgrastim market over 2014, with a share as high as 14% over the past four weeks, by offering lower prices.

17. It is unclear to me how Sandoz will price its product. I have seen statements attributed to Sandoz executives that describe Zarxio as a lower-cost product, but I have also seen statements attributed to Sandoz executives that say that Zarxio will be priced at parity with or above Amgen's Wholesale Acquisition Cost (or "WAC") for Neupogen®, which is similar to a list price. New market entries do not have an established ASP because they have not accumulated sales from which to do the ASP calculation over the requisite period of time, so until they have accumulated such a track record their WAC is their ASP. By offering discounts off the WAC price to health care providers, it would be possible for Sandoz to set a WAC price above Neupogen®'s WAC price and increase the difference between the provider's acquisition cost and the amount of Medicare reimbursement. If Sandoz were to pursue that strategy, Medicare would pay more for Zarxio than for Neupogen® (which has an ASP lower than WAC), and doctors would keep more money from prescribing Zarxio than Neupogen®, resulting in increased profits to Sandoz and the prescribing physicians, increased costs to Medicare, its patients, and to society as a whole, and lost sales to Amgen.

18. The sequester further complicates the situation. As noted in the trade press, because of the details of how it is implemented, the 2% federal sequestration cut in Medicare reimbursement can make "the biosimilar reimbursement more attractive than the innovator." [1] As that article shows, a discount in the biosimilar list price can result in an even higher difference between the amount that doctors pay to acquire the biosimilar and the amount that they are reimbursed. While this may not have been Congress's intent, "the sequester in Medicare will have the unintended impact of making Part B payments more attractive for

[1] Ex. A (Michael McCaughan, *Biosimilar Reimburssement Under the Sequester: The Lower the Price, the Bigger the Spread,* "THE PINK SHEET" DAILY, August 8, 2014).

biosimilars than they would have been."[2] That article cites Sandoz's Mark McCamish "highlighting the reimbursement formula as a key reason why the company" used the biosimilar approval route for Zarxio.

19. Because of the intricacies of the Medicare reimbursement formula, Amgen could lose sales to Sandoz whether Sandoz prices Zarxio initially above or below Amgen's WAC.

20. For example, Sandoz might also compete with Amgen on acquisition cost in the inpatient hospital segment, where the incentives can be different. If Sandoz comes in below Amgen's average selling price for Neupogen®, cost-sensitive hospitals, in order to maximize economics under fixed, DRG-based reimbursements, could switch to Sandoz's product.

21. If Sandoz chose to target both hospitals and clinics, Sandoz could seek a balance between desire for low prices and desire for higher reimbursement.

22. At the right price, Sandoz's Zarxio could draw sales not just from Neupogen® but also Neulasta®. Assuming that Zarxio is dosed like FDA-approved filgrastim products, one advantage of Neulasta® over Sandoz's Zarxio would be that an appropriate treatment is achieved in a single injection, whereas once-a-day filgrastim treatments over a number of days depends on the patient returning each day for a new injection. With sufficient economic incentives, however, providers might switch to Zarxio not only from Neupogen® but from Neulasta®. Amgen might then be forced to lower its prices on Neupogen® and Neulasta® to retain market share.

23. If Amgen were forced to lower its prices for Neupogen® or Neulasta® to compete with Zarxio in the current ASP reimbursement system, it would be very difficult if not impossible for Amgen to simply raise its prices back to what they were before Zarxio competition, particularly with the existence of another competing filgrastim product, Teva's Granix. Because of the way the ASP reimbursement formulas and timing work, a price increase could lead to a greater cost for our products than doctors would be receiving in reimbursement.

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[2] *Id.*

If that were to occur, healthcare providers may be reluctant to prescribe Neupogen® or Neulasta® to patients in need, fostering animosity towards Amgen.

24. In my view, then, Sandoz's entry in the market will therefore not just harm Amgen through lost sales, but may also harm Amgen through permanent erosion of its prices.

25. Sandoz's entry in the market will also have significant adverse effects on Amgen's sales force. Amgen's sales force consists of highly sophisticated, valuable employees, whose loss would have adverse impacts on Amgen's ability to effectively sell its products. Indeed, in recent weeks Amgen has learned that former Amgen sales representatives now working for Sandoz have improperly been trying to hire away Amgen sales representatives to join them at Sandoz.

26. Further, Amgen oncology sales representatives will necessarily be diverted away from what they would otherwise be doing in order to address Sandoz commercial marketing of its filgrastim. This, too, could cause irreparable harm to Amgen. There are currently two, and perhaps three, significant tasks for the Amgen oncology sales force besides the day-to-day sale of Neupogen® and Neulasta®. First, Amgen has just introduced an on-body injector for Neulasta®. A doctor or nurse attaches the on-body injector to the patient's arm on the day that chemotherapy is delivered. The next day, the on-body injector delivers a full dose of Neulasta® into the patient, without the patient needing to return to the clinic. The on-body injector has the potential to revolutionize patient care in this area, as returning to the clinic the day after chemotherapy can be very arduous for a patient population that is very sick, often elderly, and may not live near the health care provider. The on-body injector also has a significant in-service education component: doctors and nurses need to be taught how to use it, a process that can take several hours and involve several applications of the on-body injector through test kits before applying the on-body injector on a patient. If Amgen's Neulasta® and Neupogen® salesforces are diverted to addressing Sandoz's marketing of Zarxio because Sandoz has not waited the time required by the BPCIA before entering the market, then Amgen may miss or severely harm the chance to educate the provider population about the new on-body injector. In

my experience, products like this need sustained, daily attention early in their life cycle or fewer patients will benefit and revenues will be lost. This loss of revenue (which would have been obtained had there been effective launch) is permanent and harmful to Amgen.

27. Similarly, Amgen has recently received approval to use its Vectibix® product as a first-line treatment for colorectal cancer in combination with Folfox, a chemotherapy regimen. Vectibix® is sold by the same sales representatives who sell Neupogen® and Neulasta®. These sales representatives must spend time, now, educating oncologists about the new approval for this product. Diverting them to address the marketing of Zarxio will cause them to also spend less time on Vectibix®, likely causing that franchise lasting and irreparable harm.

28. Finally, Amgen is pursuing approval of a new therapeutic product, talimogene laherparepvec, or "Tvec," that not only destroys certain cancer cells, but also stimulates the immune system to fight those cells elsewhere in the body. If Tvec is approved, which is expected later this year, and Amgen's oncology sales and marketing resources have been diverted to address Sandoz's filgrastim marketing, Amgen's ability to support Tvec during its all-important first 6-12 months on the market may be impaired, permanently harming that franchise.

29. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed the 5th day of February, 2015, at Thousand Oaks, California.

Robert Azelby

EXHIBIT 7

indicated that [Zarxio] could be priced at parity with Neupogen" but that other mechanisms such as rebates would be in play.[93]

(74) It is clear, however, that unlawfully premature sales of Zarxio would enable Sandoz to gain market share at Amgen's expense, lead to price erosion for filgrastim products, and put Amgen at a competitive and recurring disadvantage and Sandoz at a competitive advantage after the Restricted Period relative to their positions had Sandoz complied with the requirements of the BPCIA.

(75) Hospitals use filgrastim to treat patients on an inpatient and outpatient basis. In the inpatient setting, hospitals tend to be cost-sensitive, and to maximize their profit under fixed, DRG-based reimbursements used for inpatient treatments, hospital purchasers typically focus on obtaining the lowest prices for drugs regarded to be therapeutically similar. If Zarxio were viewed by payors and providers as a therapeutic alternative for either Neupogen® or Neulasta®, Sandoz would have an incentive to price Zarxio lower than Neupogen® or the equivalent price of Neulasta® to target cost-sensitive inpatient hospital usage. In other words, competition between Sandoz and Amgen would primarily focus on which drug costs the hospital the least for the treatment provided during the patient's hospital stay. In response, Amgen may be forced to lower its prices to hospitals to retain the business.

(76) If Sandoz decided to target clinics when launching unlawfully premature Zarxio sales, the ASP-based reimbursement methodology would have the greatest impact on Sandoz's pricing strategy. Clinical filgrastim usage is focused largely on treating and preventing the onset of chemotherapy induced neutropenia, and Zarxio would be a potential substitute for both Neupogen® and Neulasta®. Because of the provider's cost recovery incentives under ASP-based reimbursements, Sandoz would compete with Neupogen® and Neulasta® by setting its prices and discounts such that the cost recovery for Zarxio (i.e., the difference between reimbursement to the clinics and the clinics' acquisition costs) is higher than, or at least equal to, that of Neupogen® and Neulasta®.

(77) A third strategy Sandoz might follow is to make unlawfully premature sales in both the hospital and clinic segments. In choosing this strategy, Sandoz would have to find the balance between the somewhat conflicting incentives of hospitals' desire for low prices on one hand and clinics' desire for higher cost recovery on the other hand. Because the methodology for calculating the ASP-based reimbursements incorporates prices in both segments, lower prices in the hospital segment would reduce Zarxio's ASP-based reimbursements and make Sandoz less competitive among clinics. Sandoz would have to determine the optimal pricing balance across the segments to compete with Amgen in both.

(78) In doing so, Sandoz would likely set its hospital net price for Zarxio below Amgen's current net prices and set Zarxio prices and discounts for clinics in such a way as to generate a larger cost recovery "profit" for clinic providers than they can obtain by purchasing and administering Neupogen® and Neulasta®. Regardless of the exact prices that Sandoz decides to charge, such a strategy would likely lead to substantial revenue reductions for Amgen through both price erosion and share loss. As in the previous examples, Amgen's primary response to Sandoz's unlawfully premature sales would be to

[93] Anees Malik and Hristina Ivanova, "Sandoz's Biosimilar Filgrastim Scores Positive Recommendation from FDA Advisory Committee," Decision Resources, January 22, 2015.

reduce prices in one or both segments, which again leads to a downward price and reimbursement spiral as a result of the ASP calculation and substantial recurring harms.

D. Tests for injunction

(79) In deciding whether to grant an injunction, I understand the Court will consider and balance the following issues:

i. The economic effects of the patent uncertainty created by Sandoz's failure to comply with the requirements of the BPCIA;

ii. Whether Sandoz's unlawfully premature Zarxio sales would cause irreparable harm to Amgen (i.e., whether the manufacture, importation into the U.S., sale, offer to sell, and/or use of Zarxio in the United States prior to the time that Sandoz could have entered in compliance with the BPCIA and prior to the expiration of any applicable Amgen patents would cause irreparable harm to Amgen);

iii. Whether monetary damages would be adequate to compensate Amgen for the harms that Sandoz's unlawfully premature sales are likely to cause;

iv. Whether an injunction is warranted given the burdens such an injunction would place on Amgen and Sandoz, respectively; and

v. Whether the public interest would be disserved if Sandoz were enjoined.

I first address the fact that the patent uncertainty created by Sandoz's failure to abide by the requirements of the BPCIA itself creates irreparable harm to Amgen. I then address the question of whether Sandoz' unlawfully premature entry causes irreparable harm to Amgen, and discuss the economic factors underlying each of these issues in tum in the sections below.

D.1. The patent uncertainty created by Sandoz's failure to comply with the requirements of the BPCIA provides grounds for granting an injunction

(80) Sandoz's refusal to comply with the requirements of the BPCIA has three effects, each of which provides grounds for granting an injunction. First, it has made it more difficult for Amgen to determine whether Sandoz is infringing Amgen's patents. This refusal to comply with requirements in the BPCIA that protect patent rights creates patent uncertainty that threatens to undermine the value and effectiveness of Amgen's patents, and is inconsistent with the efficient operation of the patent system and the BPCIA. In particular, one aspect of determining whether preliminary injunctions should be issued is the likelihood of success on the merits. However, Sandoz's refusal to comply with requirements in the BPCIA has made it difficult for Amgen to determine which patents are infringed or how. This fact leads me to conclude that, from an economic perspective, an injunction should be issued. That is, Sandoz should not be rewarded for any difficulties in demonstrating likelihood of success in this or any subsequent patent litigation created by its lack of transparency. Allowing Sandoz to evade the patent protection requirements in the BPCIA and launch a product that may well have been found to be infringing had Sandoz followed the requirements would be contrary to the public interest. Amgen has many patents to processes used in the manufacture of recombinant

proteins, including patents directed to techniques that can be used in manufacturing filgrastim products, and Amgen's ability to enforce its patents and obtain the rewards contemplated by the patent system and the BPCIA should be supported with an injunction preventing Sandoz from marketing products which it has acted deliberately to evade potential infringement claims against prior to launch. Once launched, irreparable harm to Amgen would occur even if the products were later proven to be infringing and enjoined.

(81) Second, if Sandoz had complied with the requirements of the BPCIA and Amgen had determined that Sandoz's manufacture of Zarxio infringed Amgen's existing patents, I understand that compliance with the proceedures mandated by the BPCIA would have required as many as 410 days before Zarxio entry could occur.

(82) Finally, the fact that Zarxio could be the first biosimilar product to be introduced under the BPCIA creates a potential further societal harm should Sandoz's interpretation of the BPCIA become accepted. This harm would flow from the increased patent uncertainty that other firms would have over their patent protected biologic products, and the incentives provided to generic entrants to introduce biosimilar products that could infringe upon the patents of incumbents, and to attempt to conceal any such infringement. This would create a reduction in the incentives to invest in R&D and innovate throughout the industry, thus harming society. Further, as matter of public policy, if Sandoz's interpretation of the BPCIA were to be accepted, it is likely that similar litigation in the future would face the same issue as in this litigation: absent transparency regarding possible infringement, assessing the likely harms, and whether they are irreparable, becomes very difficult.

D.2. Irreparable harm to Amgen

(83) In my opinion, if Sandoz not is enjoined from disregarding the requirements of the BPCIA and, if appropriate, from making infringing Zarxio sales in the United States, Amgen would suffer a number of recurring harms. First, as a direct result of Sandoz's unlawfully premature sales, Amgen would suffer revenue reductions, share losses, and increased costs, leading to a substantial reduction in Amgen's profits. As discussed above, these lost profits could likely be in the hundreds of millions of dollars. The lost profits caused by Sandoz's unlawfully premature sales would recur beyond the Restricted Period, particularly to the extent that Sandoz's failure to comply with the BPCIA allows it to infringe on Amgen's patents. Because these direct, recurring effects of Sandoz's unlawfully premature sales would persist into the indefinite future, there is no foreseeable date in the future when the full extent of harms to Amgen can be estimated with reasonable certainty. Second, Amgen's lost profits would cause substantial and recurring harm to Amgen's ability to invest in the R&D and commercialization needed to support its current pipeline of innovative new products and to discover and develop future products. Third, Sandoz's unlawfully premature sales would harm Amgen by reducing the success, revenues and profits of other innovative new products. In my opinion, the profit losses would be disruptive to Amgen's cycle of innovation and commercialization of new products central to Amgen's business. Fourth, as a direct result of Zarxio's unlawfully premature sales, Amgen would suffer a disruption of its customer relationships resulting from the uncertainty over the effectiveness of Amgen's patent protection, as well as other recurring harms to Amgen's business.

D.2.2.1. Recurring loss due to persistence of share losses

(88) If Sandoz is not enjoined from making disregarding its obligations under the BPCIA and, if appropriate, further enjoined from making infringing Zarxio sales prior to the expiration of Amgen's patents, Sandoz's unlawfully premature sales would cause Amgen's filgrastim market share to be lower than it would have been had Sandoz waited until after the Restricted Period to sell Zarxio. The decrease in Amgen's filgrastim share would persist for an indefinite period of time, but in any case well after the Restricted Period. Furthermore, Sandoz's unlawfully premature entry would likely divert the sales, marketing, and educational efforts of Amgen from the support of newly introduced products to supporting the sales of Neupogen® and Neulasta®, diminishing the success of these products, and further harming Amgen. I understand that Amgen has a variety of new products being introduced, such as the Neulasta® on-body injector that could be highly successful products. However, Amgen's oncology business has limited staff to conduct the sales, marketing and educational support for its products, and such sales, marketing and educational support are important for the success of its products, especially for new product launches. This diversion of support would harm Amgen by reducing the success and future profitability of these products.

(89) In my opinion, by starting unlawfully premature Zarxio sales during the Restricted Period, Sandoz would obtain a substantial head-start advantage relative to what Sandoz otherwise would achieve if it waited until after the Restricted Period. In part because of the exposure to physicians and other key decision makers and the ability to build physician experience with Zarxio during the Restricted Period as a result of its unlawfully premature sales, Sandoz would gain and maintain a higher share of the market sooner than it would otherwise achieve and it would maintain this advantage after Amgen's patents expire. Sandoz's market share gains would accrue from Amgen during the Restricted Period, persist relative to Amgen in the post-Restricted Period, and accrue from other filgrastim manufacturers that wait to enter until after they comply with the BPCIA.

D.2.3. Other intangible harms to Amgen

(90) Zarxio's unlawfully premature sales would also lead to several other less tangible but recurring harms to Amgen that are difficult to quantify and compensate by monetary damages. I discuss some of these harms below.

(91) If Amgen were unable to enforce the patent protections of the BPCIA or to enjoin unlawfully premature sales of Zarxio, the risk perception among investors for Amgen's business would likely increase. Uncertainty over patent protected revenue and cash flow would affect the market valuation of innovative drug companies.[94] This reduction in market value in turn increases the cost of capital for Amgen, reducing its ability to continue to invest in additional R&D and raising its costs to finance current operations. Increasing capital costs would also increase the expected return required to make any given R&D investment successful. As a result, if Sandoz were not enjoined from making unlawfully premature sales of Zarxio, Amgen would likely undertake fewer such opportunities and be less likely to recover its investment on those it does undertake.

[94] Henry Grabowski, "Follow-on Biologics: Data Exclusivity and the Balance between Innovation and Competition," *Nature Review Drug Discovery*, published online May 12, 2008 at 4.

(92) In addition, other generic or biosimilar product manufacturers may be inspired to challenge the enforcement of Amgen's patent-protected innovations and disregard the requirements of the BPCIA, thus increasing Amgen's litigation costs and further decreasing the investment capital available to operate its business and fund ongoing R&D. Moreover, the impact of an increase in Amgen's cost of capital and potential future litigation expenses would be difficult to estimate with reasonable confidence and would likely recur into the indefinite future.

(93) Amgen's reputation among doctors, patients, and payors could also be harmed by Sandoz's unlawfully premature sales. If Sandoz were to enter the market now, and later to be enjoined because of enforcement of a patent the applicability of which Amgen only later learns, the resulting removal of Sandoz's product from the market would cause customer confusion that Sandoz could portray as, and that could therefore be seen as, Amgen's fault. Amgen faces the risk of lasting harm to its goodwill caused by its enforcement of rights granted to it under the BPCIA and the U.S. patent system.

D.3. Inadequacy of monetary damages

(94) Monetary damages would be inadequate to compensate Amgen for the harms caused by unlawfully premature (and potentially infringing) sales of Zarxio for at least five reasons: (i) harms to Amgen from patent uncertainty (e.g., concerns that Amgen's patents will be less enforceable and hence less valuable if Sandoz were permitted to disregard the requirements of the BPCIA aimed at protecting patent rights; as well as uncertainty as to what patents are being infringed by Sandoz) are inherently difficult to quantify and hence compensate through monetary damages; (ii) other harms to Amgen that are monetary in nature are uncertain and difficult to reliably estimate, and there would be inevitable dispute over alternative measures of the magnitude of those harms; (iii) Amgen's monetary losses caused by Sandoz's unlawfully premature sales would continue to recur into the indefinite future, persisting after the Restricted Period and possibly for as long as Amgen continues to sell filgrastim products; (iv) the resulting revenue losses would have monetary and non-monetary repercussions, such as lost R&D investment opportunities, that in tum cause far-reaching harm that would persist into the distant future; (v) other intangible harms such as the disruption of Amgen's business, disruption to Amgen's customer and payor relationships, and the diminished ability to maintain and recruit key personnel, are inherently recurring and non-monetary, making it difficult to establish a monetary equivalent.

(95) Sandoz's unlawfully premature sales of Zarxio would fundamentally and irrevocably alter the nature of the market for filgrastim products by adding the first biosimilar competitor to the market. The revenue and profit losses Amgen would suffer are difficult to predict reliably ex ante, but they are likely to be substantial and recur well after the Restricted Period. Since the harms caused by Sandoz's unlawful premature entry would continue to recur for an indefinite time period well beyond the Restricted Period, the retrospective calculation of Amgen's lost profits would either have to be postponed far into the future, or multiple interim adjudications would be required to compensate Amgen as and when the harm caused by Sandoz's unlawful premature entry accrues.

(96) Zarxio's unlawfully premature sales would diminish Amgen's ability to invest in the R&D necessary for Amgen to continue to successfully develop innovative drugs. Given the inherent uncertainty in the

research on which Amgen focuses, the harm to Amgen's business from Zarxio's unlawfully premature sales will be difficult to predict and quantify, and monetary damages cannot restore to Amgen the fruits of its lost innovation. For example, Amgen was forced to delay clinical trials for denosumab after the revenue decline Amgen absorbed in 2007. The value of obtaining earlier FDA approval of such a drug would be very difficult to establish with reasonable certainty. Similarly, if Amgen were to delay or cancel a discovery R&D project and, as a result, another company were to obtain a patent that otherwise could have been Amgen's, the losses to Amgen would be potentially enormous, would recur over a long time period, and be difficult to quantify with any reasonable certainty. Monetary damages would not be adequate compensation for the loss of a potentially game-changing opportunity. In short, monetary damages are inadequate to compensate Amgen for the harm unlawfully premature sales of Zarxio would cause to Amgen's future innovation and core business.

(97) Amgen would also suffer intangible harms such as harm to its reputation, loss of customer relationships, diminished ability to maintain and recruit key personnel, and increases in its cost of capital. Monetary damages would be inadequate to compensate for these harms as they too are recurring in nature and inherently non-monetary, making it difficult to establish a monetary equivalent.

D.4. Balance of burdens

(98) The burden Amgen would bear if Sandoz were not enjoined from an unlawfully premature launch of Zarxio in the United States is far larger than the burden Sandoz would bear if Sandoz were enjoined. The different burdens faced by Amgen and Sandoz are properly analyzed in light of the different business models of the two companies. Amgen would incur greater hardships owing to the threat that unlawfully premature (and potentially infringing) entry poses to Amgen's business. In contrast, Sandoz's business routinely accommodates the calculated risks associated with adverse litigation outcomes. A failure to enjoin Sandoz's unlawfully premature sales of Zarxio would also subject Amgen to substantially larger financial losses than Sandoz would face in losing the potential for incremental sales. In addition, Amgen would suffer greater hardships in the form of disruption to its customer relationships and risk to its reputation with investors than Sandoz stands to experience from a delay in forming its customer relationships until after the Restricted Period.

(99) Each of these factors is discussed below. First, however, it is important to note that Sandoz largely brings the burdens of an injunction on itself. Sandoz could have complied with the BPCIA and, as appropriate, could wait until Amgen's patents expire to launch Zarxio. In fact, one of the steps of the BPCIA information exchange calls for the biosimilar applicant to identify those patents for which it will wait for expiry before commercially marketing its product.

D.4.1. Burdens on Amgen from the disruption of Amgen's business model are greater than the corresponding burdens imposed on Sandoz by an injunction

(100) Amgen's business depends upon its ability to sustain innovative R&D efforts by reinvesting profits from its patent-protected drugs. Amgen invests heavily in R&D to discover and commercialize innovative products for previously unmet medical needs, and this research is expensive and highly uncertain. Amgen expects and depends upon the security and predictability of its patent rights, both to provide a reliable source of internally generated funds to sustain R&D and to ensure that future

EXHIBIT 8

EXHIBIT 9

SANDOZ

Robin Adelstein
Vice President,
Legal, IP & Compliance
General Counsel, N.A.

Sandoz
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Phone: 609.627.8500
Fax: 609.627.8684
www.us.sandoz.com

July 8, 2014

Amgen, Inc.
Attn: David J. Scott, Esq.
General Counsel and Secretary
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Robert A. Bradway, Chairman
and CEO
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Amgen, Inc.
Attn: Legal Department
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Re: **Offer of Confidential Access to Sandoz Inc.'s FDA Application for its Biosimilar Filgrastim Product**

Dear Sirs:

Sandoz Inc. ("Sandoz") has filed an application for FDA approval of a Sandoz biosimilar filgrastim product (recombinant human Granulocyte-Colony Stimulating Factor, 30 Mio. Units, 48 Mio. Units), for which Amgen's NEUPOGEN® is the reference product. It is Sandoz's reasoned belief that the application will be approved by the FDA in or around Q1/2 of 2015, and Sandoz intends to launch the biosimilar filgrastim product in the U.S. immediately upon FDA approval.

In recognition that the BPCIA patent resolution framework:

(i) is not the exclusive mechanism by which parties must resolve all patent disputes,

(ii) substantially limits Amgen's access to the biosimilar application (for example, the very limited number of in-house reviewers permitted to review any material disclosed), and

(iii) fails to expressly provide meaningful protection for exchanged information;[1]

Sandoz provides the attached Offer of Confidential Access ("OCA") to Amgen to protect information exchanged prior to resolving any dispute.

The terms of our proposed OCA are generous – certainly more generous than the BPCIA patent dispute resolution framework, while also providing clear and strong protection for exchanged information. In particular, the OCA permits access by more Amgen people (10) and people having varying disciplines (in-house counsel, outside counsel, and independent consultants), and the OCA provides remedies for breach of the OCA (injunction; costs for enforcement). In short, the OCA enables Amgen to conduct a more thorough review of Sandoz's biosimilar application allowing the parties to reach a resolution of any potential patent issues before Sandoz's anticipated launch, while providing meaningful protection for Sandoz's highly sensitive information.

Accordingly, please sign the attached OCA and return it to Sandoz before **July 25, 2014**.

Please be advised that Sandoz considers the information in this letter to be confidential. It should not be disclosed to others.

Please contact me with any questions and/or proposed revisions relating to any dispute resolution and Sandoz's OCA.

Very truly yours,

Robin Adelstein
Vice President, Legal, IP & Compliance
General Counsel, North America
Sandoz Inc.

Attachment:
Offer of Confidential Access (w/Exhibit A)

[1] Indeed, the BPCIA itself contemplates parties agreeing to alternative protection for exchanged information - 42 U.S.C. §262(l)(1)(A) ("Unless otherwise agreed to by a … 'subsection (k) applicant' … and the sponsor … for the reference product … the provisions of this paragraph shall apply to the exchange of information … .").

EXHIBIT 10

comment at the end, if you have further questions. 03:53:43 03:53:45

BY MR. STONE: 03:53:45

[redacted]

[redacted]

MR. STONE: Nothing further. 03:55:03
MR. OLSON: I have no are 03:55:04
further questions for you, Mr. Thole. 03:55:05
I will reiterate the statement I made 03:55:06
earlier on in the deposition that we're 03:55:09
requesting that the deposition be 03:55:11
marked highly confidential. 03:55:12
MR. STONE: No objection. 03:55:14
MR. OLSON: And that the 03:55:14
material in it is extremely sensitive 03:55:15
to Sandoz, as I'm sure all of the 03:55:18
attorneys involved are aware. And that 03:55:20

EXHIBIT 11

biosimilars.

And, moreover, once the patent is actually granted and a new drug is filed and you go through the process of getting FDA approval, whether at the end of the day your profitability or what you are able to capture with regard to value is going to be changed because of one process versus another process of actually proving that you still have an enforceable patent and should continue to collect those rents? That uncertainty always exists.

And him now saying that this would be a concealment, and there's no way of revealing that concealment, I just think that's -- I've never -- I don't believe it. I don't believe that a particular subsequent entrant that is actually infringing an enforceable patent can conceal it. I simply don't believe it.

Q. I couldn't find anywhere in your declaration where you talked about increased patent uncertainty.

A. No.

Q. Did I miss it?

A. No, you didn't miss it, because I didn't think it was sufficient -- didn't -- wasn't of sufficient substance in terms of my analysis, given

that I'm accepting, at the outset, as you noted in a question long ago, that my entire analysis presumes that the BPCIA must be followed, and I have evaluated the consequences given that it's followed. 16:54:10 16:54:14 16:54:18 16:54:26 16:54:29

So why would I go back and then investigate whether or not -- that's a different report. That's a different analysis. That's not an analysis that I've conducted. 16:54:30 16:54:33 16:54:37 16:54:39

That's why you don't see anything about patent uncertainty. Given how he's defined it, and given my assignment, there's no need to visit that question. 16:54:42 16:54:43 16:54:46 16:54:49

Q. Now, let's look at some of the things you did talk about. Let's turn to page 54 in your declaration. 16:54:52 16:54:54 16:54:59

A. I'm there. 16:55:09

Q. Just take a moment to read paragraph 82, and let me know when you've done so. 16:55:10 16:55:13

A. 82. (Examining document.) 16:55:15

Yes, I've read it. 16:55:35

Q. Now, could you tell me whether you think there's ever a situation in which damages can't be calculated on an ex-post basis? 16:55:38 16:55:40 16:55:44

A. If there's ever a situation where it 16:55:49

EXHIBIT 12

SANDOZ
a Novartis company

Markus Hartmann
Vice President &
North American Counsel

Sandoz
100 College Road West
Princeton, NJ 08540
Phone: 609.627.8876
Fax: 609.627.8684
Email:
markus.hartmann@sandoz.com

By EMAIL: wendy@amgen.com

BY FAX: (805) 499 8011/ (805) 447 1090

March 6, 2015

Attention: Wendy A. Whiteford
AMGEN Inc.
Law Department
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
USA

SANDOZ Inc.'s FDA Application for its Biosimilar Filgrastim Product

Dear Ms. Whiteford,

As you may already be aware, the FDA today approved Sandoz's filgrastim product for sale in the United States, as per the attached correspondence from the FDA. As you know from our prior correspondence and through the current litigation, we maintain that we provided our notice of commercial marketing pursuant to 42 U.S.C. 262(l)(8)(A) on July 8th, 2014. We understand Amgen's current position is that such notice cannot be provided until after FDA approval. We continue to maintain that our previous notice of commercial marketing is operative. However, without prejudice to that position, this letter serves as further notice of commercial marketing pursuant to 42 U.S.C. 262(l)(8)(A).

We would be grateful if you could acknowledge receipt.

Yours faithfully,

Markus Hartmann
Vice President & North American Counsel

Julia Pike
Head, Global IP Litigation

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125553

BLA APPROVAL

Sandoz Inc.
Attention: John M. Pakulski, RPh
Head, US Biopharmaceutical Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Mr. Pakulski:

Please refer to your Biologics License Application (BLA) dated May 8, 2014, received May 8, 2014, submitted under section 351(k) of the Public Health Service Act for Zarxio (filgrastim-sndz).

We acknowledge receipt of your amendments dated May 23; June 5, 12, 16, 18, and 24 (2); July 1 and 24; August 22; September 4, 19, and 30; October 10, 14, 21, 28 and 31; November 12; December 2, 5, and 19, 2014; January 22 and 30 (2); and February 6, 11, and 24; and March 4 and 5, 2015.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2003 to Sandoz Inc., Princeton, NJ, under the provisions of section 351(k) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Zarxio (filgrastim-sndz). Zarxio is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; to reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML); to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT); to mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and to reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture filgrastim-sndz drug substance at Sandoz GmbH in Kundl, Austria. The final formulated drug product will be manufactured, filled, labeled, and packaged at GP Grenzach Produktions GmbH, Grenzach-Wyhlen, Germany. You may label your product with the proprietary name, Zarxio, and market it in 300 mcg/0.5mL in single-use prefilled syringes and 480 mcg/0.8 mL in single-use prefilled syringes.

DATING PERIOD

The dating period for Zarxio shall be 24 months from the date of manufacture when stored at 5 ± 3°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be 36 months from the date of manufacture when stored at -20 ± 5 °C. The stability protocol in your license application is considered approved for the purposes of extending the expiration dating period of Zarxio drug product as specified in 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Zarxio to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Zarxio, or in the manufacturing facilities, will require the submission of information to your biologics license application for our review and written approval, consistent with 21 CFR 601.12.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 601.14(b)] in structured product labeling (SPL) format, as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "*SPL Standard for Content of Labeling Technical Qs and As*" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

In addition, within 14 days of the date of this letter, amend any pending supplement that includes labeling changes for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and carton and immediate container labels submitted on March 5, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "*Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).*" Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved BLA 125553**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with final printed labeling (FPL) that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring your assessment for pediatric patients who weigh less than 36 kg for this application because this product is ready for approval for use in adults and your assessment in this population has not yet been completed.

Your deferred assessment required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) is a postmarketing requirement. The status of this postmarketing requirement must be reported annually according to 21 CFR 601.28 and section 505B(a)(3)(C) of the FDCA. This requirement is listed below.

PMR 2883-1 To develop a presentation that can be used to directly and accurately administer filgrastim-sndz to pediatric patients who weigh less than 36 kg requiring doses that are less than 0.3 mL (180 mcg), and conduct any necessary human factors studies to evaluate the ability of caregivers to measure the appropriate doses.

Preliminary Protocol Submission:	07/06/15
Final Protocol Submission:	09/06/15
Study Completion:	06/06/16
Final Report Submission:	09/06/16

Submit the protocols to your IND 109197, with a cross-reference letter to this BLA.

Reports of this required pediatric postmarketing study must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

PMC 2883-2 To enhance the control strategy of polysorbate 80 by development, validation, and implementation of an analytical method to assess polysorbate 80 concentration for release or in-process testing of Zarxio drug product.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Final Report Submission:	05/2016
Implementation of analytical test for release to assess polysorbate 80 concentration in the drug product:	05/2020

Specifications will be set latest after testing of 20 commercial batches
The final study report(s) will be reported according to 21CFR 601.12

PMC 2883-3 To confirm the stability of Zarxio (filgrastim-sndz) drug product in 5% glucose at concentrations ranging from 5 mcg/ml to 15 mcg/ml of Zarxio (filgrastim-sndz), in the presence of 2 mg/ml human serum albumin, in glass bottles, PVC and polyolefin IV bags, and polypropylene syringes. Testing will include potency and sub-visible particles.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Final Report Submission: 05/2016

The final study report(s) will be reported according to 21CFR 601.12

PMC 2883-4 To re-adjust the end of formulation, pre-filtration bioburden limit of ≤ 500 CFU/100 mL for the bulk formulated drug substance based on process capability from 10 batches of product.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Study Completion: 08/2017
Final Report Submission: 05/2018 Annual Report

PMC2883-5 Establish bioburden and endotoxin action limits for AEX flow-through after data from more than 10[1)] batches are available and provide the limits in an Annual Report.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Study Completion: 03/2017
Final Report Submission: 08/2017

[1)] In case that less than 10 batches are manufactured by the date set for study completion, a preliminary action limit for bioburden and endotoxin will be set and re-assessed as soon as required number of batches is available.

PMC 2883-6 Conduct studies to support the worst-case hold times at 18°-25°C for process intermediates (AEX flow-through, capture eluate, HIC eluate, CEX fractions/CEX pool, UF retentate, and GF pool) at scale from a microbiology perspective. Provide study results in an Annual Report.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Study Completion: 12/2015
Final Report Submission: 05/2016 Annual Report

PMC 2883-7 To update the stability program for Zarxio (filgrastim-sndz) pre-filled syringe drug product to include the syringe force measurements glide force and functional testing of the needle safety device. The update to the stability program will include establishment of appropriate specifications and verification activities for these attributes.

The timetable you submitted on March 4, 2015, states that you will conduct this study according to the following schedule:

Final Report Submission: 05/2016 Annual Report

For functional testing on the devices constituent parts of the combination product:

Implementation of analytical test for stability and inclusion of functional tests in the postapproval stability commitment (with test frequency t0 and thereafter once a year until end of shelf life) on one commercial batch per strength:

- Syringe freedom of movement inside the needle safety device;
- Removability of the flag label
- Activation of the needle safety device

For break loose and glide force on the pre-filled syringes
(combination product): 05/2016 Annual Report

- Implementation of analytical test for stability and inclusion of test in the post-approval stability commitment (with test frequency t0 and thereafter once a year until end of shelf life) 05/2020

- Shelf life specification will be set and specification included in the post-approval stability commitment after testing of sufficient commercial batches (i.e. 10 batches each per 300 mcg/0.5mL and 480 mcg/0.8mL

The updated annual stability protocol including testing and acceptance criteria (specifications) will be reported according to 21 CFR 601.12

Submit clinical protocols to your IND 109197 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans

since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80). You should submit postmarketing adverse experience reports to:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with

processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA-3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4206
Silver Spring, MD 20903

If you have any questions, call Jessica Boehmer, Regulatory Project Manager, at (301) 796-5357.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, MD
Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ZARXIO safely and effectively. See full prescribing information for ZARXIO.

ZARXIO™ (filgrastim-sndz) injection, for subcutaneous or intravenous use
Initial U.S. Approval: 2015

----------INDICATIONS AND USAGE----------
ZARXIO is a leukocyte growth factor indicated to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever (1.1)
- Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML) (1.2)
- Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) (1.3)
- Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (1.4)
- Reduce the incidence and duration of sequelae of severe neutropenia (e.g.,fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (1.5)

----------DOSAGE AND ADMINISTRATION----------
- Patients with cancer receiving myelosuppressive chemotherapy or induction and/or consolidation chemotherapy for AML
  - Recommended starting dose is 5 mcg/kg/day subcutaneous injection, short intravenous infusion (15 to 30 minutes), or continuous intravenous infusion. See Full Prescribing Information for recommended dosage adjustments and timing of administration (2.1)
- Patients with cancer undergoing bone marrow transplantation
  - 10 mcg/kg/day given as an intravenous infusion no longer than 24 hours. See Full Prescribing Information for recommended dosage adjustments and timing of administration. (2.2)
- Patients undergoing autologous peripheral blood progenitor cell collection and therapy
  - 10 mcg/kg/day subcutaneous injection (2.3)
  - Administer for at least 4 days before first leukapheresis procedure and continue until last leukapheresis (2.3)
- Patients with congenital neutropenia
  - Recommended starting dose is 6 mcg/kg subcutaneous injection twice daily (2.4)
- Patients with cyclic or idiopathic neutropenia
  - Recommended starting dose is 5 mcg/kg subcutaneous injection daily (2.4)
- Direct administration of less than 0.3 mL is not recommended due to potential for dosing errors (2.5)

----------DOSAGE FORMS AND STRENGTHS----------
- Injection: 300 mcg/0.5 mL in a single-use prefilled syringe with BD UltraSafe Passive™ Needle Guard (3)
- Injection: 480 mcg/0.8 mL in a single-use prefilled syringe with BD UltraSafe Passive™ Needle Guard (3)

----------CONTRAINDICATIONS----------
Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim or pegfilgrastim products. (4)

----------WARNINGS AND PRECAUTIONS----------
- Fatal splenic rupture: Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture. (5.1)
- Acute respiratory distress syndrome (ARDS): Evaluate patients who develop fever and lung infiltrates or respiratory distress for ARDS. Discontinue ZARXIO in patients with ARDS. (5.2)
- Serious allergic reactions, including anaphylaxis: Permanently discontinue ZARXIO in patients with serious allergic reactions. (5.3)
- Fatal sickle cell crises: Have occurred. (5.4)

----------ADVERSE REACTIONS----------
Most common adverse reactions in patients: (6.1)

- With nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs (≥ 5% difference in incidence compared to placebo) are pyrexia, pain, rash, cough, and dyspnea
- With AML (≥ 2% difference in incidence) are pain, epistaxis and rash
- With nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT (≥ 5% difference in incidence) is rash
- Undergoing peripheral blood progenitor cell mobilization and collection (≥ 5% incidence) are bone pain, pyrexia and headache. (6.1)
- (Symptomatic) with severe chronic neutropenia (SCN) (≥ 5% difference in incidence) are pain, anemia, epistaxis, diarrhea, hypoesthesia and alopecia

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------USE IN SPECIFIC POPULATIONS----------
- ZARXIO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1)
- It is not known whether filgrastim products are excreted in human milk. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: [3/2015]

EXHIBIT 13

EXHIBIT 14

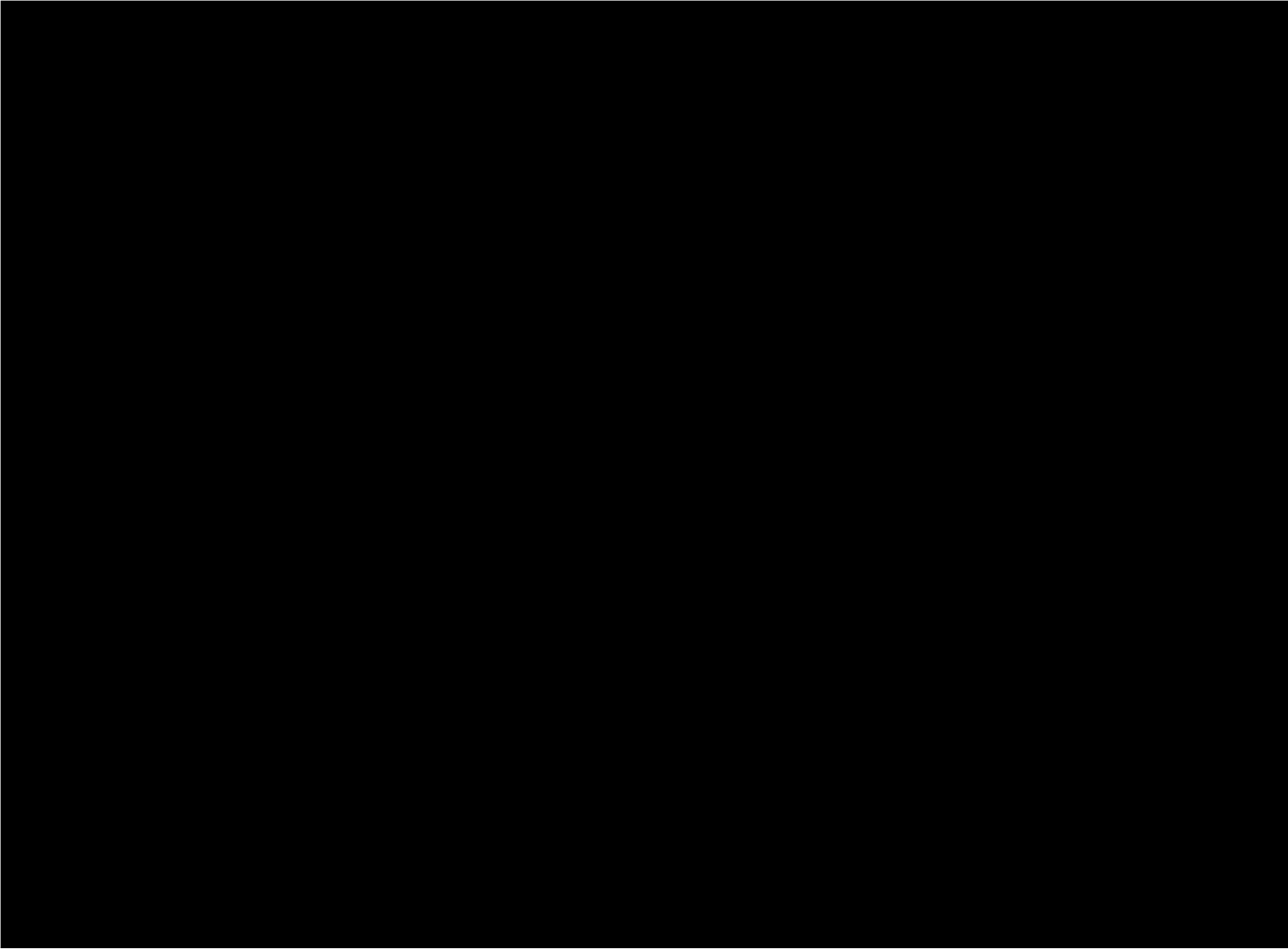

EXHIBIT 15

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER DENYING MOTION FOR INJUNCTION PENDING APPEAL

On March 25, 2015, this Court entered final judgment under Rule 54(b) of the Federal Rules of Civil Procedure as to its March 19 order on the parties' cross motions for judgment on the pleadings, dismissing with prejudice Plaintiffs Amgen, Inc. and Amgen Manufacturing, Limited's (collectively "Amgen") first and second claims for relief; granting judgment in favor of defendant Sandoz, Inc. et al.'s first through fifth counterclaims; and denying Amgen's motion for a preliminary injunction. On March 27, 2015, Amgen filed an appeal of this order with the United States Court of Appeals for the Federal Circuit. Amgen furthermore moves this Court for an injunction secured by bond that would restrain Sandoz from launching its biosimilar product pending the outcome of its appeal, pursuant to Rule 62(c), or, in the event this Court denied an injunction pending appeal, an injunction lasting until the Federal Circuit can rule on the appeal of such an order. The parties have stipulated that, upon this Court's denial of Amgen's application,

Amgen will appeal it to the Federal Circuit within two days.[1]

Rule 62(c) affords a district court from which an interlocutory order or final judgment that grants, dissolves, or denies an injunction is on appeal, the discretion to "suspend, modify, restore, or grant an injunction" while the appeal is pending "on terms for bond or other terms that secure the opposing party's rights" on a finding that such relief is warranted. Courts evaluate motions for preliminary injunction and motions for injunction pending appeal using similar standards. *See Alaska Conservation Council v. U.S. Army Corps of Engineers*, 472 F.3d 1097, 1100 (9th Cir. 2006). In *Winter v. Natural Resources Defense Council*, the Supreme Court declared that in order to obtain an injunction, a plaintiff must establish that (1) it is likely to succeed on the merits, (2) it is likely to suffer irreparable harm in the absence of injunctive relief, (3) the balance of the equities tips in its favor, and (4) an injunction is in the public interest. 555 U.S. 7, 20 (2008). *See also Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (setting forth substantially the same factors in deciding whether to grant a Rule 62(c) motion).

As noted in the prior order on the parties' cross motions for judgment on the pleadings and denying Amgen's motion for a preliminary injunction, the Ninth Circuit has clarified that courts in this Circuit should evaluate the likelihood of success on a "sliding scale." *Alliance for Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011) ("[T]he 'serious questions' version of the sliding scale test for preliminary injunctions remains viable after the Supreme Court's decision in *Winter*."). According to this test, "[a] preliminary injunction is appropriate when a plaintiff demonstrates . . . that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor," provided, of course, that "plaintiffs must also satisfy the other [*Winter*] factors" including the likelihood of irreparable harm." *Id.* at 1135; *see also Conservation Congress v. U.S. Forest Service*, 803 F. Supp. 2d 1126, 1129-30 (E.D. Cal.

[1] Sandoz has agreed to refrain from launching its filgrastim biosimilar product, Zarxio, until the earlier of May 11, 2015, or a decision by the Federal Circuit on Amgen's application for an injunction pending appeal. The Federal Circuit has already granted Amgen's unopposed motion to expedite briefing, ensuring its completion by April 30; and the parties have requested that the Federal Circuit hear this matter in its June calendar.

2011) (applying *Cottrell*'s "serious questions" version of the sliding scale test on a Rule 62(c) motion).[2]

While Amgen raises significant and novel legal questions as to the merits of its case, as noted in the Court's prior order, its tenuous and highly contingent showing of irreparable harm forecloses injunctive relief. Indeed, Amgen repeats, to no avail, its previously considered grounds for contending it will suffer irreparable harm. Even taking into account the additional evidentiary material filed subsequent to the hearing on the parties' motions, Amgen's showing of potential price erosion, harm to Amgen's customer relations and goodwill, and diversion of Amgen's sales representatives' energy, is speculative. Moreover, even if these ramifications were certain to occur, according to this Court's interpretation of the BPCIA, any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent. Amgen having made no showing as to this latter point, the likelihood of it wrongfully suffering irreparable harm appears slim and does not merit injunctive relief. Amgen's contention that Sandoz overstates the prejudice it would suffer in the face of an injunction pending appeal does not, therefore, tip the balance of equities in Amgen's favor.

Accordingly, Amgen's motion for an injunction pending appeal to the Federal Circuit of this Court's order on the parties' cross motions for judgment on the pleadings and Amgen's motion for preliminary injunction or, in the alternative, pending appeal of this order, is denied.

IT IS SO ORDERED.

Dated: April 15, 2015

RICHARD SEEBORG
United States District Judge

[2] The parties clash on which standard should apply here. In matters not unique to patent law, the Federal Circuit typically defers to the law of the regional circuit from which the case arises. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013). In any case, the issue of which standard should apply to Amgen's motion need not be decided here, as Amgen fails to clear the hurdles set forth under either standard.

CERTIFICATE OF SERVICE

I hereby certify that on this 17 of April, 2015, I caused the foregoing Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending Appeal Pursuant to Fed. R. App. P. 8(a) to be filed with the Clerk of the Court using the CM/ECF system. I also caused a true and correct copy of the foregoing Emergency Motion of Plaintiffs-Appellants Amgen Inc. and Amgen Manufacturing Limited for an Injunction Pending Appeal Pursuant to Fed. R. App. P. 8(a) to be electronically served on Defendant-Appellee Sandoz Inc.'s counsel of record, pursuant to agreement of the parties, as follows:

Deanne E. Maynard
(dmaynard@mofo.com)
Marc A. Hearron
(mhearron@mofo.com)
MORRISON & FOERSTER LLP
2000 Pennsylvania Ave., N.W.
Suite 6000
Washington, D.C. 20006

Rachel Krevans (rkrevans@mofo.com)
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

/s/ Kersuze Morancy
COUNSEL PRESS