No. 2015-1499

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California, Case No. 3:14-cv-04741-RS, Judge Richard Seeborg

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SANDOZ INC.'S OPPOSITION TO EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

NON-CONFIDENTIAL VERSION

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CERTIFICATE OF INTEREST

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

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

Sandoz Inc.

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

N/A

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

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

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

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

Dated: April 24, 2015 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

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

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INTRODUCTION

This is not a typical motion by a patentee seeking an injunction pending appeal. Amgen's appeal involves *no* claim of patent infringement. Instead, Amgen seeks to enjoin launch of Sandoz's FDA-approved biosimilar filgrastim product based solely on Sandoz's purported violations of procedures of the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 804 (2010). But the BPCIA contains no mechanism for Amgen to preclude Sandoz from launching absent a showing of patent infringement. Amgen has not attempted to make any such showing, nor sought a preliminary injunction based on any patent claim. To the contrary, Amgen repeatedly has stated that its material U.S. patents for filgrastim expired in 2013.

Amgen nonetheless argues that Sandoz's purported violations of the BPCIA entitle Amgen to an injunction under *state law*. The district court correctly rejected Amgen's state-law claims because Sandoz did not act "unlawfully" under the BPCIA. The court also properly rejected Amgen's request for an injunction pending appeal, finding as fact that Amgen's "tenuous and highly contingent showing of irreparable harm forecloses injunctive relief." A2080. Nothing in Amgen's motion undermines that finding. Indeed, Amgen cannot establish ***any*** of the four factors required to warrant an injunction pending appeal.

First, Amgen has not shown a strong likelihood of success on appeal.

The BPCIA created an abbreviated pathway for the FDA to license "biosimilar" products – i.e., biological products that are "highly similar" to already approved biological products. *See* 42 U.S.C. § 262(i)(2). The statute includes a carefully reticulated regime for the resolution of any patent disputes between biosimilar applicants and sponsors of approved biological products. In particular, the BPCIA creates a new artificial-infringement action, allowing sponsors to assert their patent rights before any actual infringement. 35 U.S.C. § 271(e)(2)(C). The particular contours of any pre-approval suit depend on the actions taken or not taken at each step of a multi-step process of information exchange between the applicant and the sponsor regarding the sponsor's possible patent claims. 28 U.S.C. § 2201(b); 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*). At each step, Congress carefully spelled out both the action the party "shall" take to continue with the process and, if the party declines, what follows.

At issue here, Section 262(*l*)(2)(A) provides that within 20 days of FDA acceptance of a biosimilar application, the applicant "shall provide" a copy to the sponsor. 42 U.S.C. § 262(*l*)(2)(A). The district court correctly concluded that the "shall" in this provision establishes a mandatory condition precedent to taking advantage of the patent-exchange process. The BPCIA expressly contemplates that an applicant might not provide its application and lays out how patent disputes are resolved in that event: patent-infringement litigation, with the scope and

timing at the sponsor's sole discretion. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). Taking a path that the BPCIA expressly provided is not unlawful.

Also at issue is Section 262(*l*)(8)(A), which provides for "[n]otice of commercial marketing" 180 days before marketing. Amgen argues Sandoz "violated" that provision by giving notice *too early*, contending notice cannot be given until after FDA licensure. The district court correctly rejected Amgen's reading, which effectively would transform the "[n]otice" provision into an automatic 180-day bar against marketing – essentially an automatic, bondless injunction – even where the sponsor has no patents.

Even if Amgen's interpretation of the BPCIA were correct, it still could not obtain an injunction against commercial marketing. Congress expressly provided that the BPCIA patent remedies are the "*only remedies* which may be granted by a court" for an applicant's submission of a biosimilar application without providing a copy to the sponsor, 35 U.S.C. § 271(e)(4) (emphasis added), and the statute likewise provides a specific remedy (immediate patent litigation) for the failure to provide a notice of commercial marketing, 42 U.S.C. § 262(*l*)(9)(B).

Second, as the district court found as fact, Amgen's claimed harms are "tenuous and highly contingent." A2080. As Amgen acknowledges, the district court concluded that "any detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen

patent," which Amgen has not tried to show. *Id.* That conclusion is correct, as the BPCIA requires proof of infringement to keep a biosimilar off the market.

The district court also made a second, independent finding on irreparable harm, which Amgen ignores. The court found that "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." *Id.* Amgen cannot show that that finding is clearly erroneous.

Finally, the balance of equities and public interest favor Sandoz. Sandoz invested years of effort and tens of millions of dollars to have the first biosimilar filgrastim in the United States. Competitors' products are expected this year. Even a brief injunction would jeopardize the first-to-market advantage Sandoz earned. The public interest also would be substantially harmed by denying patients access to Sandoz's filgrastim and the price competition promised by the BPCIA.

BACKGROUND

For 24 years, Amgen has marketed the biological product filgrastim under the brand name Neupogen®. A5. Since February 2014, Amgen has publicly stated: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States . . . ." A915; A960.

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. A5. The next day, Sandoz notified Amgen of its application,

advised Amgen that FDA approval was expected in the first half of 2015, and informed Amgen that Sandoz intended to launch its product immediately upon FDA approval. A1472-73. Sandoz also offered to provide its application on a confidential basis. *Id.* Amgen declined Sandoz's offer. A1481-82.

Concerned about sharing its application with a competitor, and in light of Amgen's statements that it has no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the most expeditious path to resolution of any patent claims. A1495-97. On July 25, 2014, Sandoz informed Amgen that "Amgen [was] entitled to start a declaratory judgment action under 42 U.S.C. § 262(*l*)(9)(C)," A1496, and that Amgen could "obtain access to the biosimilar application" in that suit under court-ordered confidentiality protections. A1495. Sandoz again offered to provide Amgen its application under industry-standard confidentiality protections. A1495-1503. Amgen rejected that offer. A1505-07.

Months later, on October 24, 2014, Amgen brought a claim under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, alleging that Sandoz's purported "violations of the BPCIA satisfy the 'unlawful' prong of § 17200." A74. Amgen also brought a state-law claim for conversion, alleging that Sandoz wrongfully used Amgen's license. Additionally, Amgen brought a claim for artificial infringement of U.S. Patent No. 6,162,427

("'427 patent"). Sandoz answered and counterclaimed. A271-88.

The parties cross-moved for partial judgment on the pleadings. And, more than three months after filing suit, Amgen moved for a preliminary injunction – based only on its state-law claims, not on alleged patent infringement. On February 9, 2015, after the court issued Sandoz's proposed protective order, Amgen finally accepted Sandoz's application. A734; A1353.

On March 19, 2015, the district court denied Amgen's motions and granted Sandoz's motion. A1-19. The court held that it was lawful for Sandoz to withhold its application, as the BPCIA contemplates applicants might, and that the sole consequence is a sponsor may start immediate patent litigation, as Amgen already has done. A9-12. The court also held that, under the plain text of Section 262(*l*)(8)(A), it was "not wrongful for Sandoz to give Amgen its 180 days' notice" of commercial marketing before FDA approval. A14. Additionally, the court noted that "[t]he 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." A15. Finally, the court denied Amgen's preliminary injunction motion because, among other reasons, Amgen's asserted irreparable harms are "at best highly speculative." A18.

The district court later entered final judgment on the non-patent claims and

counterclaims and granted the parties' joint request to stay all other proceedings, including Amgen's patent-infringement claim. A20-23. Although the FDA had approved Sandoz's biosimilar filgrastim product on March 6, 2015 (A1774-82), Sandoz agreed not to launch until the earlier of this Court's ruling on Amgen's motion for an injunction pending appeal, or May 11, 2015. A1946.

On April 15, 2015, the district court denied Amgen's motion for an injunction pending appeal. A2078-80. The court held Amgen unlikely to prevail on appeal. It also found Amgen's claimed harms "tenuous and highly contingent" because: (1) Amgen's claimed harms are "speculative," and (2) in any event, Amgen's claimed harms are "only undue if Sandoz has infringed an Amgen patent," which Amgen has not tried to show. A2080.

ARGUMENT

I. AMGEN'S MOTION SHOULD BE DENIED

An injunction is an "extraordinary remedy" requiring "a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). An injunction pending appeal requires a court to consider

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

Hilton v. Braunskill, 481 U.S. 770, 776 (1987). Satisfying one factor does not

lessen the requirement to establish the others. *See Winter*, 555 U.S. at 21-22.[1]

Where, as here, the district court denied an injunction pending appeal under Federal Rule of Civil Procedure 62(c), a motion under Federal Rule of Appellate Procedure 8 should be denied unless the district court's decision was an abuse of discretion or its factual findings are clearly erroneous. *Regents of the Univ. of Cal. v. American Broad. Cos.*, 747 F.2d 511, 522 n.7 (9th Cir. 1984); *Lightfoot v. Walker*, 797 F.2d 505, 507 (7th Cir. 1986); Fed. R. Civ. P. 52(a)(6).

Amgen has not established *any* of the four factors required for the entry of an injunction pending appeal – much less *all* of them.

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

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

The district court properly concluded that Sandoz did not act "unlawfully" when it took a path expressly laid out by the BPCIA: withholding its application and thus subjecting itself to the possibility of immediate patent litigation.

The BPCIA creates an integrated regime for resolving any patent disputes involving biosimilars, preferably before FDA approval. It amends the Patent Act

[1] Although Amgen argued in district court that it need show only "serious legal questions" if the balance of harms tips sharply in its favor (A1978), it waived that argument by not pressing it here. For good reason: that is not the standard. *See Nken v. Holder*, 556 U.S. 418, 434 (2009). In any event, the district court correctly held Amgen cannot meet even that standard. A2080 n.2; *see* A16-17.

to make submission of a biosimilar application to the FDA an artificial act of infringement under certain circumstances, thus permitting litigation before any actual infringement. 35 U.S.C. § 271(e)(2)(C). It also establishes a multi-step process in 42 U.S.C. § 262(*l*) that determines who can bring such a suit, when it can be brought, and for what relief. Although each subsection (*l*) step begins with "shall," the BPCIA contemplates that the applicant or the sponsor might not pursue the patent-exchange process to completion and expressly provides the consequences for not doing so. A2050-51 (showing consequence at each step).

As the district court explained, "to continue the process or to terminate it confers advantages and disadvantages" for both parties. A5. Amgen is thus wrong that withholding of an application brings only benefits for the applicant and harms for the sponsor. Mot. 11, 16. If the application is withheld, the sponsor gains the right to file an immediate, pre-launch suit based on the act of artificial infringement, 35 U.S.C. § 271(e)(2)(C)(ii), and the applicant loses its right to forestall it, 42 U.S.C. § 262(*l*)(9)(A), (C). The sponsor can then obtain the biosimilar application in discovery (as Amgen did here). The applicant also loses the control it would otherwise have over which patents, or how many, the sponsor can assert. *Compare* 42 U.S.C. § 262(*l*)(9)(C), *with id.* § 262(*l*)(3)-(5). The sponsor alone decides whether and when to sue and can delay suit until after FDA approval, effectively forcing the applicant to launch at risk.

In light of the BPCIA's multiple procedural paths to resolving any substantive patent rights, the district court correctly concluded that the "shall" in Section (*l*)(2)(A) denotes a condition precedent to engaging in the patent-exchange process, rather than a mandate that the process be initiated in all circumstances. A9-11; *see County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082 (D. Minn. 2013) (similarly interpreting "shall" as a condition precedent), *aff'd*, 776 F.3d 947 (8th Cir. 2014). That interpretation gives full and ordinary meaning to the word "shall." *If* an applicant wishes to engage in the patent-exchange process, then it *must* provide its application to the sponsor within 20 days of FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But "[*i*]*f* a subsection (k) applicant fails to provide [its] application," then the sponsor can immediately commence patent litigation under the BPCIA's amendments to the Patent Act making that failure an act of artificial infringement. *Id.* § 262(*l*)(9)(C) (emphasis added); *see* 35 U.S.C. § 271(e)(2)(C)(ii). In that event, the statute shifts the parties onto a different track to resolve patent disputes: immediate, pre-launch patent litigation. As the district court correctly concluded (A9-12), it cannot "violate" the BPCIA to choose this track established by the BPCIA itself.

Contrary to the district court's holistic interpretation of the BPCIA, Amgen insists on reading the word "shall" in Section 262(*l*)(2)(A) in isolation. But each statutory provision must be read "in context and with a view to [its] place in the

overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Other provisions confirm that the word "shall" in subsection (*l*) does not denote a mandatory requirement in all circumstances.

Subsection (*l*)(6) provides that at the end of the patent-exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). Nothing in the BPCIA suggests that Congress mandated that one private party sue another, or else the sponsor commits an "unlawful" act. To the contrary, despite the word "shall," the BPCIA expressly envisions that suit might be brought "*after* the expiration of the 30-day period." 35 U.S.C. § 271(e)(6)(A)(ii)(I) (emphasis added). In that event, "the sole and exclusive remedy that may be granted by a court . . . shall be a reasonable royalty." *Id.* § 271(e)(6)(B).

Contrary to Amgen's contention (Mot. 10-11), the district court's interpretation is consistent with the use of "shall," "may," "required," and "fails" in subsection (*l*). Providing the application within 20 days is "required" for an applicant to participate in the patent-exchange process, and if the applicant "fails" to satisfy that condition precedent, statutory consequences follow. If an applicant provides its application, it also "*may* provide to the reference product sponsor additional information," but doing so is not required to participate in the process. 42 U.S.C. § 262(*l*)(2)(B) (emphasis added).

2. The district court correctly held that it is not unlawful to provide notice under Section 262(l)(8)(A) 180 days before commercial marketing, rather than after FDA licensure

Nor has Amgen established a strong likelihood of success on its contention that Sandoz acted "unlawfully" under Section 262(*l*)(8)(A) by providing its notice of commercial marketing too early. That provision states that "[t]he subsection (k) 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). As the district court correctly held (A12-14), Sandoz satisfied that provision by giving notice in July 2014, more than 180 days before commercial marketing.

The text of Section 262(*l*)(8)(A) forecloses Amgen's argument that notice may not be given before the product is "licensed under subsection (k)." Mot. 12-13 (quoting 42 U.S.C. § 262(*l*)(8)(A)). The "before" in Section 262(*l*)(8)(A) modifies "the date of the first commercial marketing," so the provision is satisfied so long as notice comes at least 180 days before that event. The use of "licensed" simply recognizes that a product cannot legally be "commercial[ly] market[ed]" until it is "licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A); *see id.* § 262(a)(1)(A). After all, it is a "subsection (k) *applicant*" – not the "holder" of an approved application – that is expressly authorized to provide the notice. *Compare id.* § 262(*l*)(8)(A) (emphasis added), *with id.* § 262(m)(3).

Amgen's interpretation, under which notice may not come until after FDA licensure, would transform this mere "[n]otice" provision into the functional equivalent of an automatic, bondless six-month injunction – even when the sponsor has no valid patents. And, as the district court explained, for each first-approved biosimilar, 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)." A13. "Had Congress intended to make the exclusivity period twelve and one-half years, it could not have chosen a more convoluted method of doing so." A13-14.

3. Amgen's recourse is limited to what the BPCIA itself provides

Even if Amgen's interpretation of the BPCIA were correct, the district court correctly concluded that courts may not fashion additional remedies Congress did not provide or "hunt . . . through the laws of the fifty states to find a predicate by which to litigate a claimed BPCIA violation." A8 n.4.

Contrary to Amgen's assertion that the BPCIA does not explicitly make the remedies provided therein "exclusive" (Mot. 15), the BPCIA does exactly that for an applicant's non-disclosure of its application. The BPCIA's amendment to the Patent Act provides that "if the applicant . . . fails to provide the application" to the sponsor, the submission of the application to FDA constitutes an artificial act of infringement. 35 U.S.C. § 271(e)(2)(C)(ii). The statute then specifies patent-

specific remedies that a sponsor may seek in response. *Id.* § 271(e)(4)(A)-(D). Critically, the statute expressly provides that those remedies "are the *only remedies* which may be granted" for the statute's acts of artificial infringement. *Id.* § 271(e)(4) (emphasis added). And those remedies require proof that the proposed biologic will infringe a valid patent claim. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-56 (Fed. Cir. 2003). Although Amgen cites the exclusive-remedies provision in Section 271(e)(4) as an example of how Congress goes about expressly foreclosing additional relief when it so chooses (Mot. 15), Amgen fails to recognize that the provision expressly prescribes the exclusive remedies for the very conduct of which Amgen complains – submitting a biologics application to the FDA while "fail[ing] to provide the application and information required under section [262](*l*)(2)(A)." 35 U.S.C. § 271(e)(2)(C)(ii), (4).

The BPCIA likewise expressly provides the remedy for an applicant's failure to comply with the notice of commercial marketing provision, namely, immediate patent litigation by the sponsor. 42 U.S.C. § 262(*l*)(9)(B) (cross-referencing, *inter alia*, *id.* § 262(*l*)(8)(A)).

Unsatisfied with the BPCIA's patent remedies, Amgen suggests the creation of an implied federal right of action for an injunction to enforce the BPCIA's procedural steps. Mot. 14. But Amgen's complaint asserted no such claim, instead asserting *only* California law claims (and a patent claim). A73-80. The district

court thus correctly held waived any such claim. A8 n.4.

In any event, Amgen makes no attempt to address the governing standard for creating an implied right of action. *See, e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001). Nor does it cite any evidence of affirmative congressional intent to create the remedy it seeks, as it is required to do. *Id.* at 286-87. Moreover, the BPCIA's creation of its own remedies – regardless of whether they are to Amgen's liking – defeats the effort to imply additional ones. *Id.* at 290.

Amgen's effort to use state law to enforce the BPCIA also fails, for multiple reasons. First, Sandoz did nothing "unlawful." A14-15. Second, California law provides that UCL remedies are not permitted where, as here, the underlying law "expressly provide[s]" that its remedies are exclusive. Cal. Bus. & Prof. Code § 17205; *see* 35 U.S.C. § 271(e)(4) (exclusive remedies provision). Third, the balancing of the equities required under the UCL, *Cortez v. Purolator Air Filtration Prods. Co.*, 999 P.2d 706, 717 (Cal. 2000), leads to the same conclusion because Congress itself already has balanced those equities and provided tailored remedies. Finally, Amgen cannot show conversion of an intangible property right because, *inter alia*, the BPCIA permits applicants to use Amgen's application to file their own applications. 42 U.S.C. § 262(k)(2)(A)(iii).

B. Amgen Has Not Shown A Likelihood Of Irreparable Harm

Amgen's motion should be denied for the independent reason that, as the

district court found, Amgen cannot establish irreparable harm. A2080. That finding is not clearly erroneous. *See Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009) (irreparable harm reviewed for clear error).

No infringement of a valid patent. As the district court concluded, Amgen's purported harms "are based on the as-yet unproven premise that Sandoz has infringed a valid patent belonging to Amgen." A18. "[A]ny detriment Amgen endures due to market entry of Sandoz's biosimilar product is only undue if Sandoz has infringed an Amgen patent." A2080.

Amgen asserts it is harmed not from infringement but from Sandoz's failure to "compl[y]" with the BPCIA. Mot. 16. But even if Sandoz had followed the procedures Amgen seeks to enforce, those procedures ultimately would have led at most to Amgen's being able to file a suit for patent infringement. 42 U.S.C. § 262(*l*)(6), (8)(B). Showing infringement is the *only* way the BPCIA contemplates a sponsor's keeping a biosimilar off the market. Although Amgen asserted a patent claim in its complaint (and has now had Sandoz's application for more than two months), it has not pressed for adjudication of *any* of its patent rights. As the district court found, "[i]t must, therefore, be assumed" for purposes of this case "that no such infringement has occurred." A18.

Contrary to Amgen's suggestion (Mot. 16), Sandoz's withholding of its application did not "materially prejudice[] Amgen" but in fact *enhanced* Amgen's

ability to protect any patent rights. Had the patent-exchange steps been completed, Sandoz would have had control over how many and which patents would be litigated. 42 U.S.C. § 262(*l*)(4)(B), (5). Sandoz's withholding of its application allowed Amgen to sue for patent infringement much earlier on the patents of Amgen's choosing. *Id.* § 262(*l*)(9)(C).

Nor did Sandoz's July 2014 notice of commercial marketing "den[y] Amgen the statutory period to seek a preliminary injunction." Mot. 16. Nothing prevented Amgen from seeking a preliminary injunction during the 180 days after that notice.

No price erosion. The finding that Amgen's price-erosion claim is speculative is not clearly erroneous. A2080. [redacted] Amgen's declaration and expert report state at most that Amgen "might" or "may" lower its prices upon Sandoz's entry. A479; A516. Amgen's expert admitted that any price erosion was "highly uncertain." A895-96. Sandoz's expert concluded the price-erosion claim was unfounded. A1045-48. And any price erosion could be remedied by patent-infringement damages. *Altana Pharma*, 566 F.3d at 1010-11.

No harm to goodwill. Amgen's theory of harm to goodwill is equally

unavailing. Amgen argues that *if* Sandoz's launch forces Amgen to lower prices, *if* Amgen thereafter forces removal of Sandoz's product from the market, *and if* Amgen then tries to rapidly rehabilitate Neupogen® prices, Amgen's customer relations will be harmed. But as explained above, the record does not support a significant price reduction by Amgen. Nor has Amgen tried to establish it will be able to enforce any patent rights to remove Sandoz's product from the market.

No "patent uncertainty." Amgen fashions a novel theory of harm that it calls "patent uncertainty." Amgen cites no authority suggesting that any court has ever held that this is a legally cognizable harm, let alone an irreparable one.

Amgen argues its 400-patent portfolio is somehow diminished because, without Sandoz's application, it was "impossible for Amgen to determine which of [its] patents read on the manufacture of Sandoz's biological product." Mot. 18. But this very suit belies Amgen's argument: Amgen was able to file the patent suit Congress contemplated, and having filed it, contends it has learned through discovery about additional patent claims it could assert. Sandoz's withholding its application put Amgen in a *better* position to enforce its patent rights, permitting it to sue much earlier. 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). But Amgen has now had Sandoz's application for more than two months, and yet it did not add any patent claims to the one it asserted in its original complaint.

Amgen's actions inconsistent with claimed harms. Although Amgen

argues it was harmed by not having Sandoz's application, Amgen rejected Sandoz's repeated offers to provide it. A1481-82; A1505-07. Any harm is "self-inflicted, [and] does not qualify as irreparable." *Caplan v. Fellheimer Eichen Braverman & Kaskey*, 68 F.3d 828, 839 (3d Cir. 1995). Moreover, Amgen's delays in suing and seeking a preliminary injunction negate its claimed irreparable harm. *Apple Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

Any harm outside California not relevant. The broadest injunction Amgen could obtain in this state-law suit would apply only to "conduct occurring within California." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1360 (Fed. Cir. 2013) (reversing nationwide injunction), *pet. for cert. filed*, 82 U.S.L.W. 3690 (U.S. May 15, 2014). Amgen thus must show it would be irreparably harmed if Sandoz's launch *extends to California*, as compared to being limited to the rest of the United States. Amgen has not tried to make any California-specific showing.

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

Through considerable investment, Sandoz currently enjoys a significant head start over two biosimilar filgrastim applicants expected to receive approval and launch in 2015 or early 2016. A1063. Even an injunction pending an expedited appeal thus could cause Sandoz substantial harm. A1060-68. By contrast, Amgen already has enjoyed double the 12-year exclusivity period Congress decided sufficient to reward biologics innovation. 42 U.S.C. § 262(k)(7)(A).

D. An Injunction Would Disserve The Public Interest

The public interest disfavors an injunction. The consumer interest in more affordable filgrastim would be harmed by an injunction.

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

No injunction pending appeal is warranted. But were an injunction to be issued, it must be limited to conduct in California. *Allergan*, 738 F.3d at 1358-60. Moreover, the only act for which Amgen alleges any potential harm is launching. *See, e.g.*, Mot. 16-19. Any injunction pending appeal should thus prohibit Sandoz only from launching its filgrastim product – i.e., shipping its product to customers in commercial quantities – in California, and nothing more.

Finally, Amgen agrees it must post a bond if an injunction issues. Mot. 19. Because the bond is typically a ceiling on damages from being wrongfully enjoined, courts "should err on the high side." *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000). Any injunction should be conditioned on a bond protecting Sandoz for the maximum duration an injunction could last – 410 days under Amgen's BPCIA interpretation. The harm to Sandoz from an erroneous nationwide injunction of 410 days would exceed [redacted] A1060-68. To ensure a sufficient bond, any bond should be 120% of that: [redacted]

CONCLUSION

Amgen's motion for an injunction pending appeal should be denied.

Dated: April 24, 2015

Respectfully submitted,

/s/ Deanne E. Maynard

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TABLE OF EXHIBITS

Ex.	Description	Date Filed	Pages
9	Exhibit E to Aannestad Declaration in Support of Sandoz's Opposition to Amgen's Motion for a Preliminary Injunction: Portions of Amgen's Form 10-K for 2013 Fiscal Year [Dkt. No. 74-5]	2/24/2015	A908, A915-A916
10	Exhibit G to Aannestad Declaration in Support of Sandoz's Opposition to Amgen's Motion for a Preliminary Injunction: Excerpts from Amgen's 10-Q (June 30, 2014) [Dkt. No. 74-7]	2/24/2015	A957, A960-A961
11	Rausser Declaration in Support of Sandoz's Opposition to Amgen's Motion for a Preliminary Injunction [Dkt. No. 71-9]	2/24/2015	A1005, A1060-A1068
12	Amgen's Reply in Support of its Motion for a Preliminary Injunction [Dkt. No. 83-3]	3/6/2015	A1347, A1353
13	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	A1472-A1479
14	Exhibit 2 to Wu Declaration in Support of Amgen's Preliminary Injunction Reply: Amgen's July 18, 2014 Letter [Dkt. No. 83-7]	3/6/2015	A1481-A1482
15	Exhibit 4 to Wu Declaration in Support of Amgen's Preliminary Injunction Reply: Sandoz's July 25, 2014 Letter [Dkt. No. 83-9]	3/6/2015	A1495-A1503
16	Exhibit 5 to Wu Declaration in Support of Amgen's Preliminary Injunction Reply: Amgen's Aug. 22, 2014 Letter [Dkt. No. 83-10]	3/6/2015	A1505-A1507

Ex.	Description	Date Filed	Pages
17	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	A1774-A1782
18	Attachment A to Joint Motion for Final Judgment Under Rule 54(b), Order Establishing a Schedule for 62(c) Proceedings, and Stay of Further Proceedings: Stipulation of the Parties [Dkt. No. 106-1]	3/24/2015	A1944-A1947
19	Exhibit A to Olson Declaration in Support of Sandoz's Opposition to Amgen's Motion for an Injunction Pending Appeal [Dkt No. 118-2]	3/31/2015	A2050-A2051
20	District Court's Order Denying Amgen's Motion for Injunction Pending Appeal [Dkt. No. 129]	4/15/2015	A2078-A2080

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

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.

[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.

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

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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. _____ **COMPLAINT FOR PATENT INFRINGEMENT, CONVERSION, AND UNFAIR COMPETITION (CAL. BUS. & PROF. CODE § 17200)** **JURY TRIAL DEMANDED**

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

version of Plaintiffs' product NEUPOGEN® (filgrastim) is a business practice under California state law of unfair competition.

79. Defendants have violated Cal. Bus. & Prof. Code § 17200 et seq. by seeking FDA approval for Sandoz biosimilar product under the BPCIA's abbreviated approval pathway of § 262(k), while refusing to comply with other statutory requirements of the BPCIA, specifically those that protect the interest of Amgen (the reference product sponsor). As set forth in ¶¶ 50-58 and ¶ 64 above, Defendants' receipt of FDA notification that their BLA was accepted for review triggers a set of deadlines requiring, among other things, Defendants to provide their BLA and manufacturing information to Amgen within twenty days. Defendants have unlawfully withheld from Amgen the BLA and manufacturing information that Defendants were required to disclose under 42 U.S.C. § 262(l)(2)(A).

80. In addition and as a separate and independent unlawful act, Defendants have failed and/or will imminently fail to meet its statutory obligation under 42 U.S.C. § 262(l)(8)(A) to provide notice of commercial marketing to Amgen upon or after FDA approval. Defendants' violations of the BPCIA satisfy the "unlawful" prong of § 17200.

81. By reason of, and as a direct and proximate result of, Defendants' independent acts of unlawful conduct, Plaintiffs have suffered and will continue to suffer injury to its business and property. As set forth in ¶¶ 64-76 above, Defendants' actions deprive Amgen of the BLA and manufacturing information, Defendants' patent list(s), and Defendants' detailed statements, all of which are required under the statute. Accordingly, Plaintiffs do not have sufficient information to identify patents and infringement claims; and Plaintiffs' determination of whether to file a patent infringement action and which patent claims to assert against Defendants is delayed. Further and as an independent ground, Defendants' conduct threatens to deprive Plaintiffs of the opportunity to seek a preliminary injunction in time to prevent irreparable harm, *i.e.,* after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product.

82. By reason of and as a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs have suffered economic injury to their business in the form of lost money

that was spent to monitor and respond to Defendants' acts of unfair competition. Plaintiffs will also suffer lost profits and increased costs if Defendants are permitted to commercially market the Sandoz biosimilar product without satisfying their obligations under 42 U.S.C. § 262(l). In addition, Plaintiffs will suffer loss of value of their patents as a result of Defendants' actions by forcing Plaintiffs to assert one or more of their patents (including process patents) after Defendants' commercial entry into the market as discussed in ¶ 74 above.

83. Plaintiffs are entitled to full restitution for the revenues, earnings, profits, compensation, and benefits that Plaintiffs will lose and Defendants obtain as a result of such unlawful business practices. For example, if Defendants are permitted to commercially market the Sandoz biosimilar product without providing the required 180-day notice to Amgen that would have allowed Plaintiffs to bring a motion for preliminary injunction, then Plaintiffs are entitled to restitution for the period of time between Defendants' market entry and a court's decision on Plaintiffs' motion for preliminary injunction.

84. The unlawful conduct alleged herein is continuing and there is no indication that Defendants will cease the conduct.

85. Plaintiffs are entitled to an order enjoining Defendants from commercially marketing the biosimilar product until Plaintiffs are restored to the position they would have been had Defendants met their obligations under the BPCIA, *e.g.,* providing Amgen with the BLA and manufacturing information and the equivalent information and time required under 42 U.S.C. § 262(l) for evaluating Defendants' BLA and manufacturing information so that Plaintiffs may bring a patent infringement action and/or preliminary injunction in time to prevent irreparable harm to Plaintiffs (after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product).

86. Plaintiffs are entitled to an order compelling Defendants to provide Amgen with notice of commercial marketing on or after FDA licensure of its biosimilar product, and no later than 180 days before Defendants' first commercial marketing of that product.

SECOND CAUSE OF ACTION
(CONVERSION)

87. The allegations of ¶¶ 1-86 are repeated and incorporated herein by reference.

88. The FDA is charged by Congress with promoting "the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393. The FDA pursues this mission vigorously and effectively in cooperation with applicants who market or seek to market regulated products. One important function of the FDA is to prescribe standards and measure compliance with a multistep process for approval for drugs and biological products.

89. As discussed above in ¶ 43, for reference products, FDA approval requires a demonstration that the "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). The same demonstration is not required for FDA approval of biosimilar products under the § 262(k) pathway. Rather, a biosimilar applicant under the § 262(k) pathway selects a single reference product for which it seeks FDA evaluation of its biological product as a biosimilar, and submits to the FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). In order to obtain the benefit of the BPCIA's abbreviated approval pathway for biosimilar products, § 262(k) pathway, including reliance of the reference product sponsor's prior FDA licensure, applicants must follow the BPCIA's procedures set forth in 42 U.S.C. § 262(l) regarding the disclosure of information to the reference product sponsor, the exchange of contentions, the negotiation of disputes for resolution or litigation, and notice of commercial marketing to the reference product sponsor.

90. The biological license for NEUPOGEN® (filgrastim) is owned by Amgen and exclusively licensed to AML. Plaintiffs have a legitimate claim to exclusivity in the license because of the significant effort, investment, and expertise required to obtain the license: Amgen expended considerable time, expense, and resources in research and design; Amgen conducted the appropriate tests and compiled the necessary data; Amgen prepared the BLA

for NEUPOGEN® (filgrastim) and engaged in negotiations with the FDA regarding the BLA; Amgen demonstrated to the FDA that NEUPOGEN® (filgrastim) is safe, pure, and potent; and Amgen supplemented its BLA with the FDA. In addition, Amgen's license has value because it enables biosimilar applicants, such as Defendants, to secure approval of a biological product as biosimilar NEUPOGEN® (filgrastim) without the delay, burden, or expense of demonstrating to the FDA that such biosimilar product is independently "safe, pure, and potent." Thus, the license to NEUPOGEN® (filgrastim) owned by Amgen and exclusively licensed to AML is a property right that is recognized by the law in that Plaintiffs' interest is precisely defined and capable of exclusive possession.

91. Defendants' use of the license for NEUPOGEN® (filgrastim) to obtain a governmental privilege (FDA approval to market, manufacture, import, and sell the Sandoz biosimilar product for use in the United States) for Defendants' own benefit and profit is an act of conversion. Specifically, Defendants filed a BLA for the Sandoz biosimilar product that intentionally uses Amgen's prior demonstration of the safety, purity, and potency of NEUPOGEN® (filgrastim), but without Plaintiffs' authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(l) that apply to biosimilar applicants. By filing their BLA for the Sandoz biosimilar product under the § 262(k) pathway rather than the § 262(a) pathway, Defendants seek to obtain a valuable benefit from the license for NEUPOGEN® (filgrastim). Without Amgen's efforts, the information relied on by Defendants for the safety, purity, and potency of the Sandoz biosimilar product would not exist. As a result, Defendants have converted property belonging to Plaintiffs.

92. By reason of and as a direct and proximate cause of Defendants' wrongful acts of conversion, Plaintiffs have suffered and will continue to suffer damages due to the lost value of Amgen's biological license for NEUPOGEN® (filgrastim). The detriment caused by Defendants' conversion is presumed to include the value of Plaintiffs' property at the time of conversion. *See* Cal. Civ. Code § 3336. Here, Defendants have derived and will continue to derive value from Amgen's license by seeking approval under the abbreviated § 262(k) pathway rather than the § 262(a) pathway. Had Defendants not wrongfully

converted Plaintiffs' property, Defendants would have had to incur the time and money for filing a BLA under the § 262(a) pathway, just as Amgen did to obtain its license for NEUPOGEN® (filgrastim).

93. In addition, Defendants' conduct will diminish the value of the NEUPOGEN® (filgrastim) license that is owned by Amgen and exclusively licensed to AML. If Defendants are permitted to convert Plaintiffs' property—without authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(l) that apply to biosimilar applicants—and obtain FDA approval to launch the Sandoz biosimilar product, then the biological license will no longer be exclusive. Consequently, Plaintiffs will suffer economic injury to their business in the form of lost sales, revenue, market share, and asset value.

94. By reason of and as a direct and proximate cause of Defendants' wrongful acts of conversion, Plaintiffs have suffered economic injury to their business in the form of lost money that was spent to monitor and respond to Defendants' acts of conversion. The detriment caused by Defendants' conversion is presumed to include fair compensation for the time and money properly expended by Plaintiffs in pursuit of their property. *See* Cal. Civ. Code § 3336.

95. Upon information and belief, Defendants' conversion of Plaintiffs' property is oppressive and malicious. As a result of such conduct, Plaintiffs are entitled to punitive damages. *See* California Civil Code § 3294.

96. The unlawful conduct alleged herein is continuing and there is no indication that Defendants will cease the conduct.

97. Plaintiffs are entitled to an order enjoining Defendants from continuing to seek FDA review of their § 262(k) application and/or compelling Defendants to suspend FDA review of their § 262(k) application until Defendants have obtained permission from Plaintiffs to use the NEUPOGEN® (filgrastim) license or require Defendants to restore to Amgen the benefits afforded to reference product sponsors in the statute, *e.g.,* providing Amgen with the equivalent information and time required under the statute for evaluating

Sandoz's BLA and manufacturing information, exchanging patent lists and information, negotiating patent lists, receiving Defendants' notice of commercial marketing, and bringing patent infringement actions and preliminary injunction motions.

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT)

98. The allegations of ¶¶ 1-97 are repeated and incorporated herein by reference.

99. Amgen is the owner of all right, title and interest in the '427 patent.

100. The '427 patent is titled "Combination of G-CSF With a Chemotherapeutic Agent for Stem Cell Mobilization" and was duly and legally issued by the USPTO on December 19, 2000. The inventors of the '427 patent are Matthias Baumann and Peter-Paul Ochlich. A true and correct copy of the '427 patent is attached hereto as Ex. H.

101. Upon information and belief, the purpose of Defendants' BLA for the Sandoz biosimilar product is to obtain approval to engage in the commercial marketing, manufacture, import, and sale of a biological product for treating particular diseases in the United States, one use of which is claimed in the '427 patent before the expiration of such patent. Upon information and belief, Defendants seek to market, manufacture, import, distribute, sell, and/or offer to sell the Sandoz biosimilar product for treating particular diseases in the United States immediately upon receipt of FDA approval and prior to the expiration of the '427 patent.

102. Defendants have committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) of the '427 patent by virtue of their submission of the BLA for the Sandoz biosimilar product and failure to provide the required BLA and manufacturing information to Amgen within 20 days after the FDA notified Defendants on July 7, 2014 that their BLA was accepted for review.

103. Upon information and belief, Defendants intended to violate the statute by failing to disclose the required BLA and manufacturing information to Amgen within 20 days after the FDA accepted Defendants' BLA, and Defendants chose to disclose their non-

compliance to Amgen one day after the 20 day period had expired. Defendants' actions constitute a knowing and willful infringement under 35 U.S.C. § 271(e)(2)(C)(ii).

104. Plaintiffs are entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants' from profiting by their deliberate non-compliance with the mandatory provisions of 42 U.S.C. § 262(l) by issuing an appropriately tailored injunction against the commercial manufacture, import, offer for sale, or sale of Sandoz's biosimilar product, and restoring Plaintiffs to the position in which they would have been but for such non-compliance. Defendants must restore to Amgen the benefits afforded to reference product sponsors in the statute, *e.g.,* providing Amgen with the equivalent information and time required under the statute for evaluating Sandoz's BLA and manufacturing information, exchanging patent lists and information, negotiating patent lists, receiving Defendants' notice of commercial marketing, and bringing patent infringement actions and preliminary injunction motions.

105. Plaintiffs are further entitled to injunctive relief against Defendants to prevent the commercial manufacture, use, offer to sell, or sale within the United States of the Sandoz biosimilar product. *See* 35 U.S.C. § 271(e)(4)(B).

106. As set forth in ¶¶ 72-73 above, Plaintiffs reserve 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.

EXHIBIT 4

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SANDOZ INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiff, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **SANDOZ INC.'S ANSWER TO PLAINTIFFS' COMPLAINT AND AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** **DEMAND FOR JURY TRIAL**

Defendant Sandoz Inc. ("Sandoz"), by and through its undersigned attorneys, hereby submits this Answer and Affirmative Defenses and Counterclaim ("Answer") to the Complaint for Patent Infringement, Conversion, and Unfair Competition (Cal. Bus. & Prof. Code § 17200) ("Complaint") filed by Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs" or "Amgen") dated October 24, 2014.

The Complaint improperly refers to "Sandoz" to include co-defendants Sandoz International GmbH and Sandoz GmbH, which are separate companies based in Germany and Austria respectively, have not yet been served, and whose time to respond to the Complaint has not yet begun to run. All responses below are made solely on behalf of Sandoz Inc., and no response is made to any allegation that is properly directed at any defendant other than Sandoz

October 24, 2014, to file an action that would provide the opportunity for discovery of Sandoz's biosimilar application.

75. Sandoz denies the allegations contained in Paragraph 75. Sandoz provided the required notice of commercial marketing, and complied with the BPCIA. Sandoz has appealed the November 12, 2013 decision in *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904. Sandoz's notice of commercial marketing complies with the BPCIA.

76. Sandoz denies the allegations contained in Paragraph 76. Each of Sandoz's acts was lawful. The plain language of the BPCIA (and the patent laws) allows for the situation where the biosimilar applicant does not provide the application to the originator and gives the originator the right to file a declaratory judgment action as a consequence. The plain language of the BPCIA also allows for provision of the notice of commercial marketing before FDA approval; Amgen's contrary assertion frustrates Congress' intent to permit biosimilars to launch on approval (despite ongoing patent disputes).

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

77. Sandoz incorporates its responses to Paragraphs 1 to 76 as if fully set forth herein.

78. Sandoz denies the allegations contained in Paragraph 78, denies that there is jurisdiction over a Section 17200 claim, and further states that Section 17200 does not apply to this dispute.

79. Sandoz incorporates its responses to Paragraphs 50-58 and 64, and denies the allegations contained in Paragraph 79. These time limits are not mandatory since the biosimilar applicant has the option of providing its biosimilar BLA to the reference product sponsor. See response to Paragraph 78.

80. Sandoz denies the allegations contained in Paragraph 80. See responses to Paragraphs 75 and 78.

81. Sandoz incorporates its responses to Paragraphs 56, 57, 64-76, and denies the allegations contained in Paragraph 81. Sandoz notes that Amgen has information regarding

filgrastim, its uses, and its formulation, and has elected to proceed on the '427 patent, which it is permitted to do under the BPCIA. See response to Paragraph 78.

82. Sandoz denies the allegations contained in Paragraph 82. See response to Paragraph 78.

83. Sandoz denies the allegations contained in Paragraph 83. See response to Paragraph 78.

84. Sandoz denies the allegations contained in Paragraph 84. See response to Paragraph 78.

85. Sandoz denies the allegations contained in Paragraph 85. See response to Paragraph 78.

86. Sandoz denies the allegations contained in Paragraph 86. See response to Paragraph 78.

SECOND CAUSE OF ACTION
(CONVERSION)

87. Sandoz incorporates its responses to Paragraphs 1 to 86 as if fully set forth herein.

88. Sandoz admits that one function of the FDA is to prescribe standards and measure compliance with a multistep process for approval for drugs and biological products. The remaining allegations contained in Paragraph 88 are allegations of law to which no response is required or are allegations about which Sandoz lacks knowledge or information sufficient to form a belief.

89. Sandoz denies the allegations contained in Paragraph 89. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. Sandoz incorporates its response to Paragraph 43.

90. The allegations contained in Paragraph 90 are allegations of law to which no response is required or allegations about which Sandoz lacks knowledge or information sufficient to form a belief and therefore denies.

91. Sandoz denies the allegations contained in Paragraph 91, denies that there is jurisdiction over a conversion claim, and further states that a common law claim conversion has no place in this dispute.

92. Sandoz denies the allegations contained in Paragraph 92. See response to Paragraph 91.

93. Sandoz denies the allegations contained in Paragraph 93. See response to Paragraph 91.

94. Sandoz denies the allegations contained in Paragraph 94. See response to Paragraph 91.

95. Sandoz denies the allegations contained in Paragraph 95, and reserves all rights to seek appropriate relief after discovery on the supposed information and belief for this allegation. See response to Paragraph 91.

96. Sandoz denies the allegations contained in Paragraph 96. See response to Paragraph 91.

97. Sandoz denies the allegations contained in Paragraph 97, incorporates by reference its response to Paragraph 91, and denies that there is any basis for the relief requested by Amgen. Amgen filed a Citizen Petition with the FDA on October 29, 2014. In its Citizen Petition, Amgen requested that the FDA require BLA applicants to certify that they will provide the reference product sponsor a copy of their BLA and manufacturing process information, which presumably would force BLA applicants into the patent exchange process of the BPCIA. *See* Citizen Petition at 5.[2] In its Complaint, however, Amgen alleges that the BPCIA itself mandates that a biosimilar applicant share this information with the reference product sponsor, at the risk of facing causes of action not contemplated by the BPCIA, such as state unfair competition and conversion claims. There would be no need to ask the FDA to force applicants into the patent exchange process if the BPCIA itself mandated such a result.

[2] http://www.regulations.gov/#!documentDetail;D=FDA-2014-P-1771-0001

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT)

98. Sandoz incorporates its responses to Paragraphs 1 to 97 as if fully set forth herein.

99. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 99.

100. Sandoz admits that the U.S. Patent and Trademark Office ("PTO") issued U.S. the '427 patent on December 19, 2000. Sandoz admits that Exhibit H to the Complaint appears to be a copy of the '427 patent. Sandoz admits that the face of the '427 patent lists Matthias Baumann and Peter-Paul Ochlich as inventors. Sandoz denies that the '427 patent was duly and legally issued. Sandoz denies the remaining allegations contained in Paragraph 100.

101. Sandoz admits that it is seeking approval from the FDA to sell biosimilar filgrastim in the United States as soon as legally permissible after approval of Sandoz's application. Sandoz denies the remaining allegations contained in Paragraph 101.

102. Sandoz denies the allegations contained in Paragraph 102, and notes that 35 U.S.C. § 271(e)(2)(C)(ii), which was enacted as part of the BPCIA, confirms that Amgen's reading of BPCIA subsection (l)(2)(A) is wrong.

103. Sandoz denies the allegations contained in Paragraph 103.

104. Sandoz denies the allegations contained in Paragraph 104.

105. Sandoz denies the allegations contained in Paragraph 105.

106. Sandoz incorporates its responses to Paragraphs 72-73, and denies the allegations contained in Paragraph 106.

ANSWER TO PRAYER FOR RELIEF

Sandoz denies that Plaintiffs are entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz, on information and belief, asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Lack of Personal Jurisdiction)

1. Plaintiffs do not and cannot establish that sufficient grounds exist for this Court to exercise personal jurisdiction over Sandoz in this action. For purposes of this action only, Sandoz will not challenge personal jurisdiction over Amgen's patent claims and Sandoz's counterclaim for a declaratory judgment that the BPCIA means what it says.

SECOND AFFIRMATIVE DEFENSE
(Failure to State a Claim)

2. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

3. The '427 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(No Direct Infringement)

4. Sandoz has not, does not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '427 patent.

FIFTH AFFIRMATIVE DEFENSE
(No Indirect Infringement)

5. Sandoz has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '427 patent.

SIXTH AFFIRMATIVE DEFENSE
(Preemption)

6. Plaintiffs' claims of Unfair Competition and Conversion are preempted by federal law.

SEVENTH AFFIRMATIVE DEFENSE

(No Recovery of Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

EIGHTH AFFIRMATIVE DEFENSE
(Standing)

7. Plaintiffs have not suffered injury in fact and has not lost money or property as a result of any alleged unfair competition, and therefore lacks standing under Cal. Bus. Prof. Code § 17200, *et seq*.

NINTH AFFIRMATIVE DEFENSE
(Legitimate Business Interest)

8. Plaintiffs' claims of Unfair Competition and Conversion are barred because the acts about which Plaintiffs complain were undertaken for legitimate business purposes.

TENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

9. The Complaint, and each of its purported causes of action, is barred by Plaintiffs' unclean hands.

ELEVENTH AFFIRMATIVE DEFENSE
(Laches, Waiver, Estoppel)

10. The Complaint, and each of its purported causes of action, is barred in whole or in part by the doctrines of laches, waiver, or estoppel.

TWELFTH AFFIRMATIVE DEFENSE
(Failure to Mitigate)

11. Plaintiffs have failed to mitigate the harm they claim to have sustained, if any.

OTHER AFFIRMATIVE DEFENSES RESERVED

Sandoz reserves the right to assert any other defenses that discovery may reveal.

RESERVATION OF RIGHTS

As Sandoz's investigation is ongoing and discovery has not yet taken place, Sandoz is

without sufficient information regarding the existence or non-existence of other facts or acts that would constitute a defense to Plaintiffs' claims of patent infringement or that would establish the invalidity and/or unenforceability of the '427 patent, including additional prior art or related patents. Sandoz hereby gives notice that it may assert facts or acts which tend to establish noninfringement, invalidity, unenforceability or which otherwise constitute a defense under Title 35 of the United States Code as information becomes available to Sandoz in sufficient detail to assert such a defense.

SANDOZ'S COUNTERCLAIMS

Sandoz submits these counterclaims against Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen"):

THE PARTIES

1. Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

2. As pled in Amgen's Complaint, Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business One Amgen Center Drive, Thousand Oaks, California 91320.

3. As pled in Amgen's Complaint, Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

JURISDICTION AND VENUE

4. These counterclaims are for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for determining questions of actual controversy between the parties regarding the rights and other legal relations of the parties with respect to the Biosimilars Price Competition and Innovation Act ("BPCIA").

5. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. § 262(k)-(l), 28 U.S.C. §§ 1331, 1338(a) and 1367(a), and 35 U.S.C. § 271(e)(2)(C)(ii).

6. This Court has personal jurisdiction over each of Amgen Inc. and Amgen Manufacturing, Limited at least because they have subjected themselves to the jurisdiction of this Court in this case by filing the Complaint.

7. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and by virtue of Amgen's filing of this action in this Court.

THE CONTROVERSY RELATING TO BPCIA SUBSECTION (l)(9)(C)

8. Filgrastim is a biological product used to avoid the side effects of certain forms of cancer therapy. As pled in Amgen's Complaint, the biological product license to NEUPOGEN® (filgrastim) is owned by Amgen Inc. and exclusively licensed to AML.

9. Sandoz submitted a Biologics License Application ("BLA") for filgrastim to FDA pursuant to the procedures set forth in the BPCIA, the intent of which is to provide a "biosimilars pathway balancing innovation and consumer interest." *See* Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010).

10. The BPCIA provides for FDA's reliance on the approval of the reference product sponsor's biological product to approve the biosimilar application.

11. The BPCIA provides 12 years of exclusivity to the reference product. According to Amgen's Complaint, FDA licensed NEUPOGEN® in 1991. Therefore, Amgen's exclusivity period expired in 2003. Indeed, a biosimilar filgrastim has been marketed in Europe since 2008.

12. Now, more than ten years after its exclusivity period expired, Amgen seeks to delay Sandoz's BLA application for biosimilar filgrastim, extend its exclusivity even farther beyond the 12 years contemplated by Congress in the BPCIA, and delay patient access to a more affordable version of this drug.

13. The BPCIA sets forth a procedure by which the biosimilar applicant and reference product sponsor may exchange information relating to potential patent disputes. *See* 42 U.S.C. § 262(l). These exchanges occur after the biosimilar BLA has been submitted to FDA but before any court-enforced confidentiality protections are in place. *Id.*

14. According to the timing of the procedures set forth in the BPCIA, the information exchanges necessarily occur ***after*** the biosimilar applicant has filed the biosimilar application.

15. The BPCIA clearly and cleanly separates the FDA review and approval process described in 42 U.S.C. § 262(k) from the patent exchange process described in 42 U.S.C. § 262(l). Amgen wrongly seeks to create a link between the patent information exchange provisions and the regulatory review where one does not exist in the BPCIA.

16. This separation demonstrates and implements Congress' intent that the patent exchange process is ***not*** a mandatory prerequisite to FDA review and approval of a biosimilar applicant's subsection (k) application.

17. In addition, 42 U.S.C. § 262(l)(9)(C) governs and provides the sole consequence if the biosimilar applicant elects not to share its subsection (k) application with the reference product sponsor:

> **(9) Limitation on declaratory judgment action**
>
> **(A) Subsection (k) application provided**
>
> If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).
>
> **(B) Subsequent failure to act by subsection (k) applicant**
>
> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> **(C) Subsection (k) application not provided**
>
> If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

42 U.S.C. § 262(l)(9).

18. Under the language of subsection (l)(9)(A), if the biosimilar applicant elects to share its subsection (k) application, neither party may bring an action for declaratory judgment for infringement, validity, or enforceability of a patent at issue before the biosimilar applicant provides its notice of commercial marketing.

19. However, if the biosimilar applicant elects not to share the application, then the reference product sponsor—but ***not*** the biosimilar applicant—may seek a declaration of infringement, validity, or enforceability before the biosimilar applicant provides it notice of commercial marketing. 42 U.S.C. § 262(l)(9)(C).

20. Notably, subsection (l) does not prohibit FDA from reviewing or approving the biosimilar BLA if the biosimilar applicant elects not to provide the subsection (k) application to the reference product sponsor.

21. Reading subsections (k) and (l) together, the BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor promptly after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. And even if the subsection (l)(2)(A) disclosures were "mandatory" as Amgen contends, Congress has provided the sole consequence for any violation in subsection (l)(9)(C).

22. Any other interpretation would render superfluous both BPCIA subsection (l)(9)(C) and the BPCIA conforming amendment codified at 35 U.S.C. § 271(e)(2)(C)(ii).

23. The BPCIA does not provide for relief under state statutes or common law claims, including conversion or unfair competition claims. Nor does the BPCIA provide for injunctive relief, restitution, or damages. Instead, the BPCIA and/or 35 U.S.C. § 271(e)(4) precludes and preempts any and all such claims and remedies.

24. The BPCIA demonstrates Congress' intent not to allow a reference product sponsor to delay FDA approval of a biosimilar BLA by omitting injunctive relief and by completely separating provisions related to patents (in subsection (l)) from those related to FDA approval (in subsection (k)).

25. Amgen filed a Citizen Petition with FDA on October 29, 2014. In its Citizen Petition, Amgen requested that FDA require BLA applicants to certify that they will provide the reference product sponsor a copy of their BLA and manufacturing process information. *See* Citizen Petition at 5.[3]

26. If the BPCIA mandated that applicants provide this information to reference product sponsors, there would be no need for Amgen to request FDA to take this action.

27. The BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. *See* 42 U.S.C. § 262(l)(1)(A). Sandoz has a legitimate interest in the confidentiality of its BLA. In a letter dated July 8, 2014, Sandoz offered to share its BLA with Amgen under conditions that would adequately protect the confidential and proprietary nature of the information in the BLA. Amgen, however, refused.

28. There is a substantial controversy between Amgen and Sandoz as to whether, if a biosimilar applicant does not provide the subsection (k) application to the reference product sponsor, the BPCIA allows the reference product sponsor to obtain relief other than "a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product." 42 U.S.C. § 262(l)(9)(C).

29. This disagreement between Amgen and Sandoz over the meaning of the BPCIA is at the core of this lawsuit. Interpretation of the BPCIA would resolve Amgen's claims for conversion and violation of California's Unfair Competition Law.

30. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, as evidenced by Amgen's commencement of the instant action in this Court seeking injunctive relief, restitution, and damages in contradiction of the clear statutory language of the BPCIA. Furthermore, resolution of this controversy will directly affect Sandoz's conduct with regard to its pending BLA application for biosimilar filgrastim, and will affect the timing of Sandoz's ability to commercially market biosimilar filgrastim upon FDA's grant of the BLA license.

[3] http://www.regulations.gov/#!documentDetail;D=FDA-2014-P-1771-0001

FIRST COUNTERCLAIM

(Declaratory Judgment That Subsection (k) Applicants May Elect Not to Provide the Subsection (k) Application to the Reference Product Sponsor, Subject to the Consequences Set Forth in 42 U.S.C. § 262(l)(9)(C).

31. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 30 of these Counterclaims above.

32. As codified at 42 U.S.C. § 262(l)(9)(C), the BPCIA dictates the consequences if the biosimilar applicant elects not to provide its subsection (k) application and/or manufacturing process information.

33. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (l)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

34. Sandoz is entitled to a judgment declaring that the BPCIA allows the biosimilar applicant to elect to not provide the reference product sponsor with the subsection (k) application, subject only to the consequences set forth in 42 U.S.C. § 262(l)(9)(C).

35. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SECOND COUNTERCLAIM

(Declaratory Judgment of No Injunctive Relief, Restitution, or Damages Under BPCIA)

36. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 35 of these Counterclaims above.

37. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (l)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

38. Even if the subsection (l)(2)(A) disclosures were "mandatory" as Amgen contends, the BPCIA places limits on actions available to the reference product sponsor if the biosimilar applicant elects not to provide the subsection (k) application. 42 U.S.C. § 262(l)(9)(C).

39. The BPCIA does not allow the reference product sponsor to obtain an injunction, nor does the BPCIA entitle the reference product sponsor to an award of restitution or damages if the biosimilar applicant chooses not to provide the reference product sponsor with the subsection (k) application.

40. Sandoz is entitled to a judgment declaring that Amgen cannot obtain damages, restitution, or injunctive relief, including enjoining Sandoz from continuing to seek FDA review of its subsection (k) application for filgrastim, for Sandoz electing not to provide the reference product sponsor with the subsection (k) application.

41. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

THIRD COUNTERCLAIM

(Declaratory Judgment of Exclusive Consequence Under BPCIA)

42. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 41 of these Counterclaims above.

43. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application and information related to its manufacturing process, the BPCIA removes the biosimilar applicant's right to bring a declaratory judgment action regarding patents for the biological product or for use of the biological product, while authorizing the reference product sponsor to bring such an action immediately.

44. Sandoz is entitled to a judgment declaring that the exclusive consequence of the BPCIA for a biosimilar applicant that does not choose to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process is for the applicant to lose its right to file a declaratory judgment action regarding patents for the biological

product while authorizing the reference product sponsor to bring such an action immediately, or for use of the biological product as set forth in 42 U.S.C. § 262(l)(9)(C).

45. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Improper Remedies Under BPCIA – No Unfair Competition or Conversion)

46. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 45 of these Counterclaims above.

47. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (l)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

48. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process, the BPCIA provides the reference product sponsor a right to bring an action for "a declaration of infringement, validity, or enforceability of a patent that claims the biological product or use of the biological product." 42 U.S.C. § 262(l)(9)(C).

49. The BPCIA does not allow the reference product sponsor to obtain an injunction, nor does the BPCIA entitle the reference product sponsor to an award of restitution or damages if the biosimilar applicant does not choose to provide the reference product sponsor with the subsection (k) application.

50. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process, the BPCIA removes the biosimilar applicant's right to bring a declaratory judgment action regarding patents for the biological product or for use of the biological product.

51. Sandoz is entitled to a judgment declaring that Amgen's claims for violation of California's Unfair Competition Law and conversion cannot state a claim for relief as they seek remedies that are improper, unlawful, and/or preempted—including injunction, restitution, and damages—for a biosimilar applicant's decision not to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process.

52. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

FIFTH COUNTERCLAIM

(Declaratory Judgment that Reference Product Sponsor Does Not Have Exclusive Possession or Control over the Biological Product License)

53. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 52 of these Counterclaims above.

54. The BPCIA allows FDA to rely on the approval of the reference product sponsor's biological product in reviewing and approving a (k) application.

55. By allowing FDA to rely on the reference product's license, the BPCIA makes the reference product sponsor's property right in the reference product license non-exclusive.

56. Sandoz is entitled to a judgment declaring that the BPCIA necessarily renders a reference product sponsor's property interest in a biological product license non-exclusive.

57. Sandoz is further entitled to a judgment declaring that Amgen's cause of action for conversion fails to state a claim due to the non-exclusive property right Amgen possesses in its license for NEUPOGEN®.

58. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SIXTH COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '427 Patent)

59. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 58 of these Counterclaims above.

60. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim.

61. Sandoz asserts that the manufacture, use, offer for sale, and sale of biosimilar filgrastim do not and will not infringe any valid claim of the '427 patent under 35 U.S.C. § 271(a), (b), (c), or (e)(2)(C)(ii).

62. Sandoz is entitled to a declaration that the manufacture, use, offer for sale, and sale of biosimilar filgrastim do not and will not infringe any valid claim of the '427 patent under 35 U.S.C. § 271(a), (b), (c), or (e)(2)(C)(ii).

63. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SEVENTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '427 Patent)

64. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 63 of these Counterclaims above.

65. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim.

66. Sandoz asserts that the claims of the '427 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially created bases for invalidation.

67. Sandoz is entitled to a declaration that the claims of the '427 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially created bases for invalidation.

68. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Sandoz prays that the Court enter judgment in its favor and against Plaintiffs as follows:

1. Adjudging and decreeing that Plaintiffs be denied all relief requested under its Complaint;

2. Declaring that a subsection (k) applicant may elect not to provide the subsection (k) application or information related to its manufacturing process to the reference product sponsor, subject only to the consequences set forth under 42 U.S.C. § 262(l)(9)(C);

3. Declaring that Plaintiffs cannot obtain damages, restitution, or injunctive relief, including enjoining Sandoz from continuing to seek FDA review of its subsection (k) application for filgrastim, for Sandoz electing not to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process;

4. Declaring that the exclusive consequences of the BPCIA for a biosimilar applicant that does not choose to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process is for the applicant to lose its right to file a declaratory judgment action regarding patents for the biological product or for use of the biological product, and for the reference product sponsor to be entitled to file a declaratory relief action regarding patents for the biological product or for use of the biological product, as set forth in 42 U.S.C. § 262(l)(9)(C);

5. Declaring that Plaintiffs fail to state a claim for conversion or violation of California's Business & Professions Code § 17200 *et seq.*;

6. Declaring that Plaintiffs' property interest in the biological product license is non-exclusive and that Plaintiffs cannot state a claim for conversion;

7. Declaring that Sandoz has not and will not infringe the '427 patent;

8. Declaring that the '427 patent is invalid;

9. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Sandoz or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Sandoz, or charging them either orally or in writing with infringement of any patent asserted herein against Sandoz;

10. Granting Sandoz judgment in its favor on Plaintiffs' Complaint;

11. Denying Plaintiffs' request for injunctive relief;

12. Dismissing Plaintiffs' Complaint with prejudice;

13. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Sandoz its costs and reasonable attorneys' fees; and

14. Awarding any other such relief as is just and proper.

DEMAND FOR A JURY TRIAL

Sandoz hereby demands a jury trial on all issues so triable.

Dated: November 20, 2014

MORRISON & FOERSTER LLP

By: /s/David C. Doyle
David C. Doyle

Attorneys for Defendant
SANDOZ INC.

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EXHIBIT 5

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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

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.

---

[2] *Id.*

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS

EXPERT REPORT OF TOMAS J. PHILIPSON, PHD

February 5, 2015

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.

EXHIBIT 7

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Attorneys for Defendant
SANDOZ INC.

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

DECLARATION OF ANDERS T. AANNESTAD IN SUPPORT OF SANDOZ INC.'S OPPOSITION TO AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION

Date: March 13, 2015
Time: 10:00 a.m.
Crtrm: 3, 17th Floor

The Honorable Richard Seeborg

I, Anders T. Aannestad, hereby declare as follows:

1. I am a member of the bar of the state of California and a partner with Morrison & Foerster LLP, counsel of record for Defendant Sandoz Inc. ("Sandoz") in the above-captioned action. I am admitted to practice before this Court. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently as to these facts.

2. In a letter dated July 8, 2014, Sandoz offered to share with Amgen, via an Offer for Confidential Access ("OCA"), Sandoz's 42 U.S.C. § 262(k) application for filgrastim ("Application") under conditions that would adequately protect the confidential and proprietary nature of the information in the Application. A true and correct copy of the relevant portion of the July 8, 2014, letter is attached hereto as **Exhibit A**.

3. Attached hereto as **Exhibit B** is a true and correct copy of a document produced by Amgen in this litigation that has a Bates stamp beginning with AMG-NEUP-00002697. Amgen has designated the document "Confidential."

4. Attached hereto as **Exhibit C** is a true and correct copy of excerpts from the transcript of the Robert Azelby deposition conducted on February 15, 2015. Amgen has designated the transcript "Highly Confidential."

5. Attached hereto as **Exhibit D** is a true and correct copy of excerpts from the transcript of the Tomas J. Philipson deposition conducted on February 13, 2015.

6. Attached hereto as **Exhibit E** is a true and correct copy of excerpts from Amgen's Form 10-K for the fiscal year ending December 31, 2013.

7. Attached hereto as **Exhibit F** is a true and correct copy of Exhibit 7 to the February 15, 2015, Deposition of Robert Azelby, which is an Amgen presentation entitled "Q4 '14 Earnings Call," dated January 27, 2015.

8. Attached hereto as **Exhibit G** is a true and correct copy of excerpts from Amgen's Form 10-Q, dated June 30, 2014.

9. Attached hereto as **Exhibit H** is a true and correct copy of a 2014 document entitled, "The Cost Savings Potential of Biosimilar Drugs in the United States," published by the RAND Corporation.

10. Attached hereto as **Exhibit I** is a true and correct copy of an article by Wallace Witkowski from *MarketWatch* dated January 7, 2015, entitled, "FDA panel recommends approval for first generic biotech drug."

11. Attached hereto as **Exhibit J** is a true and correct copy of excerpts from Hospira's Form 10-K for the fiscal year ending December 31, 2014.

12. Attached hereto as **Exhibit K** is a true and correct copy of excerpts from a Hospira document entitled, "Today's Investments, Tomorrow's Opportunities," dated December 5, 2013.

13. Attached hereto as **Exhibit L** is a true and correct copy of a February 17, 2015, Apotex press release entitled, "Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Filgrastim (Grastofil™)."

14. On December 16, 2014, counsel for Sandoz had a telephone conversation with counsel for Amgen regarding a proposed protective order. Counsel for Sandoz offered to produce the Application as soon as the protective order was in place.

15. Following the December 16, 2014, phone conversation, the parties continued to negotiate the terms of the protective order until the Court entered the parties' stipulated protective order on February 9, 2015. During the course of those negotiations, beginning at least as early as January 16, 2015, counsel for Sandoz repeatedly offered to produce the Application to Amgen under interim terms, pending resolution of the final protective order. Amgen's counsel refused to accept the Application under any terms proposed by Sandoz. As one example, attached hereto as **Exhibit M** is a true and correct copy of a January 16, 2015, email, sent by my colleague Grant J. Esposito, in which Mr. Esposito offered to produce the Application under interim terms. Amgen's counsel refused to accept the Application under any interim terms proposed by Sandoz.

16. On February 9, 2015, following entry of the protective order by the Court, Sandoz produced its Application to Amgen, via overnight mail to outside counsel.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 24th day of February, 2015, at San Diego, California.

/s/ Anders T. Aannestad
Anders T. Aannestad

EXHIBIT 8

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

VIDEOTAPED DEPOSITION OF TOMAS J. PHILIPSON, PH.D.

February 13, 2015

8:34 a.m.

707 Wilshire Boulevard, Suite 6000

Los Angeles, California

REPORTED BY:

Kristi Caruthers, CLR, CSR No. 10560

introduction of Granix?

A. No. And, again, I just want to qualify that because I don't think getting at the 14 percent -- how we got to the 14 percent matters for the opinions in my report. So that's why I haven't done this.

Q. Well, one of the opinions you gave is that there may be price erosion; correct?

A. Okay, but it's -- yes, it's very uncertain. I don't know which paragraph. If you can refer me to the paragraph, I can tell you.

Q. Let me ask you: Do you have an opinion on whether or not the introduction of Neupogen will result in price erosion?

A. And we have a --

MR. SANDEL: Wait. Sorry. Let me object to the form.

You might want to look at the question you asked.

BY MR. OLSON:

Q. I will. Let me ask it again.

Do you have any opinion on whether or not the introduction of Zarxio would result in price erosion for either Neupogen or Neulasta?

A. No, we have not analyzed that, and

we think it's highly uncertain. That's why it's hard to determine damages.

Q. And that's true for both Neupogen and Neulasta; correct?

A. Correct.

Q. I'm sure I said this somewhere, but I might as well make sure it's clear.

When we say Zarxio, we're talking about Sandoz' product; right?

A. Right.

Q. Do you have any opinion on whether the introduction of Neupogen will result in a change in unit sales for Neulasta?

MR. SANDEL: Object to the form.

THE DEPONENT: I've stated -- in some parts in the report I discuss that there's substitution between Neulasta and Neupogen that has occurred in the past, and, therefore, dependent on the price of Zarxio, there might be substitution between the two as well.

BY MR. OLSON:

Q. And you used the word "might" there.

You're uncertain about that; correct?

EXHIBIT 9

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-12477

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.0001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The approximate aggregate market value of voting and non-voting stock held by non-affiliates of the registrant was $74,222,900,950 as of June 30, 2013(A)

(A) Excludes 624,964 shares of common stock held by directors and executive officers at June 30, 2013. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

755,007,290

(Number of shares of common stock outstanding as of February 13, 2014)

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Proxy Statement with respect to the 2014 Annual Meeting of stockholders to be held May 15, 2014, are incorporated by reference into Part III of this annual report.

Neulasta®/NEUPOGEN®

Total Neulasta® and total NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
Neulasta® — U.S.	$ 3,499	9 %	$ 3,207	7 %	$ 3,006
Neulasta® — ROW	893	1 %	885	(6)%	946
Total Neulasta®	4,392	7 %	4,092	4 %	3,952
NEUPOGEN® — U.S.	1,169	16 %	1,007	5 %	959
NEUPOGEN® — ROW	229	(9)%	253	(16)%	301
Total NEUPOGEN®	1,398	11 %	1,260	— %	1,260
Total Neulasta®/NEUPOGEN®	$ 5,790	8 %	$ 5,352	3 %	$ 5,212

The increase in global Neulasta® sales for 2013 was driven by an increase in the average net sales price in the United States, offset partially by a decline in units. The increase in global NEUPOGEN® sales for 2013 was driven by a $155-million order from the U.S. government. Excluding the special order, U.S. sales grew only 1% and global sales declined 1%. Units declined in 2013 in both the United States and ROW.

The increase in U.S. Neulasta® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW Neulasta® sales for 2012 was due primarily to a decrease in unit demand from loss of share to biosimilars in Europe and a decrease in the average net sales price.

The increase in U.S. NEUPOGEN® sales for 2012 was driven by an increase in the average net sales price. The decrease in ROW NEUPOGEN® sales for 2012 was driven by a decrease in unit demand from loss of share to biosimilars in Europe.

Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States, which may have a material adverse impact over time on future sales of NEUPOGEN® and, to a lesser extent, Neulasta®. Our outstanding material U.S. patent for pegfilgrastim (Neulasta®) expires in 2015.

Future Neulasta®/NEUPOGEN® sales will also depend, in part, on the development of new protocols, tests and/or treatments for cancer and/or new chemotherapy treatments or alternatives to chemotherapy that may have reduced and may continue to reduce the use of chemotherapy in some patients.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
ENBREL — U.S.	$ 4,256	7%	$ 3,967	15%	$ 3,458
ENBREL — Canada	295	10%	269	11%	243
Total ENBREL	$ 4,551	7%	$ 4,236	14%	$ 3,701

The increase in ENBREL sales for 2013 was driven primarily by an increase in the average net sales price offset partially by slight unit declines.

The increase in ENBREL sales for 2012 was driven primarily by an increase in the average net sales price and, to a lesser extent, an increase in unit demand.

ENBREL also faces increased competition. See Item 1. Business — Marketing, Distribution and Selected Marketed Products — Competition.

Aranesp®

Total Aranesp® sales by geographic region were as follows (dollar amounts in millions):

	2013	Change	2012	Change	2011
Aranesp® — U.S.	$ 747	(4)%	$ 782	(21)%	$ 986
Aranesp® — ROW	1,164	(7)%	1,258	(4)%	1,317
Total Aranesp®	$ 1,911	(6)%	$ 2,040	(11)%	$ 2,303

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMGEN INC.
(Registrant)

Date: 02/24/2014

By: /S/ MICHAEL A. KELLY
Michael A. Kelly
Acting Chief Financial Officer

EXHIBIT 10

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2014

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-12477

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**95-3540776**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Amgen Center Drive, Thousand Oaks, California	**91320-1799**
(Address of principal executive offices)	(Zip Code)

(805) 447-1000
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☑	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☑

As of July 29, 2014, the registrant had 759,607,230 shares of common stock, $0.0001 par value, outstanding.

and Selected Marketed Products, Item 1A. Risk Factors and Item 7 — Product Sales in our Annual Report on Form 10-K for the year ended December 31, 2013.

Neulasta®/NEUPOGEN®

Total Neulasta®/NEUPOGEN® sales by geographic region were as follows (dollar amounts in millions):

	Three months ended June 30,			Six months ended June 30,		
	2014	2013	Change	2014	2013	Change
Neulasta®— U.S.	$ 895	$ 897	— %	$ 1,747	$ 1,724	1 %
Neulasta®— ROW	238	223	7 %	476	435	9 %
Total Neulasta®	1,133	1,120	1 %	2,223	2,159	3 %
NEUPOGEN®— U.S.	214	267	(20)%	428	509	(16)%
NEUPOGEN®— ROW	82	57	44 %	157	114	38 %
Total NEUPOGEN®	296	324	(9)%	585	623	(6)%
Total Neulasta®/NEUPOGEN®	$ 1,429	$ 1,444	(1)%	$ 2,808	$ 2,782	1 %

Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We now face competition in the United States, which may have a material adverse impact over time on future sales of NEUPOGEN® and, to a lesser extent, Neulasta®. In addition, in July 2014, Sandoz Inc. announced that the FDA has accepted its BLA(k) for a biosimilar version of filgrastim under the new biosimilar regulatory pathway. Our outstanding material U.S. patent for pegfilgrastim (Neulasta®) expires in 2015.

Neulasta® and NEUPOGEN® underlying demand was slightly impacted by short- and long-acting competition in the United States and Europe, respectively. ROW included sales in new markets as a result of reacquiring rights to filgrastim and pegfilgrastim effective January 1, 2014.

The increase in global Neulasta® sales for the three months ended June 30, 2014, was driven mainly by an increase in the average net sales price in the United States, offset partially by the positive Medicaid rebate estimate adjustment in the prior year.

The increase in global Neulasta® sales for the six months ended June 30, 2014, was driven mainly by an increase in the average net sales price in the United States, offset partially by a unit decline in the United States.

The decreases in global NEUPOGEN® sales for the three and six months ended June 30, 2014, were driven by a unit decline in the United States and by the positive Medicaid rebate estimate adjustment in the prior year, offset partially by the increased sales as a result of reacquiring rights to filgrastim in certain regions.

ENBREL

Total ENBREL sales by geographic region were as follows (dollar amounts in millions):

	Three months ended June 30,			Six months ended June 30,		
	2014	2013	Change	2014	2013	Change
ENBREL — U.S.	$ 1,171	$ 1,089	8%	$ 2,095	$ 2,063	2%
ENBREL — Canada	72	68	6%	136	133	2%
Total ENBREL	$ 1,243	$ 1,157	7%	$ 2,231	$ 2,196	2%

The increase in ENBREL sales for the three months ended June 30, 2014, was driven primarily by an increase in the average net sales price. There was a slight inventory build at the end of the second quarter of 2014 that we expect will be drawn down in the third quarter of 2014.

The increase in ENBREL sales for the six months ended June 30, 2014, was driven primarily by an increase in the average net sales price, offset partially by a decline in unit demand.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Amgen Inc.
(Registrant)

Date: August 5, 2014

By: /S/ DAVID W. MELINE
David W. Meline
Executive Vice President and Chief Financial Officer

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, AND SANDOZ GMBH, Defendants.	Case 3:14-cv-04741-RS

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

DECLARATION OF GORDON RAUSSER, PH.D. IN OPPOSTION TO AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION

CONFIDENTIAL MATERIAL REDACTED

VIII. OPINION #4: SANDOZ WOULD SUSTAIN SIGNIFICANT ECONOMIC LOSSES IF ZARXIO'S LAUNCH WERE DELAYED

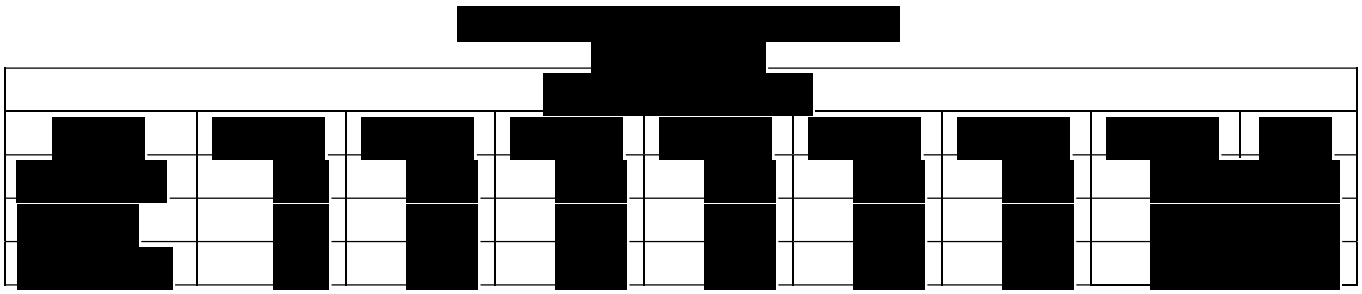
84. Dr. Philipson has failed meaningfully to explore the losses that would be sustained by Sandoz if Zarxio's launch were enjoined for up to 410 days. In undertaking any such analysis, it is important to remember that Zarxio is expected to be the first biosimilar drug approved by the FDA, that Sandoz has had to undertake pioneering work to accomplish that objective, and that Sandoz has invested based on this expectation of being the first to market. If the product launch is enjoined, much of that investment will be left idle or may be permanently lost. Further, numerous drug manufacturers are pursuing biosimilar filgrastim products and there is the distinct possibility, if an injunction issues, that one or more of these competing products may precede Zarxio to market, or launch at the same time as Zarxio. This disruption in the order of entry would have dramatic financial implications for Sandoz, as Zarxio would enter a very different, more crowded and competitive market. In order to estimate the amount of a bond necessary to assure such damages are recoverable, an ex ante analysis must be performed, but Dr. Philipson has failed to do so.

A. Sandoz's Lost Profits Due to a Delay of 410 Days.

85. To evaluate Sandoz's likely losses, I studied the experience of biosimilar filgrastim products in Europe and the line-up of companies currently pursuing such products in the U.S. [redacted]

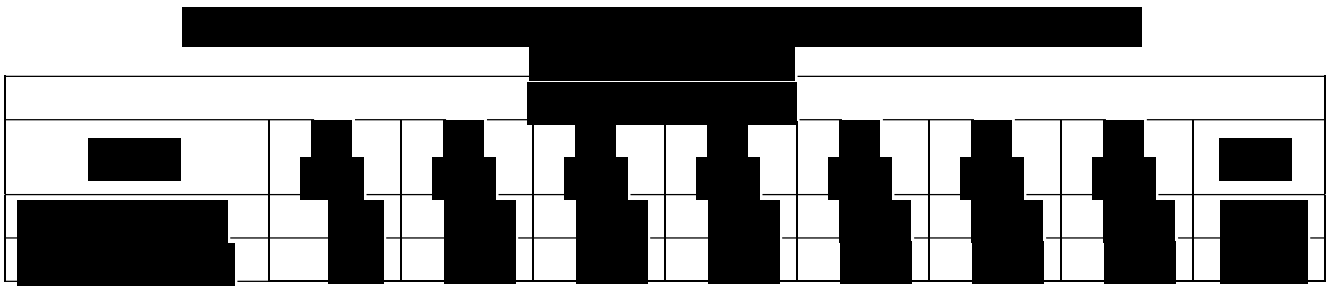
CONFIDENTIAL MATERIAL REDACTED

[redacted]



86. I find that these projections are realistic and supportable given the available market data. I note that Dr. Philipson neither looked at any projections nor inquired regarding the expected time frame in which other biosimilars would enter the market. This failing is a fundamental error in any analysis of how a market may develop over time, and how any entrant would be affected by a change in the date at which it can launch its product.

87. I prepared my own set of Zarxio estimates for 2015 and 2016 based upon a similar scenario in which there would be no injunction issued and Sandoz would preserve its status as the first biosimilar entrant. [redacted]



88. Some of the basic features employed in my model are described below.

a. I project that the U.S. short-acting filgrastim market will decline by approximately 5% per year from 2015 through 2020. This is consistent with the historical trend in the market, which has declined an average of 5% per year since 2009.[127]

b. Based upon public announcements, I project that at least two companies will launch biosimilar short-acting filgrastim in addition to Zarxio: Apotex and Hospira. Hospira has already launched a biosimilar version of Neupogen in Europe and Australia, and the FDA has accepted for filing Apotex's application for approval of a biosimilar version of Neupogen.[128]

c. I expect that each biosimilar's share of the filgrastim market will be influenced by order-of-entry effects; that is, early entrants will maintain higher market shares than later entrants even in the long term. This is consistent with academic literature on pharmaceutical markets.[129]

---

[127] IMS National Sales Perspective Sales Volume Data, "Eaches Volume_Amgen_Teva_NSP_1_Feb-09-2015.xlsx."

[128] Hospira, "Our History." Accessed February 19, 2015. http://www.hospira.com/en/about_hospira/our_history/; PR Newswire, "Apotex Announces FDA Has Accepted For Filing its Biosimilar Application for Filgrastim," February 17, 2015. Accessed February 18, 2015. http://www.prnewswire.com/news-releases/apotex-announces-fda-has-accepted-for-filing-its-biosimilar-application-for-filgrastim-grastofil-292257431.html.

[129] "For consumer packaged goods and prescription anti-ulcer drugs, the entrant's forecasted market share divided by the first entrant's market share roughly equals one divided by the square root of order of market entry". Kalyanaram, Gurumurthy, Robinson, William T. and Glen L. Urban, "Order of Market Entry: Established Empirical Generalizations, Emerging Empirical Generalizations, and Future Research," *Marketing Science* 14(3): G212-G221, at p. G215. This is based in part on a study of the antiulcer market by Berndt et al: Berndt, Ernst R., Bui, Linda, Reiley, David, and Glen Urban, "The Roles of Marketing, Product Quality and Price Competition in the Growth and Composition of the U.S. Anti-Ulcer Drug Industry," *National Bureau of Economic Research*, Working Paper #4904 (1994).

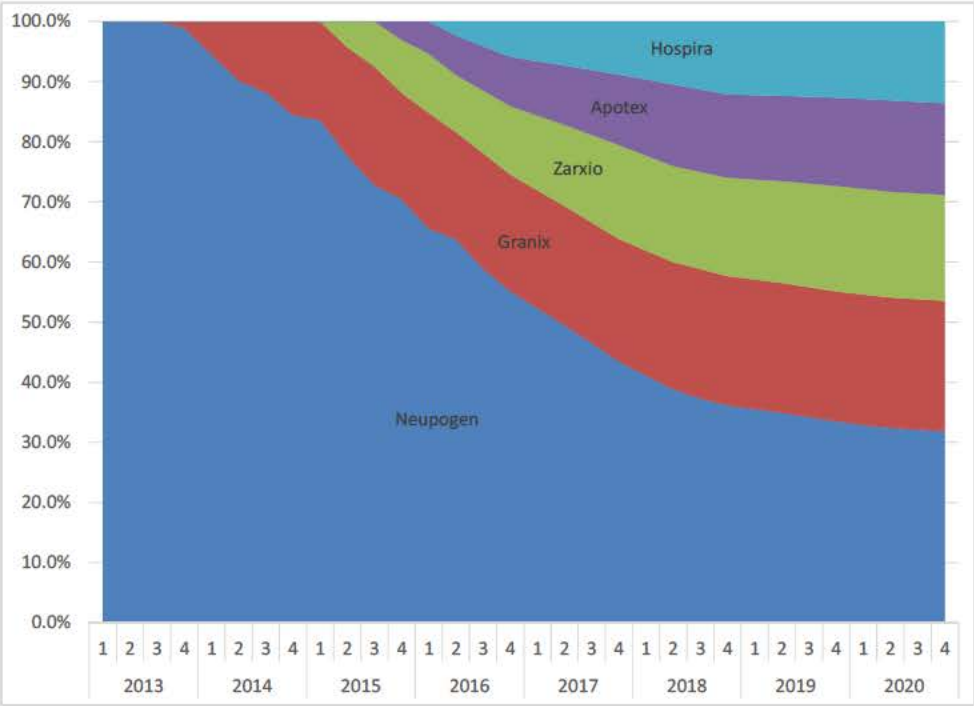
d. I assumed that price discounts will increase as the number of biosimilar competitors grows. In my model, I have evaluated these price discounts off of the contemporaneous price for Neupogen.

e. [redacted]

f. [redacted] This is consistent with my research and consulting experience with pharmaceutical companies.

89. In order to estimate the long term effect on Sandoz's profits, I have extended my projection through 2020 and have accounted for the probable entry of other biosimilar competitors. In this extended base case (which still includes no injunction) I have estimated that Zarxio will enter in April 2015, Apotex will enter in the fourth quarter of 2015, and Hospira will enter in the second quarter of 2016. At that point in time (assuming neither Apotex nor Hospira is enjoined), the short-acting filgrastim market in the U.S. would consist of five products offered by Amgen (Neupogen), Teva (Granix), Sandoz (Zarxio), Apotex, and Hospira. Figure 22 shows the projected share of total volume for each product. Note that later entrants never achieve the same results as earlier entrants, which is to be expected.

Figure 22. Projected Share of U.S. Short-Acting Filgrastim Volume



90. I have also estimated the price Sandoz would be able to command in each period and compared it to the price projected for Neupogen. These results are graphed in Figure 23 below.

CONFIDENTIAL MATERIAL REDACTED

[redacted]

91. [redacted]

92. This outcome changes dramatically if an injunction is issued. To quantify this difference, I have assumed an injunction of 410 days (what Dr. Philipson asserts as the "Restricted Period"). If an injunction of this duration were to issue in mid-March, 2015, it would continue into the second quarter of 2016. At that point, Zarxio would become the fifth out of five products in the market, having been preceded by the biosimilar launches of Apotex and Hospira. [redacted]

93. [redacted]

B. Inventory losses.

94. [redacted] It is reasonable that Sandoz would have prepared for its early 2015 launch by building an inventory sufficient for several months of sales and this amount appears consistent with Sandoz's internal projections for sales.

C. Losses from unrecoverable planned expenses.

95. Sandoz has already made preparations to launch in March or April 2015. A delay of the launch until April 2016 would force Sandoz to put those preparations on hold, which would cause Sandoz to suffer additional economic losses. [redacted] If the launch were delayed, a large portion of those planned expenses would be neither avoidable nor recoverable. The unrecoverable costs would be particularly high because this is the first biosimilar to be launched in the United States and a significant portion of Sandoz's U.S. operations are currently dedicated to Zarxio. If the launch were delayed, Sandoz would not be able simply to move these people

[130] Interview with Alex Thole and other representatives of Sandoz, February 17, 2015.
[131] Interview with Alex Thole and other representatives of Sandoz, February 17, 2015.

and resources to another biosimilar product. Some specific examples of Sandoz's lost investments are described below.

96. [redacted]

97. [redacted]

[132] Interview with Alex Thole and other representatives of Sandoz, February 17, 2015.
[133] Interview with Alex Thole and other representatives of Sandoz, February 17, 2015.

CONFIDENTIAL MATERIAL REDACTED

[redacted]

98. [redacted]

D. Bond amount.

99. [redacted] There is, however, a degree of uncertainty built into all of these analyses and it is my understanding that the bond sets an upper limit on Sandoz's recovery if an error in the issuance of the injunction has caused Sandoz to suffer losses. This counsels in favor of a bond that exceeds the amount stated above, but I have not been asked to provide an opinion on how much more would be adequate to account for the risk to Sandoz of higher losses.

134 [redacted]

EXHIBIT 12

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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'S REPLY IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION** **UNREDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED** Date: March 13, 2015 Time: 10:00 AM Location: Courtroom 3, 17th Floor

information, refuse to give appropriate notice of marketing, and Amgen could have asserted dozens or hundreds of only-potentially-applicable patents, without relevant knowledge for some or even all of them, and the parties and the Court would have to figure out in discovery which patents actually apply. The law does not contemplate or countenance Sandoz's sue-first-and-sort-out-the-patents-later approach.

Sandoz tries to mute this striking comparison by suggesting that Amgen has no relevant patents because the material patents on the filgrastim molecule itself have expired. (*See, e.g.*, Sandoz Br. at 2.) The unrebutted record evidence refutes this. Amgen's chief intellectual property officer testified that Amgen has many patents that "might be relevant to the recombinant production and purification of filgrastim." (Dkt. No. 56-1, Watt Decl. ¶¶ 3-5.) Without Sandoz's BLA and manufacturing information, however, Amgen could not "assess which of its patents may apply in order to assert those patents against Sandoz." (*Id.* ¶ 6.) Sandoz has not submitted any testimony or evidence to contradict Mr. Watt. Indeed, Sandoz noticed his deposition then canceled it. (*See* Wu Decl. ¶ 13.)

And the need for the BLA and manufacturing information has been only further demonstrated since Amgen filed this motion. Sandoz has finally produced its BLA, though not the twenty-nine amendments to its BLA listed in today's FDA approval letter and not the statutorily-mandated manufacturing information. *See* 42 U.S.C. § 262(l)(2)(A). From the limited information Sandoz has produced thus far, Amgen has identified at least two purification patents that appear to apply to Sandoz's method of manufacture, U.S. Patent No. 7,781,395 and U.S. Patent No. 8,273,707. Given all the information Sandoz has yet to produce, however, Amgen still does not know which other of its many patents may apply.

To be clear, the issue before the Court is not whether Amgen has patents that could have been listed in a subsection (l)(3)(A) exchange, but whether the BPCIA provisions that Sandoz has disregarded are mandatory. That said, the notion that Amgen must not have any patents to assert is wrong. Equally wrong is Sandoz's argument that Amgen should have just blindly sued on dozens or hundreds of patents in July, without regard to other statutory obligations that inform patent-infringement actions, wasting the Court's and the parties' time and resources.

EXHIBIT 13

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 … .").

SANDOZ'S OFFER OF CONFIDENTIAL ACCESS

Subject to the restrictions detailed below, Sandoz hereby provides this Offer of Confidential Access ("Offer") to Amgen, Inc. ("Amgen"), the BLA holder for Neupogen® (filgrastim), for the sole purpose of determining whether to bring an action under 35 U.S.C. §271(a), (b), and/or (c) asserting one or more of its patents ("Amgen's Patent(s)") with respect to the product(s) described in Sandoz's biosimilar application for recombinant human Granulocyte-Colony Stimulating Factor or filgrastim, 30 Mio. Units, 48 Mio. Units, (hereafter, "Sandoz's filgrastim Products")

1. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. Materials Accessible by Authorized Evaluators:

(i) A copy of Sandoz's Biosimilar Application ("Sandoz's Confidential Information") will be provided solely for use by Authorized Evaluators for the sole and limited purposes provided herein.

(ii) A copy of Sandoz's Biosimilar Application redacted to remove information of no relevance to any issue of patent infringement ("Sandoz's Limited Confidential Information") will be provided for use of up to two in-house counsel for Amgen as described in 1.B.(iii) for the sole and limited purposes provided herein. The restrictions as to the use and disposition of Sandoz's Confidential Information shall also apply to Sandoz's Limited Confidential Information.

(iii) Sandoz's Confidential Information and Sandoz's Limited Confidential Information shall be collectively referred to as "Sandoz's Confidential Material."

B. Persons Entitled to Access: Persons entitled to access ("Authorized Evaluators") under this Offer of Confidential Access are restricted to:

(i) no more than two outside counsel who have been engaged by Amgen to represent it and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who assist such counsel;

(ii) no more than four independent consultants and experts assisting in the evaluation of possible infringement of Amgen's Patent(s) who are not employed by Amgen, and who agree to be bound by the undertaking in Exhibit A; and

(iii) four in-house counsel for Amgen, and any assistants under the control of such in-house counsel, where two of the in-house counsel shall have access to Sandoz's Confidential Information and two of the in-house counsel shall have access to Sandoz's Limited Confidential Information,

provided that all such persons contemplated by sections (i)-(iii) in this paragraph 1.B are identified to Sandoz in writing and Sandoz is given three days' notice before disclosure to object to such disclosure for good cause, and such persons in sections (i)-(iii) are not involved, formally or informally, in the prosecution of any patent(s) or patent application(s) relevant or related to any Granulocyte-Colony Stimulating Factor and/or any communications or petitions submitted to the FDA relevant to or relating to any Granulocyte-Colony Stimulating Factor including, but not limited to, the preparation of any Citizen Petitions.

Prior to Amgen giving, showing, disclosing, making available or communicating information to any independent consultants and experts under paragraph 1.B.(ii), Amgen shall serve a written notice on Sandoz, identifying the consultant or expert and the expert's or consultant's business address, business telephone numbers, present employer and position, consulting activities (including but not limited to litigation consulting) and job history for the past three years, and providing the most recent curriculum vitae or resume of the expert or consultant, and include with such notice, a copy of the Acknowledgment of Protective Order, in the form shown in Exhibit A, which is attached hereto, signed by the expert or consultant and including all the information to be completed therein.

Each "Authorized Evaluator" shall have entered into a written agreement with Amgen that contains confidentiality and non-use obligations governing such disclosure which are at least as restrictive as those contained herein.

C. Use of Sandoz's Confidential Material:

(1) Sandoz's Confidential Material and all information contained therein or derived therefrom may be used for the sole and limited purpose of evaluating possible infringement of Amgen's Patent(s) and for no other purpose. By accepting this Offer of Confidential Access, Amgen specifically agrees that it will not use any information from Sandoz's Confidential Material or derived from Sandoz's Confidential Material in the preparation, prosecution, or maintenance of any patent application or in any documents or communications with the FDA or in preparation thereof or in research or development activities.

(2) Authorized Evaluators shall not disclose any information contained in or derived from Sandoz's Confidential Material or any notes, analyses, studies or other documents to the extent that they reflect any information in Sandoz's Confidential Material, to any person other than persons entitled to access under subsection 1.A.

(3) Notwithstanding the provisions of subsections 1.C.(1) and 1.C.(2) above, Authorized Evaluators shall be permitted to advise Amgen whether to bring suit alleging infringement of Amgen's Patent(s); provided,

however, that the information in Sandoz's Confidential Material is not thereby disclosed.

D. Disposition of the Information in Sandoz's Confidential Material:

(1) Amgen agrees that if it does not file suit against Sandoz alleging infringement of one or more of Amgen Patent(s) within 60 days after receiving Sandoz's Confidential Material, Amgen shall cause Authorized Evaluators within thirty (30) days after the expiration of said period, to destroy or return to Sandoz the entirety of Sandoz's Confidential Material provided, and all notes, analyses, studies or other documents to the extent that they contain information reflecting Sandoz's Confidential Material, and Amgen shall notify Sandoz in writing within a reasonable time that this has been done.

(2) Amgen agrees that if Amgen files suit against Sandoz alleging infringement of one or more of Amgen's Patents within 60 days after receiving Sandoz's Confidential Material:

(a) While the litigation is pending, Sandoz's Confidential Material provided and all notes, analyses, studies or other documents to the extent that they contain information reflecting Sandoz's Confidential Material, shall be treated as information under the highest level of confidentiality under any protective order entered in the action brought against Sandoz. Until such a protective order is entered, subsections 1.C.(1) and 1.C.(2) above continue to apply.

(b) Amgen shall cause Authorized Evaluators to destroy or return to Sandoz Sandoz's Confidential Material provided and all notes, analyses, studies or other documents prepared to the extent that they contain information in Sandoz's Confidential Material, within thirty (30) days after the final determination of the action brought against Sandoz.

E. Accidental Disclosure: Should information contained in or derived from Sandoz's Confidential Material, including any notes, analyses, studies or other documents to the extent that they reflect any information therein, be disclosed, inadvertently or otherwise, Amgen shall, at its earliest reasonable opportunity, by and through Authorized Evaluators, contact Sandoz and identify:

(1) what has been disclosed;
(2) the individuals to whom such information has been disclosed; and
(3) steps taken by Amgen and Authorized Evaluators to ensure the information in and/or derived from Sandoz's Confidential Material is not further disseminated.

F. No Admission, Representation, Commitment, License Or Waiver Nothing in this Offer shall be construed as an admission by Sandoz regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or

admission by Sandoz with respect to the competency, relevance, or materiality of any information, document or thing. The fact that Sandoz provides information pursuant to this Offer shall not be construed as an admission by Sandoz that such information is relevant to the disposition of any issue relating to any alleged infringement of any Amgen Patent(s), or to the validity or enforceability of any such patent(s). Nothing contained herein shall be construed as a grant of any license or other right to use the information in Sandoz's Confidential Material except for the purpose expressly stated herein.

2. Amgen acknowledges that the violation of any provision of this Offer will cause irreparable injury to Sandoz, and that an adequate legal remedy does not exist. Sandoz, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to attempt to correct any violation and to prohibit Amgen from further violating the terms of this Offer. Amgen agrees that in such an action Sandoz is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees and court costs. Amgen further agrees that it will be liable for any violation of this Offer by an Authorized Evaluator, or of any separate confidentiality agreement between Amgen and Authorized Evaluator, as if the violation were committed by Amgen.

3. Amgen agrees that any claims for breach of this Agreement may be brought in courts located in the State of New Jersey and consents to the jurisdiction and venue of such courts for any such claims.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional or unenforceable, the remaining provisions shall continue in full force and effect.

5. When accepted by Amgen, this document shall constitute the entire agreement of the parties with respect to the subject matter herein and may not be amended or modified except in writing executed by all of the parties.

6. Amgen may request access to Sandoz's Confidential Material by executing one copy of this Offer where indicated and returning the executed copy, within a reasonable time before **July 25, 2014**, to Robin D. Adelstein, VP, Legal, IP & Compliance NA Gen Counsel, Sandoz Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Thereupon, the terms contained in this document shall be considered an enforceable contract between Sandoz and Amgen.

SANDOZ INC.
By its authorized agent:

_____

ACCEPTED AND AGREED:

Amgen, Inc.
By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Company: _____

Date: _____

EXHIBIT A

ACKNOWLEDGEMENT OF PROTECTIVE ORDER

I, _____, state that:

My business address is _____

_____.

My present employer and job description are _____

_____.

I have read and reviewed in its entirety the annexed Offer of Confidential Access ("Offer") that has been signed and entered in this matter.

I have attached a listing of my consulting activities, including but not limited to litigation activities, and job history for the past three years, and have provided my most recent curriculum vitae or resume. With respect to litigation activities, I have identified the case by case number, party and jurisdiction, have identified the party that retained my services, and identified whether or not I testified by deposition and/or live.

I hereby agree to be bound by and comply with the terms of the Offer, and not to disseminate or disclose any information subject to the Offer that I review or about which I am told, to any person, entity, party, or agency for any reason, except in accordance with the terms of the Offer.

I understand that contempt sanctions may be entered for violation of this Offer and further agree to submit to the jurisdiction of any Court for the purposes of enforcement of the terms of this Offer.

DATED this _____ day of _____, 2014.

_____

(Signature)

_____

(Typed or Printed Name)

EXHIBIT 14

Wendy A. Whiteford
Vice President Law
Intellectual Property and Litigation

AMGEN

Amgen
One Amgen Center Drive
Mail Stop 28-2-C
Thousand Oaks, CA 91320-1799
Direct Dial 805 447 1008
Fax 805 447 1090
E-mail wendy@amgen.com

July 18, 2014

Sent Via UPS

Robin Adelstein
Vice President, Legal IP & Compliance
General Counsel, N.A.
Sandoz, Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540

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

Dear Ms. Adelstein:

I write in response to your letter of July 8, 2014 notifying Amgen that Sandoz has filed an application for FDA approval of a filgrastim biosimilar product for which Amgen's NEUPOGEN® (filgrastim) is the reference product. Included with your letter was Sandoz's Offer of Confidential Access ("OCA"). By your letter and the OCA, Amgen understands that Sandoz is proposing an agreement to conduct an exchange of information independent of, as opposed to satisfying, the provisions of 42 USC 262(l). I would welcome the opportunity to confirm this with you as this is fundamental to Amgen's consideration of Sandoz's OCA. Amgen does not accept Sandoz's statement that your July 8th letter is confidential and should not be disclosed to others. If you would like to discuss this as well, I am available early next week.

I note that Sandoz did not elect to disclose to Amgen whether or not the FDA has yet accepted Sandoz's filgrastim BLA for review. I also note that a biosimilar applicant has only 20 days from acceptance to provide the reference product sponsor with the subsection (k) application and information that describes the process(es) used to manufacture the product that is the subject of the subsection (k) application. Amgen is prepared to receive, without delay, the required disclosures from Sandoz subject to the confidentiality provisions set forth in 42 USC 262(l)(1)(A) .

While the confidentiality provisions of the statute may not be ideal, with cooperation between the parties I am confident that we can meet our respective deadlines and provide meaningful protection for one another's information. To the extent that the statute is silent, Amgen is certainly amenable to negotiating further terms of confidentiality, either prior to or concurrent with Sandoz's required disclosures, as time permits. When Sandoz is ready to provide Amgen with the required disclosures, please contact me so that I may assist you in directing Sandoz's confidential information to the appropriate attorneys.

Sincerely,

Wendy Whiteford

Wendy A. Whiteford
Vice President Law

WAW/sp

EXHIBIT 15

SANDOZ
a Novartis company

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 25, 2014

Amgen, Inc.
Attn: Wendy A. Whiteford
Vice Present Law
Intellectual Property and Litigation
One Amgen Center Drive
Mail Stop 28-2-C
Thousand Oaks, CA 91320-1799

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

Dear Ms. Whiteford:

I write in response to your July 18, 2014 letter, and to inform Amgen that Sandoz received notification from the FDA on July 7, 2014, that its 351(k) application for FDA approval of a biosimilar filgrastim product (recombinant human Granulocyte-Colony Stimulating Factor, 30 Mio. Units, 48 Mio. Units), for which Amgen's NEUPOGEN® is the reference product, has been accepted by the FDA for review.

As you recognize in your letter, under the patent information exchange provisions of the BPCIA, the biosimilar applicant may provide a copy of the biosimilar application (and in some cases other information) to the reference product sponsor not later than 20 days after FDA notifies the applicant that its application has been accepted for review. 42 U.S.C. §262(l)(2). This step initiates an exchange of patent lists and descriptions, as well as patent resolution negotiations. 42 U.S.C. §§262(l)(2)-(5). Any resulting infringement action would occur thereafter. 42 U.S.C. §§262(l)(4)-(8).

However, the BPCIA also expressly covers the situation where the biosimilar applicant does not provide its biosimilar application to the reference product sponsor within 20 days of FDA notification of acceptance. 42 U.S.C. §262(l)(9)(C). In such a circumstance, the reference product sponsor may bring a declaratory judgment action over a patent claiming "the biological product or a use of the biological product" and thus obtain access to the biosimilar application. *Id.* Should the biosimilar applicant's product information be disclosed to the reference product sponsor as a consequence of that declaratory judgment action, it would only be disclosed under the protection of a court

order, which I think Amgen would agree offers an appriopriate level of protection to exchanged confidential information.

We appreciate that Amgen understands the need to meaningfully protect each company's proprietary information. As acknowledged in your July 18 letter, the BPCIA confidentiality provisions are less than ideal. In particular, there are no specific penalties under the BPCIA if Sandoz's confidential information is improperly used or disclosed.

After very careful consideration of the BPCIA confidentiality and information exchange provisions, Sandoz has chosen to use the flexibilities contained therein and has opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance. We acknowledge that under the BPCIA, this means Amgen is entitled to start a declaratory judgment action under 42 U.S.C. §262(l)(9)(C) to require Sandoz to disclose our biosimilar application. Sandoz is of the view that, if Amgen will not agree to an appropriate OCA, disclosure to Amgen only under a court order is the best option to ensure our confidential information is adequately protected.

However, we continue to hope to resolve any potential dispute with Amgen well before our launch, which would not be possible if we followed the BPCIA patent information exchange and negotiation process.

To that end, our attached Offer of Confidential Access ("Second OCA") will permit Amgen to conduct a thorough review of Sandoz's biosimilar application well before our anticipated launch, while also providing meaningful protection for Sandoz's highly-sensitive information. It contains the same enhancements as our July 8, 2014 OCA, including access by more Amgen people (10) and people having varying disciplines (in-house counsel, outside counsel, and independent consultants) while providing remedies for breach of the OCA (injunction; costs for enforcement). Like Amgen, we are open to discussing the terms of this Second OCA.

In answer to your July 18 query regarding the OCA, the OCA is intended to allow our companies to resolve any patent disputes prior to our planned launch of our filgrastim product. If Amgen is of the view that such an exchange of confidential information must be designated as an exchange under 42 U.S.C. §262(l) of the BPCIA in order for our two companies to progress with resolving any potential patent issues prior to Sandoz's launch, we'd like to understand your reasoning as we are not sure this is necessary for our companies to timely resolve any potential patent disputes. We remain prepared to provide our biosimilar application to Amgen under an OCA. If Amgen would like to see Sandoz's biosimilar application prior to Sandoz's anticipated launch, please sign the attached Second OCA and return it to Sandoz before **August 25, 2014**.

Please be advised that Sandoz considers the information in this letter to be confidential. It should not be disclosed to others.[1]

---

[1] We understand that Amgen has disagreed that our previous letter was confidential. Both letters contain information that is not available to the public, and should not be disclosed.

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

Very truly yours,

Robin Adelstein

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

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

cc:

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

SANDOZ'S SECOND OFFER OF CONFIDENTIAL ACCESS

Subject to the restrictions detailed below, Sandoz hereby provides this Offer of Confidential Access ("Offer") to Amgen, Inc. ("Amgen"), the BLA holder for Neupogen® (filgrastim), for the sole purpose of determining whether to bring a legal action asserting one or more of its patents ("Amgen's Patent(s)") with respect to the product(s) described in Sandoz's biosimilar application for recombinant human Granulocyte-Colony Stimulating Factor or filgrastim, 30 Mio. Units, 48 Mio. Units, (hereafter, "Sandoz's filgrastim Products")

1. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. Materials Accessible by Authorized Evaluators:

(i) A copy of Sandoz's Biosimilar Application ("Sandoz's Confidential Information") will be provided solely for use by Authorized Evaluators for the sole and limited purposes provided herein.

(ii) A copy of Sandoz's Biosimilar Application redacted to remove information of no relevance to any issue of patent infringement ("Sandoz's Limited Confidential Information") will be provided for use of up to two in-house counsel for Amgen as described in B(iii) for the sole and limited purposes provided herein. The restrictions as to the use and disposition of Sandoz's Confidential Information shall also apply to Sandoz's Limited Confidential Information.

(iii) Sandoz's Confidential Information and Sandoz's Limited Confidential Information shall be collectively referred to as "Sandoz's Confidential Material."

B. Persons Entitled to Access: Persons entitled to access ("Authorized Evaluators") under this Offer of Confidential Access are restricted to:

(i) no more than two outside counsel who have been engaged by Amgen to represent it and the staff of such outside counsel, including paralegal, secretarial and clerical personnel who assist such counsel;

(ii) no more than four independent consultants and experts assisting in the evaluation of possible infringement of Amgen's Patent(s) who are not employed by Amgen, and who agree to be bound by the undertaking in Exhibit A; and

(iii) four in-house counsel for Amgen, and any assistants under the control of such in-house counsel, where two of the in-house counsel shall have access to Sandoz's Confidential Information and two of the in-house counsel shall have access to Sandoz's Limited Confidential Information,

provided that all such persons contemplated by sections (i)-(iii) in this paragraph B are identified to Sandoz in writing and Sandoz is given three days' notice before disclosure to object to such disclosure for good cause, and such persons in sections (i)-(iii) are not involved, formally or informally, in the prosecution of any patent(s) or patent application(s) relevant or related to any Granulocyte-Colony Stimulating Factor and/or any communications or petitions submitted to the FDA relevant to or relating to any Granulocyte-Colony Stimulating Factor including, but not limited to, the preparation of any Citizen Petitions.

Prior to Amgen giving, showing, disclosing, making available or communicating information to any independent consultants and experts under paragraph 1.B.(ii), Amgen shall serve a written notice on Sandoz, identifying the consultant or expert and the expert's or consultant's business address, business telephone numbers, present employer and position, consulting activities (including but not limited to litigation consulting) and job history for the past three years, and providing the most recent curriculum vitae or resume of the expert or consultant, and include with such notice, a copy of the Acknowledgment of Protective Order, in the form shown in Exhibit A, which is attached hereto, signed by the expert or consultant and including all the information to be completed therein.

Each "Authorized Evaluator" shall have entered into a written agreement with Amgen that contains confidentiality and non-use obligations governing such disclosure which are at least as restrictive as those contained herein.

C. Use of Sandoz's Confidential Material:

(1) Sandoz's Confidential Material and all information contained therein or derived therefrom may be used for the sole and limited purpose of evaluating possible infringement of Amgen's Patent(s) and for no other purpose. By accepting this Offer of Confidential Access, Amgen specifically agrees that it will not use any information from Sandoz's Confidential Material or derived from Sandoz's Confidential Material in the preparation, prosecution, or maintenance of any patent application or in any documents or communications with the FDA or in preparation thereof or in research or development activities.

(2) Authorized Evaluators shall not disclose any information contained in or derived from Sandoz's Confidential Material or any notes, analyses, studies or other documents to the extent that they reflect any information in Sandoz's Confidential Material, to any person other than persons entitled to access under subsection 1.A.

(3) Notwithstanding the provisions of subsections 1.C.(1) and 1.C.(2) above, Authorized Evaluators shall be permitted to advise Amgen whether to bring suit alleging infringement of Amgen's Patent(s); provided,

however, that the information in Sandoz's Confidential Material is not thereby disclosed.

D. Disposition of the Information in Sandoz's Confidential Material:

(1) Amgen agrees that if it does not file suit against Sandoz alleging infringement of one or more of Amgen Patent(s) within 60 days after receiving Sandoz's Confidential Material, Amgen shall cause Authorized Evaluators within thirty (30) days after the expiration of said period, to destroy or return to Sandoz the entirety of Sandoz's Confidential Material provided, and all notes, analyses, studies or other documents to the extent that they contain information reflecting Sandoz's Confidential Material, and Amgen shall notify Sandoz in writing within a reasonable time that this has been done.

(2) Amgen agrees that if Amgen files suit against Sandoz alleging infringement of one or more of Amgen's Patents within 60 days after receiving Sandoz's Confidential Material:

(a) While the litigation is pending, Sandoz's Confidential Material provided and all notes, analyses, studies or other documents to the extent that they contain information reflecting Sandoz's Confidential Material, shall be treated as information under the highest level of confidentiality under any protective order entered in the action brought against Sandoz. Until such a protective order is entered, subsections 1.C.(1) and 1.C.(2) above continue to apply.

(b) Amgen shall cause Authorized Evaluators to destroy or return to Sandoz Sandoz's Confidential Material provided and all notes, analyses, studies or other documents prepared to the extent that they contain information in Sandoz's Confidential Material, within thirty (30) days after the final determination of the action brought against Sandoz.

E. Accidental Disclosure: Should information contained in or derived from Sandoz's Confidential Material, including any notes, analyses, studies or other documents to the extent that they reflect any information therein, be disclosed, inadvertently or otherwise, Amgen shall, at its earliest reasonable opportunity, by and through Authorized Evaluators, contact Sandoz and identify:

(1) what has been disclosed;
(2) the individuals to whom such information has been disclosed; and
(3) steps taken by Amgen and Authorized Evaluators to ensure the information in and/or derived from Sandoz's Confidential Material is not further disseminated.

F. No Admission, Representation, Commitment, License Or Waiver Nothing in this Offer shall be construed as an admission by Sandoz regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or

admission by Sandoz with respect to the competency, relevance, or materiality of any information, document or thing. The fact that Sandoz provides information pursuant to this Offer shall not be construed as an admission by Sandoz that such information is relevant to the disposition of any issue relating to any alleged infringement of any Amgen Patent(s), or to the validity or enforceability of any such patent(s). Nothing contained herein shall be construed as a grant of any license or other right to use the information in Sandoz's Confidential Material except for the purpose expressly stated herein.

2. Amgen acknowledges that the violation of any provision of this Offer will cause irreparable injury to Sandoz, and that an adequate legal remedy does not exist. Sandoz, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to attempt to correct any violation and to prohibit Amgen from further violating the terms of this Offer. Amgen agrees that in such an action Sandoz is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees and court costs. Amgen further agrees that it will be liable for any violation of this Offer by an Authorized Evaluator, or of any separate confidentiality agreement between Amgen and Authorized Evaluator, as if the violation were committed by Amgen.

3. Amgen agrees that any claims for breach of this Agreement may be brought in courts located in the State of New Jersey and consents to the jurisdiction and venue of such courts for any such claims.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional or unenforceable, the remaining provisions shall continue in full force and effect.

5. When accepted by Amgen, this document shall constitute the entire agreement of the parties with respect to the subject matter herein and may not be amended or modified except in writing executed by all of the parties.

6. Amgen may request access to Sandoz's Confidential Material by executing one copy of this Offer where indicated and returning the executed copy, within a reasonable time before **August 25, 2014**, to Robin D. Adelstein, VP, Legal, IP & Compliance NA Gen Counsel, Sandoz Inc., 506 Carnegie Center, Suite 400, Princeton, NJ 08540. Thereupon, the terms contained in this document shall be considered an enforceable contract between Sandoz and Amgen.

SANDOZ INC.
By its authorized agent:

_____

ACCEPTED AND AGREED:

Amgen, Inc.
By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Company: _____

Date: _____

EXHIBIT A

ACKNOWLEDGEMENT OF PROTECTIVE ORDER

I, _____, state that:

My business address is _____

_____.

My present employer and job description are _____

_____.

I have read and reviewed in its entirety the annexed Offer of Confidential Access ("Offer") that has been signed and entered in this matter.

I have attached a listing of my consulting activities, including but not limited to litigation activities, and job history for the past three years, and have provided my most recent curriculum vitae or resume. With respect to litigation activities, I have identified the case by case number, party and jurisdiction, have identified the party that retained my services, and identified whether or not I testified by deposition and/or live.

I hereby agree to be bound by and comply with the terms of the Offer, and not to disseminate or disclose any information subject to the Offer that I review or about which I am told, to any person, entity, party, or agency for any reason, except in accordance with the terms of the Offer.

I understand that contempt sanctions may be entered for violation of this Offer and further agree to submit to the jurisdiction of any Court for the purposes of enforcement of the terms of this Offer.

DATED this _____ day of _____, 2014.

_____

(Signature)

_____

(Typed or Printed Name)

EXHIBIT 16

Wendy A. Whiteford
Vice President Law
Intellectual Property and Litigation

AMGEN

Amgen
One Amgen Center Drive
Mail Stop 28-2-C
Thousand Oaks, CA 91320-1799
Direct Dial: 805.447.1008
Fax: 805.447.1090
E-mail: wendy@amgen.com

August 22, 2014

Via Facsimile to (609) 627-8684 and
UPS Next Day Air

Robin Adelstein
Vice President, Legal IP & Compliance
General Counsel, N.A.
Sandoz, Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540

RE: Sandoz Inc.'s FDA Application for its Biosimilar Filgrastim Product

Dear Ms. Adelstein:

I have not received any response or even acknowledgement of my letter to you dated July 25, 2014. In that letter, Amgen provided you with a proposed revision to Sandoz's July 8th Offer of Confidential Access ("OCA") that would have provided for mutual confidentiality protections, the additional remedies Sandoz was seeking, specific logistics for an efficient information exchange and, most importantly, under, and in accordance with, 42 U.S.C. § 262(l). While you may have thought a response unnecessary given your letter of the same date announcing that the time period for Sandoz's compliance with its 42 U.S.C § 262(l)(2)(A) disclosure had expired, ignoring Amgen's efforts to address Sandoz's desire for heightened confidentiality and quick identification and resolution of disputes, if any, raises concerns that Sandoz's purpose in making offers of confidential access over the past two months may not have been to "protect information exchanged prior to resolving any dispute" or to expeditiously resolve any potential disputes prior to Sandoz's intended launch of its biosimilar candidate.

In this regard, I note that Sandoz's July 8th OCA and its July 25th OCA each attempt to narrow the scope of Sandoz's disclosures compared to that set forth at § 262(l)(2)(A) and the July 8th OCA attempted to limit the statutory bases of infringement that Amgen could consider in reviewing the narrowed scope of information to be provided by Sandoz. These offers do not appear to be aimed at facilitating identification of "any potential disputes" while protecting the information exchanged.

Likewise, it does not appear that Sandoz is interested in interacting with Amgen in a manner that facilitates speedy identification and resolution of disputes, if any. Your July 8th letter came one day after Sandoz had learned that the FDA had accepted Sandoz's biosimilar BLA for review and presumably well after Sandoz had submitted that BLA. Your letter omitted these facts. Sandoz set a date by which Amgen had to accept Sandoz's July 8th OCA knowing it was coincident with the statutory deadline by which Sandoz was to make its § 262(l)(2)(A) disclosures, but kept that information from Amgen as well. Although your July 8th letter invited Amgen to contact you with any questions or revisions to the July 8th OCA, you provided only Sandoz's corporate address, phone number and facsimile number. Despite having provided my email address and direct-dial phone number in my letter of July 18th, your response was dated a week later, sent by mail, again failed to provide your direct contact information, and was coincident in time with Novartis' press release announcing that Sandoz's biosimilar BLA had been accepted for FDA review. These do not appear to be the types of actions taken by a party seeking cooperation and speed to identify and resolve disputes. And, as I noted above, I have yet to receive any response or acknowledgement of my letter sent more than three weeks ago.

We were disappointed to learn that Sandoz has chosen not to follow the procedure required by the statute and again proposed a different mechanism for exchange of information than that spelled out by the provisions of 42 U.S.C. § 262(l). These provisions require that, not later than 20 days after the FDA notifies Sandoz that its application has been accepted for review, Sandoz "shall provide to the reference product sponsor [Amgen] a copy of the application submitted to the Secretary under subsection (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)(A). Amgen confirmed its readiness to receive Sandoz's disclosure in full compliance with the confidentiality provisions of the statute, offered to negotiate further confidentiality protections, and even provided proposed revisions to Sandoz's July 8th OCA for use within the statutory scheme.

Sandoz failed to make the required disclosures within 20 days of notification of FDA acceptance (by July 27, 2014). We understand this was a deliberate decision. You state that "[a]fter very careful consideration" Sandoz "opted not to provide Amgen" with the required information. We further understand that Sandoz does not wish to follow the procedures required by 42 U.S.C. § 262(l) because it intends to launch its filgrastim biosimilar product at a date substantially before those procedures could be completed under the time periods provided in the statute.

Amgen and Sandoz appear to have a fundamental disagreement as to the law. In particular, we disagree with your characterization that Sandoz has the "option" of not providing its biosimilar application and manufacturing processes to Amgen. Provision of the BLA application and manufacturing process information within 20 days is a mandatory provision of the statute, and not optional. As noted above, the statute expressly states that the biosimilar applicant "shall provide to the reference product sponsor" this information. 42 U.S.C. § 262(l)(2)(A). The later provision in the statute to which you refer, 42 U.S.C. § 262(l)(9)(C), does not override this requirement or make it optional but merely addresses one of the consequences if the biosimilar applicant fails to comply with § 262(l)(2)(A).

Amgen is currently evaluating how best to proceed given Sandoz's failure to comply with the statutory disclosure requirements and in that connection wish to make clear that Amgen reserves all legal rights available to it. Nonetheless, Amgen remains willing to engage in discussions with Sandoz if you feel that such a discussion would be productive. I would be happy to arrange a time to discuss these issues and request that you provide direct contact information to simplify and speed our communications.

Sincerely,

W. Whiteford

Wendy A. Whiteford

EXHIBIT 17

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,

Marcus 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

EXHIBIT 18

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Attorneys for Plaintiffs AMGEN INC. and
AMGEN MANUFACTURING, LIMITED

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

STIPULATION OF THE PARTIES

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited ("Amgen") and Defendant Sandoz Inc. ("Sandoz") hereby stipulate as follows:

1. On Tuesday, March 24, 2015, the parties will jointly propose a Rule 54(b) judgment to the Court in accordance with the decision of March 19, 2015. The parties will request that the Court enter the Rule 54(b) judgment by Wednesday, March 25, 2015. On the same day that the Rule 54(b) judgment is entered (or denied), or early the next morning if the order/judgment is entered after 5:00 pm PT, Amgen will note its appeal to the Federal Circuit of the Court's Order of March 19, 2015, denying its preliminary injunction, and of the Rule 54(b) judgment, if any.

   a. If the Court has not yet ruled on the pending Rule 54(b) judgment by the close of business on March 25, 2015, the parties will jointly call the Court during the morning of March 26, 2015, to try and secure an agreement that the Court will rule by March 26, 2015.

   b. If the Court has not ruled on the pending Rule 54(b) judgment by close of business on March 26, 2015, Amgen will, on March 27, 2015, file its notice of appeal as to this Court's March 19, 2015, denial of Amgen's motion for a preliminary injunction and, if the Court thereafter issues a Rule 54(b) judgment, the parties will jointly seek to consolidate an appeal from that judgment with its appeal from the Court's denial of its motion for a preliminary injunction.

2. Amgen will make any motion for an injunction pending appeal in the district court by Tuesday, March 24, 2015. Sandoz will respond by Tuesday, March 31, 2015. Amgen will file any reply by April 2, 2015. The parties will inform the Court that they agree that it continues to have jurisdiction to decide that Rule 62(c) motion, despite any notice of appeal.

3. If the Court denies Amgen's motion for an injunction pending appeal, Amgen will make a motion for an injunction pending appeal in the Federal Circuit within 2 business days of the Court's denial of its injunction-pending-appeal motion, Sandoz will respond within 5 business days, and Amgen will file any reply within 2 business days.

a. Amgen (in its motion) and Sandoz (in its response) will note Sandoz's agreement not to launch its biosimilar filgrastim product in the United States until the earlier of May 11, 2015, or a ruling by the Federal Circuit on Amgen's motion for an injunction pending appeal, and will respectfully request that the Federal Circuit rule on the injunction-pending-appeal motion prior to May 11, 2015.

4. The parties agree to seek oral argument in the Federal Circuit on Amgen's appeal of the Rule 54(b) judgment, if any, and the district court's March 19, 2015, Order at the Federal Circuit's June 2015 sitting, and to request the following expedited briefing schedule as to which there will be no extensions:

a. Amgen will file its appellate merits brief by April 3, 2015.

b. Sandoz will file its responsive merits brief by April 21, 2015.

c. Amgen will file its reply brief by April 28, 2015.

d. Amgen will file the joint appendix by April 30, 2015. The parties agree to coordinate and work together toward this date.

e. The parties agree to abide by this briefing schedule even if, when the due dates arrive, the Federal Circuit has not yet issued an order agreeing to it.

5. Sandoz agrees not to launch its product until a decision by the Federal Circuit on Amgen's motion for an injunction pending appeal, or May 11, 2015, whichever is earlier.

6. The parties mutually agree that from the date of this agreement until issuance of the Federal Circuit's mandate in the appeal from the district court's March 19, 2015, Order and the Rule 54(b) judgment, if any, all other proceedings in this litigation are stayed. During the pendency of the stay, Sandoz will not challenge the validity of U.S. Patent No. 6,162,427 (which has been asserted in this litigation), and the two patents that have been identified but not asserted in this litigation (U.S. Patent No. 7,781,395 and U.S. Patent No. 8,273,707) in connection with the manufacture or use of filgrastim. During the pendency of the stay, Amgen will not try to enforce the '427, '395, or '707 patent against Sandoz in connection with the manufacture or use of filgrastim. Should Amgen try to enforce any of those patents during the stay, Sandoz is free to

challenge, including but not limited to commencing inter partes review against, all three identified patents. As the sole exception to the stay, the parties agree that 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: March 24, 2015

Respectfully submitted,

By: /s/Rachel Krevans
Rachel Krevans

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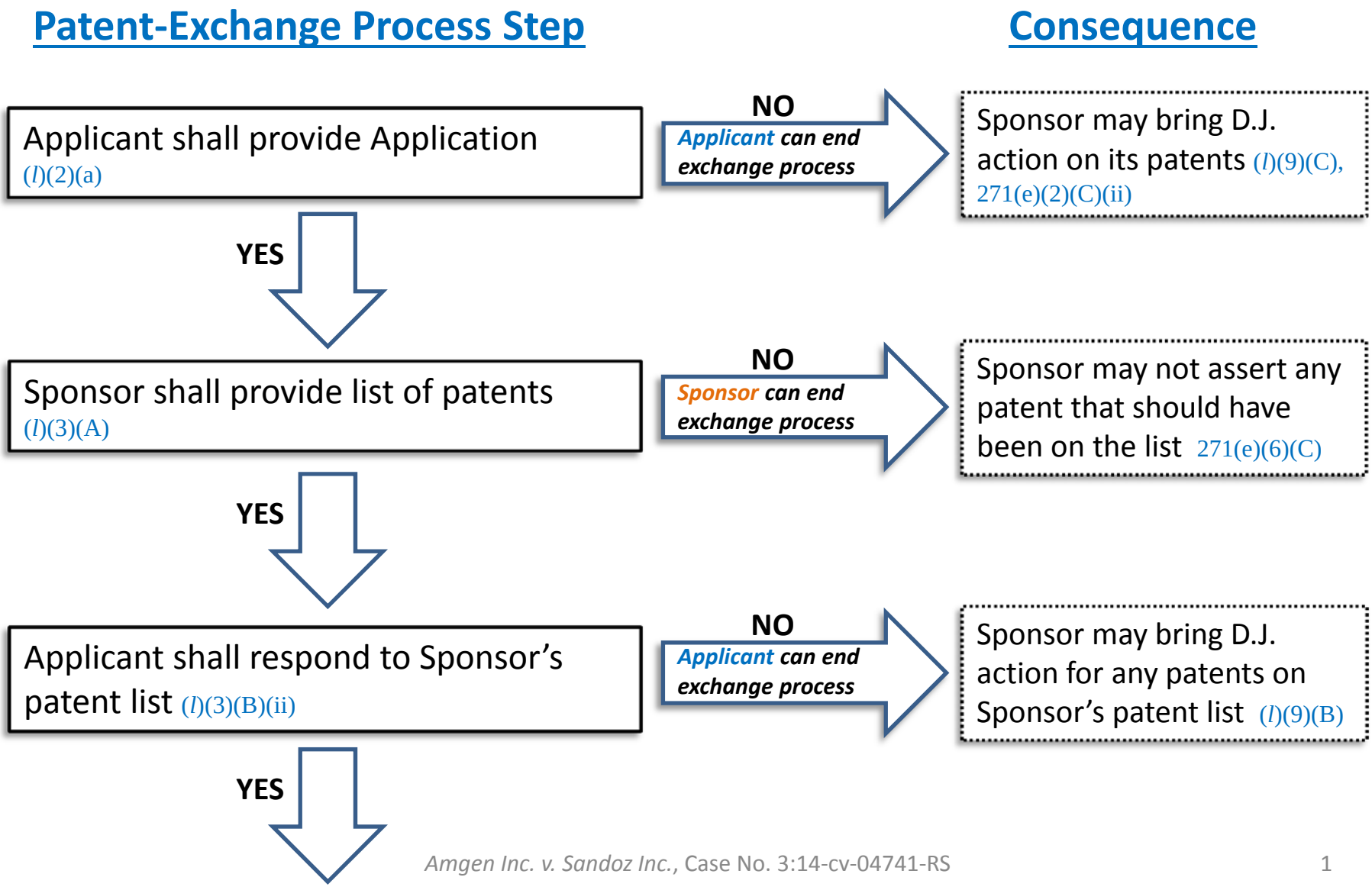
Attorneys for Plaintiffs AMGEN INC. and
AMGEN MANUFACTURING, LIMITED

EXHIBIT 19

BPCIA Section (*l*) Exchanges and Scenarios



BPCIA Section (*l*) Exchanges and Scenarios

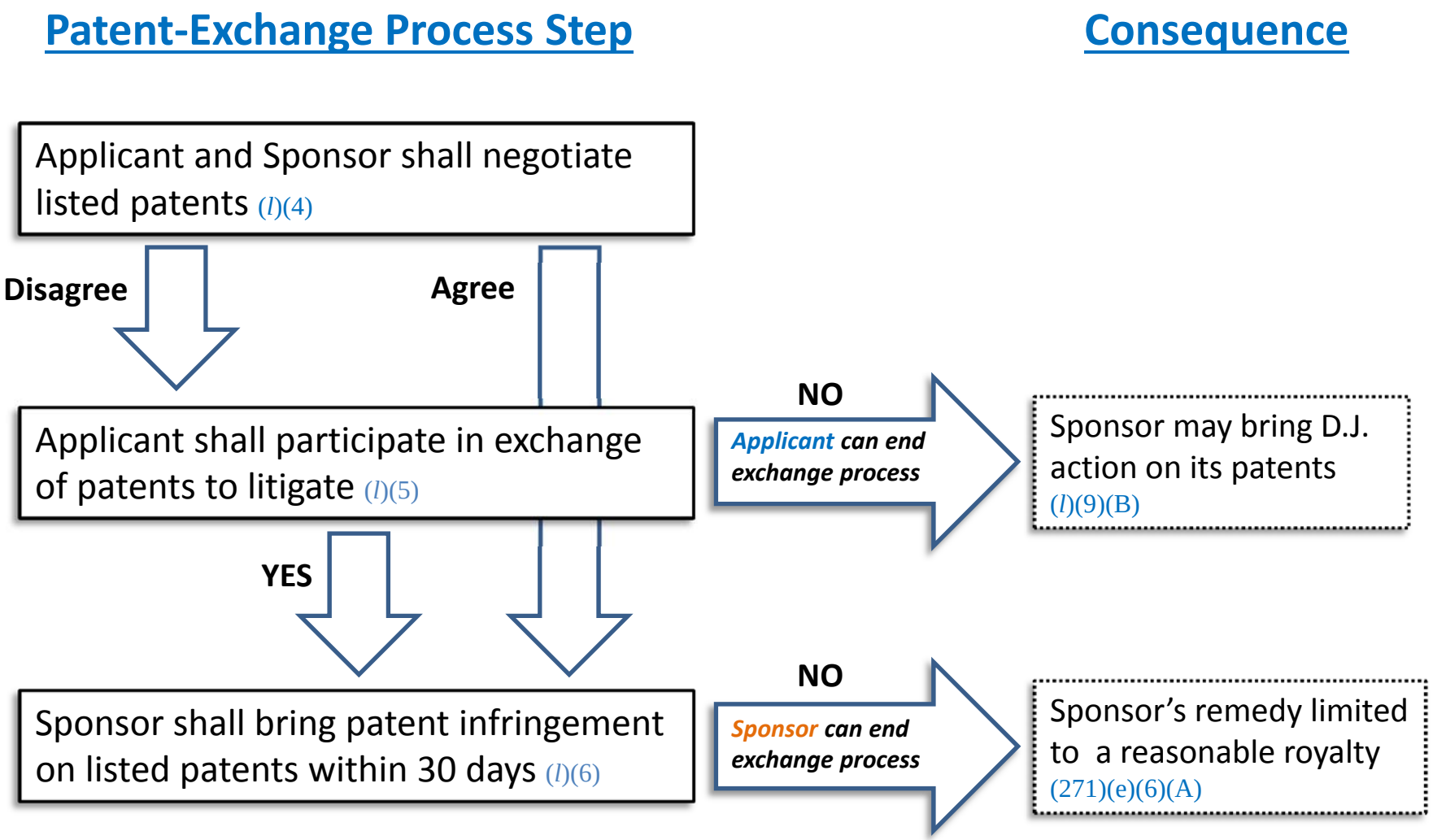


EXHIBIT 20

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 I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on April 24, 2015.

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

Dated: April 24, 2015 /s/ Deanne E. Maynard