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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

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

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I. INTRODUCTION

A party seeking the "extraordinary remedy" of a preliminary injunction must "clearly show" that it is likely to succeed on the merits; that it will suffer irreparable harm without an injunction; that the balance of equities tips in its favor; and that an injunction is in the public interest. *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 24 (2008). Amgen has not established *any* of these factors, let alone all four. And Amgen's motion entirely ignores a critical fact that forecloses as a matter of law any finding of irreparable harm here: Amgen waited for *seven months* after the issues crystalized to bring its motion, during which time it made deliberate choices that caused the very harm it now asserts. Settled law precludes the issuance of an injunction to heal any such self-inflicted wounds.

Amgen's motion fails for multiple additional reasons. ***First***, Amgen cannot show it is likely to succeed on the merits. Amgen seeks to convert a "notice" provision for resolving patent disputes into an "exclusivity" provision. Adopting Amgen's interpretation would defy Congress's intent (as expressed in the statute's plain language) by extending the exclusivity period from 12 years to 12.5 years. Amgen alternatively argues that Sandoz is competing "unlawfully" although Sandoz is proceeding down a path Congress expressly contemplated and authorized for these very circumstances. Neither argument has merit.

Second, Amgen cannot show irreparable harm for multiple reasons, beginning with the hornbook rule that "a party may not satisfy the irreparable harm requirement if the harm complained of is self-inflicted." 11A Wright, Miller & Kane, Federal Practice & Procedure § 2948.1 (3d ed. 2014). That is precisely the situation here. Amgen claims that it has been harmed because it did not receive Sandoz's filgrastim application in July 2014, and so it allegedly could not determine what patents it might potentially be able to assert against Sandoz. But that alleged harm is of Amgen's own making. The BPCIA contemplates a maximum of *60 days* for a Sponsor to identify any applicable patents after receiving a 42 U.S.C. § 262(k) application. Amgen cannot deny (and therefore ignores) that Sandoz offered to produce its Application *seven months* ago in July 2014, and multiple times since then, subject only to reasonable confidentiality protections. Amgen chose to decline all of those offers. It was only after court intervention that

Amgen accepted Sandoz's proposed confidentiality protections and the Application. That is the definition of "self-inflicted" harm.

That Amgen caused its own harm is confirmed by the fact that Amgen refused Sandoz's offer in December 2014 to produce its Application under a *temporary* protective order while the parties negotiated a *final* protective order – a reasonable offer a party would reject only if intent on delaying rather than expediting the resolution of any patent disputes. Similarly, ever since the 20-day period expired and Sandoz provided notice of commercial marketing in July 2014, Amgen has had the right to immediately bring a lawsuit, seek discovery of Sandoz's Application, and seek a preliminary injunction. Amgen instead waited three months to file this lawsuit in October 2014, and another four months after that to seek a preliminary injunction.

Indeed, it is beyond dispute that Amgen has had all the tools it needed to remedy its alleged harm itself and to assert any patent it wished since July 2014. Its decision not to use those tools appears to have been calculated to manufacture the current dispute in this Court at a time it was likely to cause the greatest possible delay, and to enable Amgen to avoid discussing for more than seven months whether it actually owns *any* patents that could support a showing of irreparable harm. All of Amgen's "material patents" covering filgrastim "expired in December 2013," as it admitted to the SEC last year, when announcing that it "now face[s] competition in the United States." (Decl. of Anders T. Aannestad ("Aannestad Decl.") Ex. E, Amgen 2013 Form 10-K at 42.) That lack of material patents is why Amgen has so steadfastly refused to expedite the resolution of any patent disputes. In a patent infringement action, "[s]ales lost" to an allegedly infringing product "cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature." *Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1324 (Fed. Cir. 2012). Amgen's delay and inaction has been deliberate and strategic.

Amgen's alleged harms are not only self-inflicted, they run afoul of two other black-letter rules governing preliminary injunctions: neither speculative injuries nor compensable monetary losses qualify as irreparable harm. Amgen attempts to bootstrap a basic economic harm – its potential loss of sales revenue due to biosimilar competition – into various speculative forms of allegedly irreparable harm due to business decisions that Amgen "could" or "might" make due to

reduced revenue. But all of these alleged harms are monetary, and all are speculative.

Third, the balance of equities heavily favors Sandoz. Sandoz is poised to launch the first biosimilar filgrastim in the United States, and an injunction would jeopardize the first-to-market advantage in which it has invested years of effort and tens of millions of dollars. By contrast, denial of the requested injunction would not impose any undue hardship on Amgen. Amgen has enjoyed 24 years of exclusivity, from which it has derived more than $60 billion in revenue. Amgen's business people have been planning for the entry of multiple biosimilar filgrastim products since long before the FDA accepted Sandoz's Application in July 2014. If Amgen does have any valid and infringed patents to assert (and Amgen makes no attempt to show any such thing in this motion), money damages can be added to the $60 billion.

Furthermore, Sandoz has been entirely fair and transparent with Amgen from the outset, bearing in mind the inherent uncertainty of being the first company to use this pathway. It provided Amgen with ***more*** notice of its intention to commercially market than the minimum 180 days the statute envisions, 42 U.S.C. § 262(*l*)(8)(A), and it effectively offered Amgen ***more*** time to evaluate its Application for potential patent issues (if only Amgen had accepted it) than the mere 60 days the statute envisions. What's more, Sandoz gave up many strategic advantages available to it under the Patent-Exchange Process.

Fourth, the public interest factor forecloses Amgen's request. The BPCIA expressly seeks to balance two key public purposes: innovation and consumer interests. Amgen has been amply rewarded for its innovation, enjoying 24 years of exclusivity although Congress concluded in the BPCIA that 12 years meets the public's interest in innovation. The consumer interest in the availability of lower-priced biosimilar drugs would be substantially harmed by awarding Amgen an injunction stopping public access to biosimilar filgrastim for an additional 410 days.

Amgen has failed to show that it is entitled to a preliminary injunction, and given the undisputed facts about its delay could not possibly make such a showing.

II. STATEMENT OF FACTS

Sandoz has incorporated all facts necessary to resolve Amgen's motion into the Argument section below. Sandoz also refers the Court to the parties' briefing on the pending motions for

judgment on the pleadings. (ECF Nos. 35, 45, 57 & 61.)

III. LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" never awarded as of right. *Winter*, 555 U.S. at 24. A plaintiff seeking a preliminary injunction must make a "clear showing" that he is entitled to extraordinary relief and "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 20. A plaintiff's failure to establish any one of these factors precludes entry of an injunction. *Id.* at 20, 23-24. The Federal Circuit applies the *Winter* standard. *Apple*, 678 F.3d at 1333.

Because the BPCIA provisions at issue concern patent-dispute resolution between reference product sponsors ("Sponsors") and subsection (k) applicants ("Applicants"), Federal Circuit law applies. *See Revision Military, Inc. v. Balboa Mfg. Co.*, 700 F.3d 524, 525 (Fed. Cir. 2012) (preliminary injunction involving matters unique to patent law is governed by the law of the Federal Circuit).[1] The presence of the supposed state-law claims does not alter that conclusion because they are entirely derivative of the BPCIA claims.

When applying the four-part test, even if a plaintiff has succeeded on the merits in establishing that a statute has been violated, injunctive relief does not reflexively follow. As the Supreme Court has long held, "[t]he grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge

[1] While the Ninth Circuit has articulated an alternative formulation of the *Winter* test that balances the first and third factors, requiring that the balance of hardships tip "***sharply*** in the plaintiff's favor" if the plaintiff can show only "serious questions going to the merits", *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011) (emphasis added), Amgen has not argued application of that alternative formulation. (Mot. at 12.) "Because [Amgen] does not argue that the balance of hardships tips sharply in its favor, [the Court should] not consider its claims under this standard." *Fox Broad. Co. v. Dish Network L.L.C.*, 747 F.3d 1060, 1066 n.2 (9th Cir. 2013). In any event, Amgen's motion should be denied under the alternative formulation too, because Amgen does not and cannot show that the balance of hardships tips sharply in its favor. *See San Francisco Herring Ass'n v. U.S. Dep't of the Interior*, No. 13-cv-01750-JST, 2014 WL 172232, at *6-*7 (N.D. Cal. Jan. 15, 2014) (denying a motion for preliminary injunction under *Cottrell* because the harms to plaintiff did not "sharply" outweigh harms to defendant). Nor can Amgen satisfy the remaining *Winter* factors that apply regardless of which approach the Ninth Circuit follows. *Cottrell*, 632 F.3d at 1135 (preliminary injunction may not issue even under "serious questions" test unless remaining two factors are satisfied).

sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982). In other words, "[a]n injunction is a matter of equitable discretion; it does not follow from success on the merits as a matter of course." *Winter*, 555 U.S. at 32. Thus, a statutory violation, by itself, is an insufficient basis for an injunction, even where a plaintiff has a statutory right to exclude others. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006) ("[T]he creation of a right is distinct from the provision of remedies for violations of that right.").

Finally, where a plaintiff alleges harm that is speculative or compensable by money damages, injunctive relief is not available. *See Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991) (speculation that market losses might occur cannot justify preliminary injunction); *Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60, 75-76 (1992) (court should determine adequacy of remedy in law before resorting to equitable relief).

IV. ARGUMENT

Amgen is not entitled to preliminary injunctive relief. The supposed harm it asserts is entirely self-inflicted: after it rejected Sandoz's repeated offers to provide the Application and resisted Sandoz's efforts to expedite the resolution of any patent disputes, Amgen deliberately chose to sit on its hands for seven months before filing this motion. That alone is reason to deny the extraordinary relief Amgen seeks. Nor has Amgen sustained its burden of establishing ***any*** of the four factors required for the entry of preliminary injunctive relief – much less ***all*** of them.

A. Amgen Has Not Shown Likelihood of Success on the Merits.

Amgen cannot show a likelihood of success on the merits, because Sandoz's actions were fully consistent with the text and purpose of the BPCIA. (*See* ECF Nos. 45 & 61.) Compliance with the BPCIA defeats Amgen's derivative state-law claims, which fail for additional reasons as well: California's unfair competition law ("UCL") does not apply at all, and conversion law provides no relief where Amgen improperly seeks to use state law to turn the Patent-Exchange Process into a prerequisite for FDA approval.

1. Sandoz Fully Complied with the BPCIA.

As explained more fully in earlier briefing, Amgen's contention that Sandoz failed to

comply with the BPCIA is without merit for multiple reasons. First, Section (*l*)(8)(A) is a notice provision that Amgen improperly seeks to convert into an exclusivity provision. The text has only one plain meaning: notice must be given at least 180 days before the Applicant begins commercial marketing, which Sandoz clearly did. (*See* ECF No. 45 at 7; ECF No. 61 at 4.) Sandoz's interpretation not only is consistent with the plain meaning of the statute, but also avoids the public harm of extending the Sponsor's exclusivity beyond the 12-year period Congress provided. (*See* 42 U.S.C. § 262(k)(7)(A); ECF No. 45 at 8; ECF No. 61 at 3-5.) There is no basis for rewriting the statute.

Second, Sandoz fully complied with Sections (*l*)(2)(A) and (*l*)(9)(C) of the BPCIA, which set forth an integrated statutory scheme that provides mechanisms for both Sponsor and Applicant to resolve patent disputes in a timely manner prior to FDA approval. Congress achieved this balance by prescribing specific consequences for the choices that an Applicant (as well as a Sponsor) makes. If an Applicant engages in the Patent-Exchange Process by disclosing its Application, it retains control over the maximum number of patents the Sponsor may litigate, and can obtain clarity as to each and every patent that may be a risk to its launch. If, on the other hand, the Applicant foregoes the Patent-Exchange Process entirely, or exits it after defined points (as expressly contemplated by Sections (*l*)(9)(B)-(C)), the Sponsor can immediately bring suit on *any* patent.[2] Regardless of how the patent-dispute resolution process unfolds, the Sponsor always maintains the ability to protect its intellectual property rights. Following the statute, including accepting the specific consequences of foregoing the Patent-Exchange Process under the Section (*l*)(9)(C) path, can hardly be deemed a violation of the BPCIA. Nor can this statutory framework be reconciled with Amgen's view that the Patent-Exchange Process is the BPCIA's sole and "mandatory" patent-dispute resolution mechanism. Sandoz's interpretation gives full effect to Section (*l*) and reads it within the context of the statute as a whole. *See, e.g.*, *Cnty. of*

[2] *See* BPCIA § 7002(c)(1)(A)(iii), codified at 35 U.S.C. § 271(e)(2)(C)(i)-(ii) (creating a statutory act of infringement for *any* patent that "could be identified" during the Patent-Exchange Process – including manufacturing patents – whenever the Sponsor does not receive the biosimilar application within 20 days). (*See also* ECF No. 61 at 8.)

Ramsey v. MERSCORP Holdings, Inc., 962 F. Supp. 2d 1082, 1087 (D. Minn. 2013), *aff'd*, 2014 U.S. App. LEXIS 23961 (8th Cir. Dec. 19, 2014) (no violation of statute stating that parties "shall" record conveyances, since law "specifically contemplates that not all conveyances will be recorded and outlines the consequence of failing to do so").

The contradictions between Amgen's contentions and the BPCIA are illustrated by the fact that had Sandoz elected to follow Section (*l*)(2)(A), litigation would likely still not have commenced *today* because Amgen – on its own admission – could not have filed suit until March 18, 2015 (which is *after* the date of expected FDA approval). (Mot. at 9-10.) Sandoz would still not know *today* what patents (if any) Amgen wanted to assert, and resolution of those patent issues would have been delayed for many months. Under Amgen's interpretation of the statute, Congress's intent to allow affordable biosimilars get to market as quickly as possible would be frustrated. Only Sandoz's view honors established principles of statutory construction and congressional intent, compelling the conclusion that Amgen cannot succeed on the merits of its claims. (*See* ECF No. 45 at 10-13; ECF No. 61 at 6.)

2. Amgen's State-Law Claims Have No Merit.

Neither of Amgen's state-law claims can survive because there has been no wrongful conduct. *See, e.g.*, *Schnall v. Hertz Corp.*, 93 Cal. Rptr. 2d 439, 451 (Ct. App. 2000) (no UCL claim where allegedly unlawful conduct was authorized by statute); *Burlesci v. Petersen*, 80 Cal. Rptr. 2d 704, 706 (Ct. App. 1998) (wrongful conduct is necessary element of conversion claim). The state-law claims fail for additional reasons. First, conversion is inapplicable here. Amgen claims that Sandoz "unlawfully" used the information in Amgen's license "to gain licensure of Sandoz's own filgrastim product without Amgen's permission or compliance with the BPCIA." (Mot. at 5.) But the BPCIA expressly authorizes Sandoz's reliance on Amgen's license, and does not condition Sandoz's right to FDA approval on either disclosure of the Application or completion of the Patent-Exchange Process. Amgen knows there is no such connection because it recently asked FDA to create one. (*See* ECF No. 61 at 13.) Moreover, Amgen's conversion claim would interfere with the balance struck by the BPCIA between putative property rights and the public interest in important technologies. *See Miles, Inc. v. Scripps Clinic & Research*

Found., 810 F. Supp. 1091, 1095 (S.D. Cal. 1993) (refusing to expand California law to recognize a cause of action for conversion of the intangible right to commercialization of a cell line). And as explained in Sandoz's cross-motion briefing, *G.S. Rasmussen & Associates, Inc. v. Kalitta Flying Service, Inc.*, 958 F.2d 896 (9th Cir. 1992), on which Amgen relies, has no place here. (*See* ECF No. 61 at 12.)

Second, as explained in greater detail in Sandoz's cross-motion briefing, New Jersey, not California, law should apply to Amgen's claims under California's three-part governmental interest test. (*See* ECF No. 61 at 10.) Application of New Jersey law would protect the interests of California's consumers, employers, and governments, while application of California law would harm those interests to Amgen's sole benefit. (*See id.*) Practical considerations further weigh against an injunction, because Amgen concedes that any injunctive relief would be limited to conduct occurring in California. (ECF No. 57 at 19.) The Federal Circuit recently reversed a district court's nationwide injunction under the UCL, finding that the scope of such an "injunction impermissibly imposes the UCL on entirely extraterritorial conduct regardless of whether the conduct in other states causes harm to California." *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358 (Fed. Cir. 2013). Thus, Amgen would benefit from an injunction at the expense of only California patients and California payors, while patients and payors in the rest of the country would benefit from access to more affordable drugs. This imbalance among consumer interests cannot be what Congress intended.

Amgen has no likelihood of success on the state-law claims.

B. Amgen Cannot Establish Irreparable Harm as a Matter of Law.

For multiple reasons, Amgen cannot establish irreparable harm.

1. Amgen's Alleged Harms Are Self-Inflicted.

Amgen ignores well-established law that defeats its motion: a "party may not satisfy the irreparable harm requirement if the harm complained of is self-inflicted." 11A Wright, Miller & Kane at § 2948.1; *see also Salt Lake Tribune Publ'g Co. v. AT&T Corp.*, 320 F.3d 1081, 1106 (10th Cir. 2003) ("We will not consider a self-inflicted harm to be irreparable."); *Caplan v. Fellheimer Eichen Braverman & Kaskey*, 68 F.3d 828, 839 (3d Cir. 1995) ("If the harm

complained of is self-inflicted, it does not qualify as irreparable.") (citation omitted).

Amgen's alleged harms are entirely self-inflicted. It contends that it did not receive Sandoz's Application within 20 days after FDA accepted the Application for review and has not had an adequate opportunity to assert its patents. But Sandoz repeatedly offered its Application to Amgen in July 2014 – within the 20-day period – subject only to industry-standard confidentiality protections. Amgen inexplicably refused to accept those terms or negotiate a reasonable alternative within the 20-day period (or afterward). Under these circumstances, any "injury" Amgen may have suffered from not obtaining Sandoz's Application within the 20-day deadline was both avoidable and entirely self-inflicted. That alone is grounds for denying Amgen's invocation of this Court's extraordinary equitable powers.

Amgen also sat on its hands when it came to enforcing any patent rights it might have. It is well settled that "delay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement." *Apple, Inc.*, 678 F.3d at 1325; *see also Oakland Tribune, Inc. v. Chronicle Publ'g Co.*, 762 F.2d 1374, 1377 (9th Cir. 1985) ("[A] plaintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm."); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995) (collecting cases); *Tech. & Intellectual Prop. Strategies Grp. PC v. Fthenakis*, No. C 11-2373 MEJ, 2012 U.S. Dist. LEXIS 5193, at *13 (N.D. Cal. Jan. 17, 2012) (denying preliminary injunction where plaintiff waited roughly ten months to file); *Larsen v. City of San Carlos*, No. 14-CV-04731-JD, 2014 U.S. Dist. LEXIS 152687, at *6 (N.D. Cal. Oct. 28, 2014) (denying preliminary injunction where plaintiff waited over three months to file new action); *Hiramanek v. Clark*, No. C-13-0228 EMC, 2013 U.S. Dist. LEXIS 131355, at *1, *3 (N.D. Cal. Sept. 13, 2013) (denying motion for interim injunctive relief where plaintiff waited one month after claim arose before filing).

This case law defeats Amgen's request for an injunction. Though BPCIA Section (*l*)(9)(C) gave Amgen an immediate right to file suit against Sandoz upon the expiration of the 20-day period and thereby obtain prompt access to Sandoz's Application, Amgen waited three full months before doing so in October 2014. Those three months were "lost" not because of

Sandoz's actions, but because of Amgen's delay. When Amgen finally sued, Sandoz again offered to provide Amgen with access to its Application – first on December 16, 2014, and again on January 16, 2015 – under a temporary protective order while the parties continued to negotiate over the final order, and Amgen again rejected the offer. (*See* Aannestad Decl. ¶¶ 14-15, Ex. M.) Indeed, it was only after this Court was called upon to resolve the parties' dispute regarding the protective order – and agreed with Sandoz – that Amgen finally consented to the terms and accepted Sandoz's Application. (*See id.* ¶ 16.)

Since July 2014, Amgen has also continually and inexplicably chosen to delay seeking preliminary injunctive relief, either in relation to the claims it brings here or under any patents. It finally filed its motion on February 5, 2015 (ECF No. 56), some seven months after the statute authorized Amgen to initiate suit and seek relief from this Court and four months after it finally filed suit. Amgen now seeks to sidestep the consequences of its delay by asserting that it only recently became aware that Sandoz might launch its product in March 2015. (Mot. at 11.) But that is demonstrably false: Amgen has known since July 8, 2014, that Sandoz intended to launch its product upon approval, which was expected in the first quarter of 2015. (Aannestad Decl. Ex. A, July 8, 2014 Letter at 1.) **REDACTED** Sandoz also made that point clear in its November 20, 2014, Answer to Amgen's Complaint: "Sandoz admits that it received notification from the FDA on July 7, 2014 that the FDA had accepted the [Application] for Sandoz's biosimilar filgrastim and admits that in accordance with BSUFA guidelines, FDA may approve the [Application] by as early as March 2015." (ECF No. 22, ¶ 63.)

Amgen's long, unexplained, and inexcusable delay belies any claim that it has suffered or will suffer irreparable harm or that an injunction is warranted.

2. The Alleged Violation of the BPCIA's Procedures Does Not Give Rise to *Per Se* or Presumptive Irreparable Harm.

The overriding theme of Amgen's motion is that the BPCIA's Patent-Exchange Process somehow provides a Sponsor with the right to exclude Applicants from the market if the statute's disclosure provisions allegedly are violated. Amgen is wrong. It does not, and it is "an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." *Religious Tech. Ctr. v. Wollersheim*, 796 F.2d 1076, 1088 (9th Cir. 1986).

Sections (*l*)(2)(A) and (*l*)(8)(A) of the BPCIA do not authorize injunctive relief where an Applicant fails to comply. (*See* ECF No. 45 at 17.) Congress clearly knew how to authorize injunctive relief when it wanted to; other sections of the BPCIA explicitly authorize it. *See, e.g.*, 42 U.S.C. § 262(*l*)(1)(H) (breach of the BPCIA's confidentiality requirements "shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy"). In contrast to those provisions, the pertinent provisions of the BPCIA instead provide that if the Applicant does not disclose its Application in 20 days under Section (*l*)(2), the Sponsor can file suit immediately and assert whatever patents it believes are relevant. (*See* ECF No. 45 at 11; ECF No. 61 at 8.) The Sponsor thus can obtain an injunction only by filing such a lawsuit, and only if it satisfies the standard four-factor test, including proof that it is likely to succeed *on the merits* of infringement and validity. In these circumstances, the Sponsor can control both the timing of any litigation and the number of patents it may assert free of the constraints of the Patent-Exchange Process. Amgen's attempt to rewrite the remedies Congress provided is improper.

Amgen's alleged harm in "losing" 180 days of extra exclusivity under Section (*l*)(8)(A) fares no better, as set out in Sandoz's prior briefing. (ECF No. 45 at 6-9; ECF No. 61 at 3-5.)

Amgen's assertion that it "presumptively" will suffer irreparable harm due to Sandoz's alleged violation of the BPCIA is doubly flawed. First, that argument relies on a now-discredited body of case law holding that a "presumption of irreparable harm" arises from alleged patent

infringement.[3] But the Supreme Court rejected that supposed presumption years ago. *eBay*, 547 U.S. at 392-93 ("[T]his Court has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a copyright has been infringed.").

Second, the cases Amgen cites are inapposite on their own terms: they require a showing that the plaintiff is likely to succeed *on the patent merits* and would face competition from an infringing product. But Amgen is not asserting infringement of *any* patent as the basis for its motion, much less a patent that could overcome the rule *against* injunctions where the allegedly infringing sales will occur "for reasons other than the patented feature." *Apple*, 678 F.3d at 1324. Indeed, Amgen previously admitted that its "material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013." (Aannestad Decl. Ex. E, Amgen 2013 Form 10-K at 42.)

In short, any claim that Sandoz's failure to follow the BPCIA's *procedural* mechanisms leads to a presumption of irreparable harm is unsustainable in light of the Supreme Court's holding that irreparable harm cannot be presumed even where *substantive* patent rights have been found valid and infringed. *eBay*, 547 U.S. at 391-92; *see also Park Vill. Apt. Tenants Ass'n v. Mortimer Howard Trust*, 636 F.3d 1150, 1162 (9th Cir. 2011) ("'[W]e do not presume irreparable harm' simply because a defendant violates a statute that authorizes injunctive relief.").

3. Amgen Has Not Been Deprived of an Opportunity To Select and Enforce Patents.

Amgen's argument that it will be irreparably harmed because it has been "foreclosed from seeking preliminary injunctive relief on its patents," fails as a matter of both law and fact. (Mot. at 18.) In reality, the parties' inability to agree on confidentiality terms that would govern the delivery of Sandoz's Application within the 20-day period provided Amgen with a *broader* range

[3] *See* Mot. at 19 (citing *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1565-66 (Fed. Cir. 1996) (applying "presumption of irreparable harm because Genentech made a strong showing of infringement and validity"); *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006) ("Having found that Sanofi has clearly established a likelihood of success on the merits, the Court also finds that Sanofi receives the benefit of a presumption of irreparable harm."); *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 607 (D.N.J. 2009) (citing pre-*eBay* authority for proposition that "[i]rreparable harm is presumed when a clear showing of patent validity and infringement has been made.").

of opportunities to assert its patents against Sandoz, including immediately requesting preliminary injunctive relief thereon, than if Sandoz had provided its Application under Section (*l*)(2)(A). Amgen chose to forego each of these opportunities.

First, Amgen could have filed suit for patent infringement and sought injunctive relief as soon as the 20-day period for disclosing Sandoz's Application expired. Given Sandoz's election, the BPCIA specifically authorized Amgen to assert *whichever* patents it wanted, *however many* patents it wanted, *whenever* it wanted. By contrast, if Sandoz had provided its Application within 20 days pursuant to Section (*l*)(2)(A), the BPCIA would have limited the number of patents on which Amgen could have sued. 42 U.S.C. § 262(*l*)(5)(B)(ii)(II); *id*. § 262(*l*)(6)(B). It is not credible for Amgen to claim that this clear advantage amounts to irreparable harm.

Second, Amgen's argument that it may not have been able to file such a lawsuit without access to Sandoz's Application is belied by its own conduct. After all, Amgen ultimately did file suit on the '427 patent despite not having Sandoz's Application at the time. (Mot. at 16.) That is no surprise. Amgen is a sophisticated biotechnology firm that routinely engages in patent litigation and knows what patents claim its filgrastim product. Neither the BPCIA nor the Federal Rules of Civil Procedure requires Amgen, or any patent-litigation plaintiff, to have perfect knowledge of its competitors' products before filing an infringement action. *See K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1286 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1026 (2014) ("That K-Tech cannot point to the specific device or product within TWC's or DirecTV's systems that [infringes] – especially when the operation of those systems is not ascertainable without discovery – should not bar K-Tech's filing of a complaint.").

Third, even putting aside the fact that Sandoz offered to provide its Application to Amgen as far back as July 8, 2014 (and several times thereafter), Amgen concedes it could have sued and obtained the relevant information about Sandoz's product through discovery. (Mot. at 18.) That concession is critical, as it underscores that Amgen has in fact deprived *itself* of the opportunity to assess whether any of its patents might be infringed. And even after Amgen finally brought this action in October 2014, it declined Sandoz's offers to produce the Application under reasonable confidentiality protections. Amgen tellingly offers no explanation for why it did not accept any

of those offers. *See Dunphy v. Ryan*, 116 U.S. 491, 498 (1886) (equity not available to relieve party of consequences from party's own failure to act). Amgen was free to accept Sandoz's Application under the reasonable confidentiality protections, review it, and immediately sue to enforce any patents it believed were infringed. It was also free to sue on a single patent (as it later did) and then seek immediate discovery to ascertain which of its other patents could be asserted (which it did not do). Ultimately, by following the Section (*l*)(9)(C) process, selection of patents was and is entirely within Amgen's control, both at the outset and as the case progresses.

Finally, by providing Amgen with its notice of commercial marketing under Section (*l*)(8)(A), Sandoz enabled Amgen to immediately seek a preliminary injunction under Section (*l*)(8)(B) in July 2014 even apart from the possibility of seeking such relief in the "ordinary" patent litigation authorized by the BPCIA. Amgen chose not to do so.

Given the broad range of options available to Amgen, it is telling that Amgen has not sued Sandoz on any patent other than the '427 patent, a fact which strongly suggests that Amgen has no other patents to assert. This comes as no surprise, since Amgen has repeatedly informed its shareholders since 2004 that its "material U.S. patents for filgrastim (NEUPOGEN®)" would expire in December 2013 and expects to "face competition in the United States, which may have a material adverse impact over time on future sales of NEUPOGEN®." (Decl. of Gordon Rausser ("Rausser Decl.") ¶¶ 24-27; Aannestad Decl. Ex. E, Amgen 2013 Form 10-K at 42; Ex. G, Amgen 10-Q at 27.) Indeed, the only response that Amgen can muster – that some of its patents "could cover" Sandoz's product, and that others "could be relevant" (Mot. at 17) – is pure speculation, which cannot be evidence of irreparable harm. Amgen's apparent disinterest in obtaining access to Sandoz's Application also casts doubt on whether it has any other valid patent claims.

Amgen has had every opportunity to assert any patent that it believes is valid and infringed, but chose to sit on its hands for months. That is hardly Sandoz's fault. Amgen thus has not shown and cannot show that it has suffered any irreparable harm here.

4. Amgen's Economic Arguments Are Speculative and Remediable by Money Damages.

Amgen's economic arguments that it will suffer irreparable harm are legally misguided and rely on speculation about what might occur rather than competent evidence specific to recent events in the market. Amgen presents no evidence whatsoever demonstrating a substantial likelihood that Amgen will suffer any harm, let alone irreparable harm. None of what Amgen tenders to the Court suffices to support the injunction that it seeks or justifies the harms an injunction would impose on Sandoz and consumers.

a. Any Alleged Harm Is Speculative.

All of Amgen's irreparable harm arguments are predicated on speculation, not actual economic proof. Amgen's declarations turn on what "could" happen, what "may" happen, and what is "possible," but none provide any analysis of the actual filgrastim marketplace. (Rausser Decl. ¶¶ 16, 20-23, 30-39, 54-71.) For example, Dr. Philipson relies on the following hearsay "guess" from a stock analyst as the basis for his calculation of Amgen's lost profits: "Bernstein analyst Ronny Gal stated that 'I'm guessing that in the US in five years, Sandoz will be at least half the market.'" (Philipson Rpt. ¶ 50, ECF No. 56-5 (emphasis added).) Suffice it to say, a third party's "guess" about possible harms in the future is not enough to justify the entry of injunctive relief. *Winter*, 555 U.S. at 22 (rejecting Ninth Circuit's prior standard permitting preliminary injunction based on the "possibility" of irreparable harm). Instead, every preliminary-injunction plaintiff must prove that the asserted "harm is real, imminent and significant, not just speculative or potential." *Groupon, LLC v. Groupon, Inc.*, 826 F. Supp. 2d 1156, 1167 (N.D. Cal. 2011) (citing *Winter*, 555 U.S. at 20) (denying preliminary injunction). "[T]he absence of a substantial likelihood of irreparable injury would, standing alone, make preliminary injunctive relief improper." *Signeo USA, LLC v. SOL Republic, Inc.*, No. 5:11-cv-06370-PSG, 2012 U.S. Dist. LEXIS 79356, at *38 (N.D. Cal. June 6, 2012) (citation omitted) (denying preliminary injunction). Amgen has not proffered any actual evidence that could justify relief.

b. Amgen's Alleged Harms All Reflect Monetary Losses That Cannot Be Irreparable Harm.

At its core, Amgen's claim is that Sandoz's product will enter the market; that Amgen will lose some sales of Neupogen® and/or Neulasta® (Amgen's long-acting version of filgrastim); that prices may fall; and that Amgen will have less cash. According to Amgen, if all of these things happen, that *might* lead Amgen to make a business decision that it might not otherwise have made. Not only are such claims of future harms purely speculative, they all are readily remedied by money damages, and injunctive relief is unwarranted for that reason as well. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1010-11 (Fed. Cir. 2009) (affirming denial of preliminary injunction where plaintiffs had not shown that generic manufacturers were unable to respond in money damages); *Lydo Enters. v. Las Vegas*, 745 F.2d 1211, 1213 (9th Cir. 1984) ("Purely monetary injuries are not normally considered irreparable."); *Nutrition 21*, 930 F.2d at 871 ("[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial.").

Indeed, Amgen's own brief cites *Apotex, Inc. v. FDA*, in which the court held that lost sales due to the entry of competing products "cannot be called anything other than 'merely economic.'" No. Civ. A. 06-0627 JDB, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) (denying preliminary injunction). "To successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence." *Id.* (citation omitted). Amgen will not suffer any meaningful hardship, and its arguments all stem from an alleged loss of future money. Indeed, this is precisely how Mr. Azelby characterized the harm in his own words: **REDACTED**

REDACTED

c. Amgen's Ability To Conduct Research and Development Has Not Been Impaired.

Next, Amgen claims that it "could" decide to reduce research and development spending should Sandoz enter the market, and that this possibility constitutes irreparable harm warranting injunctive relief. But Amgen provides no document, internal plan, budget or any other preexisting evidence supporting that claim. Dr. Philipson's reliance on an alleged link to revenue is both unproven and reflects a fundamental logical error. (Rausser Decl. ¶¶ 47-53.) In fact, Amgen's proffered expert Dr. Philipson admitted that he did not know what Amgen's free cash flow was and had not formed any opinion on the question whether Amgen in fact has sufficient resources to fund its research and development should its filgrastim sales decline. (Aannestad Decl. Ex. D at 138:17-141:7.) And for good reason, because the data actually show that Amgen is ***not*** under any financial constraint: it holds over $27 billion in cash and investments and had $7.8 billion in free cash flow in 2014. (Aannestad Decl. Ex. F at 8, "Q4 '14 Earnings Call" Presentation; Rausser Decl. ¶¶ 52-53.) If Amgen wants to continue or increase its current level of research and development because doing so will provide prospective returns, Amgen has the resources to do it both before and after a new filgrastim product is introduced. (Rausser Decl. ¶¶ 52-53.) It is entirely within Amgen's own control how best to deploy its vast financial resources. That choice is not an irreparable harm; it is what businesses do in the normal course.

The Federal Circuit has held that, absent severe cash flow concerns, arguments in this form do not suffice to meet the irreparable harm requirement. In *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996), the Federal Circuit held that such a claim "is

not materially different from any claim of injury by a business that is deprived of funds that it could usefully reinvest." It explained that "[i]f a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim." *Id.*; *see also Altana*, 566 F.3d at 1010-11 (affirming denial of preliminary injunction against generic manufacturer based on findings that price erosion, loss of market share, loss of profits, loss of research opportunities, and possible layoffs were not irreparable harm).[4]

d. Amgen Has Not Proven Any Irreparable Harm Relating to Its Sales Force.

Amgen argues, without citation to authority, that its sales force is a fixed asset and that the need for salespeople to talk to customers about a competing product is an irreparable harm. The first premise is plainly wrong. Companies hire and fire salespeople all the time. Amgen has known of Sandoz's plans since at least July 2014 and repeated to its investors on August 5, 2014 that "[o]ur 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® . . . ." (Aannestad Decl. Ex. G, Amgen 10-Q at 27.)

REDACTED

[4] The cases cited in Amgen's brief underscore the lack of irreparable harm to Amgen here. In *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d 789, 824 (E.D. Tex. 2011), the irreparable harm claim was based on lost revenue of a magnitude that threatened to force the company out of business. Cash-rich Amgen faces no such threat here. And in *AstraZeneca LP*, 623 F. Supp. 2d at 612-13, the court specifically rejected AstraZeneca's argument that its research and development activities would be irreparably harmed by reductions in revenue.

REDACTED Amgen has had ample time to hire and train new salespeople. (Rausser Decl. ¶¶ 54-61.) Put simply, Amgen has long been preparing for the entry of biosimilar competition, which in and of itself belies any suggestion that it will suffer irreparable harm, particularly when such a suggestion is based on speculative claims about what "could" happen to a sales force REDACTED

e. Amgen Has Not Proven That Prices Will Be Eroded or That Any Erosion Cannot Be Remedied with Damages.

Amgen provides no economic evidence or quantitative economic study to support its speculation that its prices will be eroded. Dr. Philipson admitted that any possible price erosion was "very uncertain" and "highly uncertain." (Aannestad Decl. Ex. D at 119:7-11; 119:21-120:2.) REDACTED Additionally, the evidence from actual data on the filgrastim market in the last two years contradicts Amgen's claims. (Rausser Decl. ¶¶ 62-64.) For example, Amgen's argument entirely ignores what happened when Teva introduced its competing Granix product in November 2013. (*Id.* ¶¶ 40-43, 63-64 & Figs. 4, 5, 11.) Granix is a variant on filgrastim (tbo-filgrastim) that is sold for use in the medical indication that makes up approximately 80% of all prescriptions, REDACTED Rausser Decl. ¶¶ 20, 40-41 & Fig. 11.) By the end of 2014, Granix had taken 14% of the filgrastim market. (*Id.* ¶ 40.) Despite the entry of this competing product, however, Neupogen®'s price has held stable and Neulasta®'s price has *risen*. (*Id.* ¶¶ 63-64 & Fig. 11.)

Perhaps because it totally undermines Amgen's speculative assertions, Dr. Philipson makes no effort to examine the data on market share, revenues, or pricing since the introduction of Granix. (*Id.* ¶¶ 20-23.) Although he said he wanted to use "the most recent numbers," he did not consider any 2014 sales data, and did not know that Neupogen® sales dropped by more than $300 million in the year after Granix was launched. (Aannestad Decl. Ex. D at 89:8-92:10.)

REDACTED

Rather than face the reality of Granix's impact on the economic situation, Dr. Philipson ignores the issue, basing his opinions on the self-serving, subjective claim of Mr. Azelby that Sandoz "has competitive advantages" relative to Granix. (Philipson Decl. ¶ 70, ECF No. 56-5.) This is not competent evidence of price erosion. (Rausser Decl. ¶¶ 62-67.) REDACTED Because the facts are so consistently against it, Amgen speculates that Zarxio will be priced at or above the current prices for Neupogen based on partial quotes from a Sandoz representative. The statements on which Amgen relies are taken out of context (*id*. ¶¶ 105-106), REDACTED

Finally, of course, price erosion, if it did occur, might reduce Amgen's revenue and or profits, but those harms would still be remedied by money damages – not injunctive relief.

f. Amgen's Theory Regarding Goodwill Does Not Apply to These Circumstances.

Amgen relies on the further speculation that Sandoz sales of filgrastim "may irreparably damage Amgen's relationships with its customers and goodwill." (Mot. at 23 (emphasis added).) This argument depends on proof that Amgen will lower prices and *will* be able to use a patent in the future to remove filgrastim from the market – two propositions for which Amgen has offered no evidence. If Amgen does not lower prices, consistent with its plans, it will not be forced to raise them later. If Amgen does not have a valid, infringed patent that would justify an injunction, then there is no logical basis for Amgen's hypothetical future scenario whereby Sandoz's product would be launched now and then later removed from the market.

C. The Public Interest Would Be Disserved by a Preliminary Injunction.

Amgen's request for preliminary injunction also should be denied because it is contrary to the public interest. The whole point behind the BPCIA, after all, is to balance the interests of

innovators *and consumers* by expediting the public's access to more affordable medical treatments, like Sandoz's biosimilar filgrastim, while ensuring that Sponsors receive clearly defined exclusivity periods and that they *always* have the right to initiate patent litigation. *See* BPCIA § 7001(b), Pub. L. No. 111-148, 124 Stat. 804 (2010) (Congress intended to develop a "biosimilars pathway balancing innovation and consumer interests"). Congress decided that a 12-year period of exclusivity meets the public's interest in rewarding innovation, an exclusivity period that Amgen has doubled. *See* 42 U.S.C. § 262(k)(7)(A). Entry of a preliminary injunction, however, would prevent consumers from accessing a more affordable filgrastim product, which would undermine the very goals of the statute.

Amgen's twelve-year exclusivity period having long expired, Sandoz had a dilemma. It knew the Patent-Exchange Process would necessarily have delayed resolution of patent disputes until after it expected FDA approval. But it wanted to have all patent issues resolved before approval if possible, allowing it to launch immediately thereafter. Under the BPCIA, Sandoz could achieve that goal by declining to provide its Application, thereby allowing Amgen to sue immediately and reveal whether Amgen had any patents to assert. Sandoz chose not to provide its Application, because it believed this path would resolve the patent issues as quickly as possible, thereby serving the public interest by allowing the product to come to market sooner.

Other courts have considered the public interest and come to the same conclusion. In *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 214 (D.D.C. 1996), for example, the plaintiff sought a preliminary injunction that would have blocked a generic pharmaceutical competitor from entering the market on a product for which the plaintiff's Hatch-Waxman exclusivity had already expired. Among the considerations that the court cited in denying relief was Congress's balancing of the interests of brand companies, generics, and the public:

> To balance the interests of generic drug manufacturers and those of pioneer drug manufacturers, Congress provided the latter with varying periods of exclusivity prior to FDA approval of a competing generic drug. Presently, Bristol has benefitted from the period of exclusivity to which it was entitled. The using public will therefore now benefit from increased competition.

Id. at 221-222 (citation and footnote omitted). These same considerations are at play here: an

injunction that delays public access to Sandoz's more affordable filgrastim product would harm consumers' and health care organizations' interests, and is completely unnecessary to reward Amgen for its innovation, given its lengthy exclusivity and more than $60 billion in revenue.[5]

REDACTED The articles cited by Amgen corroborate the conclusion that Sandoz's product will result in lower costs to the public. (*See, e.g.*, Winters Decl. Ex. 4 at 2, ECF No. 56-10 ("The cost [of Sandoz's product] will be less to the consumer, to the payer, to the health care economy."); *id.* Ex. 5 at 2, ECF No. 56-11 ("[U]ltimately, the cost to the supplier, to the patient, will be lower.").) It cannot be disputed that biosimilars as a class, including Sandoz's product, are expected to reduce healthcare costs significantly in the next decade, which will benefit the public and businesses alike. (Rausser Decl. ¶¶ 19, 100-111; Aannestad Decl. Ex. H at 1.)

Amgen's argument that the launch of Sandoz's product will harm the public interest by hampering Amgen's investment in drug development and its introduction of new therapeutics is belied by the facts, including Amgen's $27 billion reserves. (Aannestad Decl. Ex. F at 8.) The launch of Sandoz's filgrastim product will have no effect on Amgen's financial ability to introduce its "on-body injector" or any other worthwhile new product. (Mot. at 24.)

Finally, even if Amgen's interpretation of BPCIA procedures are adopted by the Court, the public interest is fully served by a ruling guiding the parties' *prospective* BPCIA conduct. The public would gain nothing from an injunction in this case and would be affirmatively harmed by the delay of more affordable filgrastim. *See Weinberger*, 456 U.S. at 312 ("[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy

[5] Amgen's reliance on *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006) is misguided. (Mot. at 24.) In *Sanofi-Synthelabo*, the Federal Circuit's public interest analysis turned on the desire to encourage innovation by "protecting the exclusionary rights conveyed in valid pharmaceutical patents." 470 F.3d at 1384. Here, Amgen never argues that Sandoz should be enjoined because *it* is infringing a valid patent. Instead, Amgen seeks an injunction based solely on perceived procedural violations of the BPCIA, an issue with equities not contemplated by the Federal Circuit in *Sanofi-Synthelabo*. And unlike the brand company in *Sanofi-Synthelabo*, Amgen has already enjoyed twice the exclusivity period authorized by Congress. Amgen's reliance on *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364 (Fed. Cir. 2005) is inapt for the same reason. (Mot. at 24.)

of injunction."). The public interest factor therefore strongly favors Sandoz.

D. Considering the Balance of Hardships, Injunctive Relief Is Unwarranted.

The balance of hardships strongly disfavors issuance of a preliminary injunction. Amgen claims hardship because it might have been able to identify at an earlier time more patents to assert against Sandoz, if Sandoz had provided the Application in July 2014. But Amgen has had access to all the tools necessary to assert any patents since July 2014, when Sandoz first offered to provide its Application and notified Amgen of its intent to start commercial marketing. Amgen rejected every offer from Sandoz to provide its Application and waited months to file suit, seek discovery on Sandoz's Application, or move for injunctive relief. Amgen's decision to sit on its rights negates any possibility that the balance of hardships could be in its favor.

Filing a lawsuit here was certainly no hardship for a company the size of Amgen. Amgen's claim of suffering a hardship "that the statute was designed to avoid," (Mot. at 16), fundamentally mischaracterizes the BPCIA procedures at issue. Section (*l*) of 42 U.S.C. § 262, which contains the BPCIA provisions at issue, is entitled "Patents." On their face, these provisions expressly address the process for resolving patent disputes and require a Sponsor to file an action for patent infringement, if the Sponsor wants to obtain an injunction. Amgen could have avoided its alleged hardship by promptly filing suit in July 2014, immediately seeking the Application through discovery, and then evaluating whether any additional patents could be asserted. Amgen's failure to do so then is the sole cause of any hardship Amgen now claims.

Even if Amgen's claim of hardship were accepted, those supposed harms do not weigh in favor of injunctive relief. Amgen will not incur any hardship unless it has valid, infringed patent claims, and it has provided ***no*** proof on that issue. Moreover, any harm to Amgen can be compensated by money damages.

Finally, Sandoz would suffer severe hardship if it were enjoined from launching for another 13 months or longer. Sandoz has made a significant investment in years of research, including expensive clinical trials, to develop its product for the U.S. market. After earning unanimous approval of FDA's Oncologic Drugs Advisory Committee (Aannestad Decl. Ex. I),

Sandoz is poised to launch and has rightfully earned the first-to-market advantage that is critical to biosimilar companies. *See Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997) ("the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants"); *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 9, 29 (D.D.C. 2012) (denying injunction and finding that harm to generic entrants "would be dramatically greater" than harm to the brand company). As at least two other companies have the potential to launch a biosimilar filgrastim product in the U.S. within 12 months, every day Sandoz is kept off the market is a significant loss that can never be recouped. (Rausser Decl. ¶¶ 84-99; Aannestad Decl. Ex. J, Hospira Form 10-K at 36; Ex. K, Hospira presentation at 24; Ex. L, Apotex press release; **REDACTED** An injunction could have devastating effects on Sandoz's business by making it the second or third biosimilar to enter the market. (Rausser Decl. ¶¶ 84-99.) The balance of hardships decidedly favors Sandoz.

E. The Injunction Amgen Requests Exceeds the Scope of the Alleged Harm.

To the extent any equitable relief is considered, there is no evidentiary or legal basis for enjoining Sandoz from launching its biosimilar filgrastim product for longer than 60 days from the production of Sandoz's Application to Amgen, which occurred on February 9, 2015. (Aannestad Decl. ¶ 16.) Under the BPCIA path that Amgen claims is mandatory, Amgen has only 60 days following receipt of the Application to identify all patents it believes could reasonably be asserted. *See* 42 U.S.C. § 262(*l*)(3)(A). Thus, even under Amgen's interpretation, an injunction should run only until April 11, 2015, 60 days after receipt of the Application by Amgen, which would provide Amgen with the full statutory allotment for identifying relevant patents. After that 60-day period, if Sandoz opts not to provide Amgen with a detailed statement on invalidity, unenforceability, and/or noninfringement of the identified patents, the process terminates, and Amgen has the right to bring a declaratory judgment action for infringement of any of the identified patents. *See* 42 U.S.C. § 262(*l*)(3)(B)(ii); § 262(*l*)(9)(B). Thus, there is no statutory basis for extending any injunction beyond April 11, 2015.

In contrast, Amgen offers no justification for the 410-day period that its expert,

Dr. Philipson, used to calculate the alleged harm. Amgen's proposed period arises from two fundamental errors. First, it assumes that each side will use the maximum time provided for each step in the exchange procedures, even though there is no statutory mandate to do so. It also assumes that a notice of commercial marketing can only be given after the completion of the Patent-Exchange Process, but even if Amgen were right about the timing of the notice, there is no statutory justification for any link between FDA approval and the use of the Patent-Exchange Process or any other part of Section (*l*). No injunction should issue, but, to the extent equitable relief applies, the injunction cannot exceed the 60 days stated above.

F. If a Preliminary Injunction Is Ordered, It Should Be Conditioned on the Posting of a Substantial Bond.

Amgen has failed to satisfy a single prong of the four-part traditional test for an injunction. But were an injunction to be issued, Amgen must post a substantial bond to ensure that Sandoz can be fully compensated in the event it is later determined that the injunction was improper. Fed. R. Civ. P. 65(c). Without a bond, Sandoz will be deprived of relief for any injury it suffers while wrongly enjoined. *See Russell v. Farley*, 105 U.S. 433, 437 (1881); *W.R. Grace & Co. v. Local Union 759, Int'l Union of United Rubber, Cork, Linoleum & Plastic Workers of Am.*, 461 U.S. 757, 770 n.14 (1983) ("A party injured by the issuance of an injunction later determined to be erroneous has no action for damages in the absence of a bond."). "When setting the amount of security, district courts should err on the high side." *Mead Johnson & Co. v. Abbott Labs.*, 201 F. 3d 883, 888 (7th Cir. 2000).

Here, the harm to Sandoz from an erroneous injunction of 410 days would be in excess of **REDACTED** (Rausser Decl. ¶¶ 84-99 & Figs. 20, 22-23, Table 21.) To ensure that the bond is sufficient to protect Sandoz, Sandoz proposes the bond be set at 120% of the total: **REDACTED** If the Court decides to issue an injunction, but sets a shorter time period, Sandoz is prepared to provide an additional statement of the appropriate bond on 48 hours of notice from the Court.

V. CONCLUSION

For the reasons stated above, Sandoz respectfully requests that the Court deny Amgen's motion.

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