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

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

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

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **NOTICE OF MOTION AND MOTION BY AMGEN FOR A PRELIMINARY INJUNCTION** Date: March 2, 2015 Time: 1:30 PM Location: Courtroom 3, 17th Floor

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES (CONTINUED)

Page(s)

Statutes

Rules

Other Authorities

NOTICE OF MOTION

TO ALL PARTIES AND THEIR COUNSEL: PLEASE TAKE NOTICE that on March 2, 2015, at 1:30 PM (Dkt. No. 55), Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen"), will move this Court for a preliminary injunction under Rule 65 against Defendant Sandoz Inc. ("Sandoz"), based on the Federal Rules of Civil Procedure, the Local Rules of this District, this memorandum, the record and hearing of this proceeding, and any matters of which the Court takes judicial notice.[1]

ISSUE TO BE DECIDED AND RELIEF SOUGHT

As soon as March 8th, Sandoz may begin marketing a copy of Amgen's successful Neupogen® (filgrastim) product. Sandoz is waiting only for FDA approval. It is not, however, waiting to comply with the law. Sandoz will launch its product even though it has not complied with the provisions of the Biologics Price Competition and Innovation Act ("BPCIA") that are designed to protect Amgen, the sponsor (and innovator) of the reference product for Sandoz's biosimilar product. The BPCIA required Sandoz to provide Amgen with a copy of its Biologics License Application ("BLA") and manufacturing information and to participate in a detailed information exchange designed to allow Amgen to commence a patent infringement suit and seek a preliminary injunction before Sandoz's commercial entry. Amgen alleges that Sandoz's use of the FDA license for Neupogen®—which is allowing Sandoz to greatly shortcut the time for development and approval of its own product—while denying Amgen the benefits that the law requires is an unlawful business practice under California Business & Professions Code § 17200 et seq. ("section 17200") and an act of conversion. On March 2nd, the Court will hear argument on the parties' cross-motions for judgment on the pleadings, which will resolve whose reading of the BPCIA is correct. Sandoz has refused to refrain from launching its biosimilar filgrastim until the Court can resolve those motions. As set forth in the accompanying Proposed

[1] Amgen refers to Sandoz Inc. as "Sandoz" in this motion. The Complaint is also against Sandoz International GmbH and Sandoz GmbH, which with Sandoz Inc. is alleged to have acted in concert. Nothing herein is intended to waive claims against the foreign defendants.

Order, Amgen now seeks a preliminary injunction restraining Sandoz from launching its product until the Court decides the pending motions for judgment on the pleadings and, if the Court rules in Amgen's favor on those motions, further restraining Sandoz from commercially manufacturing, using, selling, offering for sale, or importing its biosimilar product until the parties have been placed in the position they would be in had Sandoz complied with the BPCIA. Given the immediacy of Sandoz's proposed unlawful commercial marketing, the irreparable harm that Amgen faces, the public's interest in ensuring compliance with laws, and the equities strongly favoring Amgen, should the Court grant a preliminary injunction?

PRELIMINARY STATEMENT

Amgen brings this motion for a preliminary injunction to prevent Sandoz from entering the U.S. market with a biosimilar filgrastim product, which could happen as soon as March 8th. Because Sandoz's market entry will be unlawful and will irreparably harm Amgen, and because the public interest and the equities favor an injunction to stop that unlawful entry and prevent that irreparable harm, the Court should enter an injunction. That injunction should last until the Court decides the parties' pending motions for judgment on the pleadings, set to be argued along with this motion on March 2nd, and should continue thereafter if the Court agrees with Amgen's reading of the plain text of the applicable law.

This case is about what may be the first FDA approved "biosimilar," roughly akin to a generic but for a biologic product, not a small-molecule drug. Sandoz's estimated FDA approval date for its biosimilar filgrastim product is March 8th, and Sandoz has said it will enter the U.S. market—and compete directly with Amgen's Neupogen® (filgrastim) product—as soon as it obtains FDA approval. The law forbids this. Sandoz seeks FDA licensure under a new statute, the BPCIA, that created an abbreviated approval pathway for "biosimilar" copies of previously licensed biologic products in which the biosimilar applicant references another's pre-existing biologics license, a reference that would otherwise be impossible without the license-holder's permission. *See* 42 U.S.C. § 262(k)(2)(A)(iii)(I); 21 C.F.R. 314.420. That statute imposes obligations on Sandoz and protections for Amgen: contemporaneous with the start of

FDA's consideration of Sandoz's application for biosimilar licensure, Sandoz was required to give Amgen a copy of Sandoz's BLA and information about how it manufactures its biosimilar filgrastim product, and thereafter to engage in a series of detailed exchanges to identify patents that would be at issue if Sandoz were to gain licensure and commence commercial activity in the U.S. *See* 42 U.S.C. § 262(l)(2)-(5). The information exchanges include detailed contentions regarding infringement, validity, and enforceability, and ultimately ensure that Amgen would have adequate time and information to seek a preliminary injunction after FDA licensure and before commencement of commercial activity. That exchange would have proceeded, concurrent with FDA's review of Sandoz's BLA, over some 230 days, culminating in a patent infringement action if necessary. Even after this 230-day period, the obligation to continue the exchanges for newly issued or licensed patents persists. If FDA licenses Sandoz's biosimilar product, the statute affords a further 180-day period before first commercial marketing to give the reference product sponsor (here, Amgen) time to seek preliminary injunctive relief. *See* 42 U.S.C. § 262(l)(8).

Sandoz has refused to comply with the Act. It intends to enjoy the full advantage of the BPCIA's abbreviated pathway and launch its product without having met any of its information-disclosure exchange and timing obligations under the Act. To be clear, Sandoz made a choice: it could have conducted the full complement of pre-clinical and clinical trials for all therapeutic uses on which it seeks FDA licensure, submitted the data from these trials to FDA in its own, full application, and thereby sought licensure without reference to Amgen's license. But Sandoz chose instead the advantages of the abbreviated pathway, including savings of time and cost, and less uncertainty. That decision had consequences, however, that Sandoz refuses to accept, and thus Sandoz has simply decided it does not have to comply with the BPCIA because, it says, the statute's information exchanges are "optional."

For the reasons set forth below and in the accompanying papers, the Court should enter an injunction restraining Sandoz from commercially manufacturing, using, offering to sell, or selling its biosimilar filgrastim product until the Court decides the parties' pending motions for

judgment on the pleadings and, if the Court resolves those motions in Amgen's favor, further restraining Sandoz until the parties are in the same position they would be in had Sandoz complied with the BPCIA (which steps are spelled out in detail in the accompanying Proposed Order). All of the factors favor the grant of an injunction here.

Likelihood of Success: Amgen seeks this preliminary injunction based on its contention that the BPCIA means exactly what it says. The information exchanges in 42 U.S.C. § 262(l)(2)(A) through (l)(5) are not, as Sandoz says, optional. They are mandatory, phrased repeatedly as what Sandoz "shall" do (but did not do) and what Amgen "shall" do (but could not do, because Amgen was denied that opportunity when Sandoz unilaterally determined not to comply with those portions of the BPCIA it found disadvantageous to it). The details of the parties' dispute are explored in the pending motions for judgment on the pleadings. In this brief we merely summarize for the Court's convenience, and address those elements of Amgen's section 17200 and conversion claims that are not addressed in those motions.

Irreparable Harm: The harm here is recognized in the BPCIA itself. Congress expressly forbade biosimilar applicants from putting reference product sponsors in the position in which Sandoz's lawlessness puts Amgen: facing entry of a biosimilar into the marketplace without the ability—the information and the time—to seek a preliminary injunction on the full and relevant breadth of its patent portfolio. That is why the Act specifically directs the disclosure of otherwise confidential information, directs the exchange of patent contentions, and provides time to seek a preliminary injunction before the marketplace is changed by commercial entry of the biosimilar product. As set forth in the accompanying declaration of Amgen's Stuart Watt, Amgen and its subsidiaries are the owners by assignment of more than 1,400 United States patents that have issued since 1998, many of which are directed to manufacturing and purification processes for recombinant proteins. Watt Decl. ¶ 3. Over 400 of Amgen's patents fall into U.S. Patent and Trademark Office's classes and subclasses that could include patents that might be relevant to the recombinant production and purification of filgrastim. *Id.* ¶ 4. While not all of the 400 patents would apply to Sandoz's biosimilar product, some of them

could cover the recombinant manufacture and purification of filgrastim in bacterial cells. *Id.* And there could be even more Amgen patents in other classes and subclasses that could be relevant to the production of Sandoz's biosimilar product or its use. *Id.* ¶ 5. Without reviewing Sandoz's BLA and manufacturing information, Amgen cannot assess which of its patents may apply (including Amgen's manufacturing patents) in order to assert those patents against Sandoz. *Id.* ¶ 6. That is exactly why subsection 262(l)(2)(A) required Sandoz to provide Amgen with not only its BLA but also "information that describes the process or processes used to manufacture the biological product that is the subject of such application." Sandoz, having withheld that information from Amgen for more than six months in the face of Amgen's assertion that Sandoz was in violation of the BPCIA and in the face of this lawsuit, continues to seek the benefit of the abbreviated regulatory approval pathway at Amgen's expense. Specifically, as alleged in Amgen's conversion claim, Sandoz is unlawfully using the safety, purity, and potency determination represented in Amgen's biological license for Neupogen® to gain licensure of Sandoz's own filgrastim product without Amgen's permission or compliance with the BPCIA. *See* Compl. ¶¶ 87-97. If Sandoz is permitted to launch its product without having provided the information and time to Amgen as the statute provides, Amgen will be irreparably harmed by losing the opportunity afforded it under the BPCIA to exercise its exclusionary patent rights and seek a preliminary injunction before Amgen is injured by the entry of Sandoz's biosimilar product. As alleged in Amgen's Complaint, the result of Sandoz's violating the BPCIA is the entry of Sandoz's biosimilar product to directly compete with Amgen, which causes Amgen's injury to its business and property. *Id.* ¶¶ 77-86.

The harm that Amgen faces is irreparable, as often befalls an innovator when a generic (or, here, a biosimilar) version of its product improperly comes on the market. As set forth in the declaration of University of Chicago economist Tomas Philipson, the harm that Amgen faces takes several forms, each irreparable and sufficient to support an injunction:

- **Harm to Research and Development:** Revenue from Amgen's commercial products funds Amgen's research into and development of potentially lifesaving

new treatments, which would be immediately, significantly, and irreversibly harmed if Sandoz's biosimilar filgrastim product were to draw sales away from Amgen's products. The delay or missed opportunity to conduct research or advance development of a product cannot be remedied by a later issued injunction or damage award. Sandoz's entry into the market also could cause the research and development projects of Amgen's highly skilled scientists to go unfunded, compounding the harm by creating risk of losing the scientists. *See* Philipson Decl. Ex. B ("Philipson Report") ¶¶ 20-59, 83-101. The law recognizes this as irreparable harm.

- **Harm to New Products In Their Infancy:** Amgen has recently launched or is poised to launch three new products that are all handled by the same salesforce that markets Neupogen®: (i) an on-body injector for Amgen's Neulasta® product (a long-acting version of filgrastim), which will eliminate the need for chemotherapy patients to return to the clinic the day after chemotherapy to receive their filgrastim treatment (i.e., Neulasta®, Neupogen, or Sandoz's biosimilar filgrastim product), but which requires significant time and effort to train doctors and nurses in its use; (ii) Tvec, a cancer-killing virus currently being studied for the treatment of melanoma and other cancers; and (iii) a new, first-line indication for Vectibix®, a treatment for colorectal cancer. *Id.* ¶¶ 53-54; Azelby Decl. ¶¶ 26-28. If Sandoz launches its biosimilar filgrastim product now, Amgen's sales force will be diverted to competing against Sandoz. They will not be able to devote their attention to these three new products, which are in the critical/sensitive launch stages and need their attention.

- **Price Erosion:** Sandoz's public statements about its pricing plans for its biosimilar filgrastim product suggest that Sandoz plans to harm the public interest while lining its own pockets, irreparably harming Amgen in the process. Sandoz may actually increase the amount that Medicare and private insurance pay, but in a way that also requires Amgen to cut its own prices to maintain market share. And Sandoz's pricing could cause oncologists to prescribe biosimilar filgrastim rather than Amgen's long-acting filgrastim product Neulasta®, causing Amgen to have to lower prices on Neulasta® as well. The price erosion for Neupogen® and Neulasta® would be effectively permanent and irrevocable. If Sandoz were

later compelled to leave the market to comply with the BPCIA, Amgen would be left in the position to accept effectively permanent and irrevocable price erosion, or to damage Amgen's ongoing relationship with its customers by taking a precipitous price increase resulting in irreparable loss of goodwill. *See generally* Philipson Report ¶¶ 49-105; Azelby Decl. ¶¶ 14-25.

- **Damage to Customer Relationships and Loss of Goodwill:** Sandoz's entry into the market may damage Amgen's ongoing relationship with its customers and result in an irreparable loss of goodwill. If Sandoz launches its biosimilar filgrastim and then the Court enters an injunction, Amgen's efforts to enforce its rights will be portrayed as trying to take a medicine off the market. And if Amgen then tries to raise its prices to where they were prior to Sandoz's wrongful entry, Amgen will further harm its goodwill in the market, particularly under reimbursement rules that would likely leave doctors without full reimbursement after the price increase. *See* Phillipson Report ¶¶ 51, 57-59, 93-105.

The Public Interest: We are a nation of laws. The public has no interest in permitting lawlessness. The BPCIA requires an orderly and predictable process for the resolution of patent disputes with the least disruption to the treatment of patients and the ongoing businesses of the companies involved. Sandoz's game of catch-me-if-you-can is a violation of federal and state law, and the uncertainty and disruption it injects into the process is not in the public interest. The public interest lies instead in a stable and predictable process (as set forth in the BPCIA) for resolving patent disputes so as to encourage the continued investment in R&D that produce such patents while also allowing for biosimilar applicants to launch their products after the process for resolving patent disputes has been followed. The public interest also lies in Amgen's successful introduction of new therapeutics, which Sandoz's unlawful activities threaten to impede. *See* Philipson Report ¶¶ 106-128.

Further, Sandoz has repeatedly suggested its biosimilar product is "lower-cost" and a "less expensive version" than Neupogen®. (Dkt. No. 45 at 1, 4, 7, 9, 20.) This is inconsistent with how Sandoz has indicated it may price its products. In the media, Sandoz has suggested it may not price biosimilar filgrastim product below Neupogen®. *See, e.g.*, Winters Decl. Ex. 1,

at 5. If Sandoz prices its product at or above Neupogen®, then Sandoz will be reimbursed at a higher cost to the government than Amgen's reference product. There is no public interest to lining Sandoz's pockets at the expense of the American public.

Balance of Equities: Amgen asks that Sandoz be compelled to follow the federal statute before they engage in commercial activity. The risk to Amgen of an unlawful launch by Sandoz is enormous and irreparable. Sandoz's purported interest, on the other hand, is in launching its product and making money. The risk to it of an injunction until, in the first instance, the court decides the motions it is currently scheduled to hear on March 2nd, is comparatively minor. If the Court rules in Amgen's favor, the risks to Sandoz of a further injunction are simply that it will have to do what the law requires it do. The balance of equities tips strongly in Amgen's favor.

STATEMENT OF FACTS

The parties' pending motions for judgment on the pleadings, (Dkt. Nos. 35, 45), describe in detail Sandoz's refusal to comply with the BPCIA, beginning with Sandoz's submission of its BLA to FDA under 42 U.S.C. § 262(k), the notification by FDA of acceptance of that BLA on July 7, 2014, Sandoz's immediate proposal that Amgen accept terms other than those set forth in 42 U.S.C. § 262(l) as a precondition to Sandoz providing a copy of its BLA to Amgen, Sandoz's July 25, 2014 declaration that it had opted not to provide Amgen with that BLA and manufacturing information within 20 days of FDA's notification of acceptance, as would have been required by 42 U.S.C. § 262(l)(2)(A), and Sandoz's repeated assertions that it provided notice of commercial marketing to Amgen under 42 U.S.C. § 262(l)(8)(A) in the summer of 2014, and thus that the 180-day period under that statute had already run, even though the statute provides that such notice may not be provided until the FDA has issued a license for the biosimilar product, which has not yet happened. (Dkt. No. 35 at 6-7.)

Rather than repeating that chronology, Amgen lays out below where the parties would be at this point in the Subsection 262(l) exchanges had Sandoz complied with the law at the time those obligations accrued, and responds to Sandoz's accusations of delay.

The But-For World in Which Sandoz Complied With the Law

This is what would have happened if Sandoz had complied with the BPCIA. While the FDA was, in parallel, reviewing Sandoz's BLA, and prior to Sandoz's anticipated date of FDA approval on March 8, 2015, all of this would have occurred:

- Sandoz would have provided Amgen with a copy of its BLA and manufacturing information on or before **Monday, July 28, 2014**. *See* 42 U.S.C. § 262(l)(2)(A).
- Amgen would have reviewed that information and provided to Sandoz a list of patents for which Amgen reasonably believes a claim of patent infringement could be asserted, as well as a list of those patents it would be willing to license, within 60 days, or on or before **Friday, September 26, 2014**. *See* 42 U.S.C. § 262(l)(3)(A).
- Sandoz would then have had until **November 25, 2014** to, if it chose, supplement the list of patents with others it believes could reasonably be asserted against it, and to provide for each patent (whether listed by Amgen or Sandoz) either a statement that it would remain off the market until the patent expires or a detailed statement describing, on a claim by claim basis, why the patent is unenforceable, invalid, or will not be infringed by the marketing of Sandoz's biosimilar filgrastim. *See* 42 U.S.C. § 262(l)(3)(B).
- Amgen would then have had sixty days, or until **January 26, 2015**, to respond with a claim by claim assertion of why Amgen believes that each patent will be infringed by Sandoz's biosimilar product and to respond to Sandoz's statements of invalidity and enforceability. *See* 42 U.S.C. § 262(l)(3)(C).
- Thereafter, the parties would have negotiated in good faith which listed patents, if any, should be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6). *See* 42 U.S.C. § 262(l)(4). If commenced immediately after the exchange above had been completed, the negotiations would have ended **February 11, 2015**.
- If the parties agreed, then Amgen would have had to bring—the statute says "shall bring"; the lawsuit is mandatory—a patent infringement suit on the agreed-on patents within 30 days, or approximately **March 13, 2015** depending on the start date of negotiations. *See* 42 U.S.C. § 262(l)(6)(A).

- If the parties had not agreed on the list of patents to be included in the (l)(6) lawsuit within fifteen days of negotiations commencing, then the parties would have followed the dispute-resolution procedures of subsection 262(l)(5), and would have arrived at a list of at least one patent to be included in the lawsuit within 5 additional days (**by February 16, 2015**), *see* 42 U.S.C. § 262(l)(5), and Amgen would have been compelled to bring the subsection (l)(6) lawsuit on the listed patents **by approximately March 18, 2015**.
- Once the FDA licensed Sandoz's biosimilar filgrastim, then Sandoz would have given notice to Amgen 180 days before the date of first commercial marketing under 42 U.S.C. § 262(l)(8)(A) and Amgen could have used that period to bring a preliminary injunction motion on any patent that was included in the parties' early exchanges of patents under 42 U.S.C. § 262(l)(3), as supplemented in accordance with 42 U.S.C. § 262(l)(7), but not designated for inclusion in the subsection (l)(6) lawsuit. *See* 42 U.S.C. § 262(l)(8)(A), (B).

The most remarkable thing about this but-for-world chronology is how it plays out in the real world: the parties would be almost done by now, before Sandoz's anticipated date of FDA approval on March 8, 2015. They would currently be negotiating the list of patents to be included in the subsection (l)(6) lawsuit. And if the FDA gives Sandoz a license for its product on March 8th, as may happen, Sandoz would give notice to Amgen 180 days before the date of first commercial marketing, and Amgen could seek a preliminary injunction in that period rather than imposing on the Court's limited resources for a preliminary injunction that gives force to the BPCIA in the first place. For each of those patents, Amgen would have received detailed non-infringement, invalidity, and unenforceability contentions from Sandoz, and would have prepared detailed infringement and validity/enforceability positions of its own. The preliminary injunction practice would have been orderly and informed and focused on the patents rather than the BPCIA.

Instead, Sandoz has sandbagged Amgen. It has refused to provide its BLA and manufacturing information, frustrating Amgen's ability to determine which of its many patents it can assert against Sandoz. And Sandoz intends to launch its product immediately upon FDA

licensure, rather than waiting the 180 days required by the law. That is why Amgen brings this motion for a preliminary injunction.

The Timing of Amgen's Motion

Sandoz has complained that Amgen has delayed filing this motion, and should have filed the motion in 2014. The fervor of the charge is exceeded by its inaccuracy. On January 15, 2015, the parties submitted a Joint Case Management Statement in which Sandoz states that it "expects that FDA approval of Sandoz's biosimilar product may occur as early as March 8, 2015, and Sandoz anticipates launch of its biosimilar product immediately thereafter." (Dkt. No. 40 at 4.) It was only in the negotiation of that joint statement, and specifically in an email the previous day, that Sandoz identified March 8th as a specific potential launch date. (Dkt. No. 51-1 ¶ 5.) By then, Amgen had already moved for partial judgment on the pleadings (which it did on January 6, 2015, *see* Dkt. No. 35), and that motion had a hearing date of February 12, 2015, nearly a month before Sandoz's proposed launch. The parties also discussed a preliminary injunction application with the Court at the CMC on January 22nd, and the Court expressed a desire to hear a preliminary injunction application simultaneously with the motion for judgment on the pleadings. But Sandoz not only opposed Amgen's motion on January 23, 2015, it cross-moved for judgment on the pleadings too (Dkt. No. 45.) The parties discussed the possibility of obviating the need for preliminary injunction proceedings by Sandoz agreeing to postpone the launch of its biosimilar product pending resolution of the BPCIA issues by this Court. (Dkt. No. 51-1 ¶ 8.) Those efforts were unsuccessful. (*Id.*) Amgen also asked if Sandoz would provide Amgen and the Court with five business days' notice before launch so that Amgen could seek emergency relief if needed. (*Id.* ¶ 11.) Sandoz did not agree. Accordingly, Amgen now brings this motion, seeking in the first instance a preliminary injunction until the Court can decide the parties' motions for judgment on the pleadings, and thereafter—if the Court agrees with Amgen's reading of the BPCIA—an injunction, as set forth in the accompanying Proposed Order, putting the parties where they would be had Sandoz

complied with the BPCIA. The Court ordered that the parties' motions for judgment on the pleadings and this motion for preliminary injunction be heard on March 2nd. (Dkt. No. 55.)

ARGUMENT

"A plaintiff seeking a preliminary injunction 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." *Winter* v. *Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Federal Circuit applies the law of the regional circuit (here, the Ninth Circuit) in reviewing the grant or denial of an injunction, which is an issue not unique to patent law. *See Allergan, Inc.* v. *Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013).

I. Amgen Is Likely to Succeed on the Merits of Its California Business and Professions Code and Conversion Claims

Counts One and Two of Amgen's Complaint rest in the first instance on an allegation that Sandoz has violated the BPCIA, by refusing to provide its BLA and manufacturing information under 42 U.S.C. § 262(l)(2)(A) and by providing notice of commercial marketing not after FDA approval, as the statute requires, *see* 42 U.S.C. § 262(l)(8)(A), but when it filed its BLA, rendering the 180-day notice period meaningless. *See Sandoz Inc.* v. *Amgen Inc.*, No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013). The parties' briefing on the cross-motions for judgment on the pleadings fully explores the statute, its plain text, and Sandoz's striking argument that it is free not to comply with the law because it does not want to comply. Amgen does not repeat that briefing here, and instead addresses its likelihood of succeeding at the remaining elements of its section 17200 claim (Count One) and its conversion claim (Count Two) if the Court agrees with Amgen's reading of the BPCIA.

A. Amgen Is Likely to Succeed on its California Business and Professions Code Claim

Sandoz's unlawful refusal to provide the information called for by 42 U.S.C. § 262(l)(2)(A) and premature notice of commercial marketing under subsection 262(l)(8)(A) are acts of unfair competition under section 17200. Unfair competition is "any unlawful, unfair or

fraudulent business act or practice[.]" Cal. Bus. & Prof. Code § 17200. As described in Amgen's motion for judgment on the pleadings, the "unlawful" prong of section 17200 "'borrows' violations of other laws and treats these violations, when committed pursuant to business activity, as unlawful practices independently actionable under section 17200 et seq . . . ." *Farmers Ins. Exch.* v. *Superior Court*, 2 Cal. 4th 377, 383 (1992). "Virtually any law-federal, state, or local-can serve as a predicate for a section 17200 action." *State Farm Fire & Casualty Co.* v. *Superior Court*, 45 Cal. App. 4th 1093, 1102–03 (1996) (abrogated on other grounds by *Cel–Tech Commc'ns, Inc.* v. *Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999)).

If the Court agrees with Amgen that Sandoz has violated the BPCIA and that this violation is sufficient to support a section 17200 claim, Amgen will also have to demonstrate standing under Cal. Bus. & Prof. Code § 17204 by proving that Amgen has "(1) suffered an injury in fact and (2) lost money or property as a result of the unfair competition." *Birdsong* v. *Apple, Inc.*, 590 F.3d 955, 959 (9th Cir. 2009). Lost money or property may be shown in "innumerable ways" including "hav[ing] a present or future property interest diminished" or "be[ing] required to enter into a transaction, costing money or property, that would otherwise have been unnecessary." *Kwikset Corp.* v. *Superior Court*, 51 Cal. 4th 310, 323 (2011). Here, Sandoz has diminished Amgen's present and future property interests and required the needless expenditure of funds. Sandoz made clear that it would not provide Amgen with its BLA and manufacturing information pursuant to 42 U.S.C. § 262(l)(2)(A) and said that Amgen would have to file suit in order to protect its rights. Amgen then did so, incurring the cost of this lawsuit, and the cost of this injunction motion, all of which would have been (and should have been) avoided by Sandoz's compliance with the law. And Amgen's future property interests are further reduced by the elements of irreparable harm (detailed below) that will befall Amgen if Sandoz launches its product without giving Amgen the time and information the BPCIA affords it to commence enforcement of its patents and to seek an injunction on any applicable patents before first commercial marketing of Sandoz's biosimilar filgrastim. Sandoz will harm Amgen

through premature competition, price erosion, loss of goodwill, lost research & development opportunities, the risk of losing uniquely qualified employees, and simply lost revenue. Any one of those is sufficient to sustain Amgen's burden of proving a likelihood of success on its Business and Competition Law claim.

B. Amgen Is Likely to Succeed on its Conversion Claim

To succeed on its conversion claim, Amgen must prove (1) its "ownership or right to possession of personal property," (2) Sandoz's "disposition of the property in a manner that is inconsistent with" Amgen's "property rights," and (3) "resulting damages." *Fremont Indem. Co.* v. *Fremont Gen. Corp.*, 148 Cal. App. 4th 97, 119 (2007). Three criteria must be met to recognize a property right: "First, there must be an interest capable of precise definition; second, it must be capable of exclusive possession or control; and third, the putative owner must have established a legitimate claim to exclusivity." *G.S. Rasmussen & Assocs., Inc.* v. *Kalitta Flying Serv., Inc.*, 958 F.2d 896, 903 (9th Cir. 1992).

Amgen's FDA license for Neupogen® meets these requirements: Amgen owns the biological product license to NEUPOGEN® (filgrastim). Winters Decl. Ex. 2, at 2; Winters Decl. Ex. 3. While the BPCIA permits Sandoz to make use of Amgen's FDA license for Neupogen® by reference to it, the right to this use comes with the obligation to provide Amgen with the information at the times dictated by 42 U.S.C. § 262(l). By instead using Amgen's BLA under the BPCIA without also complying with the information-exchange and timing provisions of that very statute, Sandoz used Amgen's FDA license in a manner inconsistent with Amgen's property rights.

In *Rasmussen*, the Ninth Circuit confirmed that this type of act is an act of conversion. There, Rasmussen held a Supplemental Type Certificate (STC) that allowed "an airplane owner to obtain an airworthiness certificate for a particular design modification [of an airplane] without the delay, burden and expense of proving to the FAA that a plane so modified will be safe." 958 F.2d at 903. The defendant, Kalitta, decided to modify a used passenger airplane to cargo use, "a use that would be uneconomical without the modification described in

Rasmussen's STC." *Id.* at 899. Kalitta, however, neither generated nor submitted the requisite information showing that modifications to his planes were safe, nor did Kalitta license the STC from Rasmussen. *Id.* at 899-900. Instead, Kalitta relied on Rasmussen's STC in his application to the FAA to secure an airworthiness certificate for itself, which the FAA then granted. *Id.*

The Ninth Circuit held that Rasmussen stated a claim for conversion based on Kalitta's improper use of Rasmussen's certificate to its own advantage because Rasmussen had a property right in the STC even though it "has value only because it helps secure a government privilege to do something that would otherwise be forbidden." *Id.* at 900-01 (emphasis omitted). "The time, money and effort Rasmussen devoted to obtaining his STC would largely be wasted but for the fact that they generated the data necessary to satisfy the requirements of the Federal Aviation Act and the Code of Federal Regulations." *Id.* at 901. Having determined that the government-issued STC was a property right, the Court found that Rasmussen asserted a valid claim for conversion. So, too, here, where Sandoz improperly uses Amgen's FDA license, Amgen has a valid claim for conversion.

The damages from Sandoz's violation of the BPCIA began immediately upon Sandoz's refusal to comply. Sandoz used Amgen's FDA license to its own advantage, but did not provide Amgen with a copy of its BLA or with information about how it manufactures its biosimilar filgrastim, depriving Amgen of the information needed to assess how to protect its patent rights and thus devaluing those patent rights. Amgen was forced to bear the cost of this lawsuit and this preliminary injunction motion to secure a ruling that Sandoz has to comply with the law, an expense that the existence of a system of laws is intended to avoid. And the damages to Amgen will only continue to grow and accelerate, as it suffers all of the forms of irreparable harm that are described below in Point III. Coupled with the expense that Sandoz's lawlessness has already cost Amgen, any one of these many categories of harm is sufficient to make out a likelihood of Amgen prevailing on its conversion claim.

II. The Balance of Equities Tips Strongly in Amgen's Favor

The balance of the equities strongly favors a preliminary injunction. If Sandoz launches before this Court can decide whether that launch is unlawful under the BPCIA, Sandoz will have unleashed the cascade of harms that the statute was designed to avoid and that Dr. Philipson details. Worse, from the perspective of the judicial system, Sandoz will have deprived this Court of the ability to provide a meaningful remedy. If, on the other hand, this Court grants the preliminary injunction requested but soon finds on the motion for judgment on the pleadings that Amgen's interpretation of the BPCIA is wrong, then the BPCIA will no longer be a bar to Sandoz launching its product. It will have been delayed to permit the Court to rule, but then it will get to launch. Given that the statute itself imposes such a delay, Sandoz should not be heard to complain about complying with the law. The equities all favor Amgen.

III. Amgen Will Be Irreparably Harmed if Sandoz Enters the Market in Violation of the BPCIA

Provided FDA licensure is obtained and maintained, Sandoz will eventually enter the market. But the entire purpose of section 262(l), "Patents," is to ensure that reference product sponsors like Amgen receive the information and the time they need to enforce their patent rights. Sandoz has hidden from Amgen its BLA and its manufacturing information, frustrating Amgen's ability to identify those patents in its portfolio that could reasonably be asserted against Sandoz's manufacture, use, offer for sale, sale, or import into the U.S. of its biosimilar filgrastim product. (The one patent that Amgen has asserted reads on a method of treatment, and Amgen does not yet know the indications for which Sandoz's product will ultimately be licensed.) The irreparable harm question here, then, is whether Amgen will be harmed by Sandoz marketing its biosimilar product now, rather than after (a) the statutory periods inherent in the BPCIA, which together total over 400 days, and (b) expiration of any patents that Sandoz infringes and Amgen could have asserted had Sandoz provided its BLA and manufacturing information.

Sandoz seeks to whitewash its disregard of the statute by asserting that the patents that cover Neupogen®'s composition of matter have long expired. That tells only the smallest part

of the story. As set forth in the accompanying declaration of Amgen's Stuart Watt, over 400 of Amgen's patents fall into U.S. Patent and Trademark Office's classes and subclasses that could include patents relevant to the recombinant purification or production of filgrastim. Watt Decl. ¶ 4. While not all 400 patents would apply to Sandoz's biosimilar product, some could cover the recombinant manufacture and purification of filgrastim in bacterial cells. *Id.* There could also be other Amgen patents in other classes and subclasses that could be relevant to the production of Sandoz's biosimilar product or its use. *Id.* ¶ 5. Without reviewing Sandoz's BLA and manufacturing information, Amgen cannot assess which patents it can assert against Sandoz. *Id.* ¶ 6. If Sandoz unlawfully launches its product without having provided the information and engaged in the processes that the BPCIA required, Amgen will be irreparably harmed by losing the statutory right to assess and enforce its patents for injunctive relief prior to commercial entry. "[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (citing multiple Supreme Court cases). The harm to Amgen is more than monetary, it comes in all the forms the cases recognize, and it is irreparable.

A. Disregarding the BPCIA Timeline Causes Irreparable Harm

The BPCIA expressly forbids Sandoz from putting Amgen in its current position. Sandoz is poised to launch a biosimilar version of Amgen's product, but Sandoz has hidden away the information that Congress mandated Sandoz provide so that Amgen could act against Sandoz, if necessary to protect Amgen's patent protected inventions.

Concurrent with FDA review of a biosimilar application, the BPCIA contemplates an orderly process to resolve patent disputes, starting with the subsection (k) applicant (here, Sandoz) providing its BLA and manufacturing information to the reference product sponsor (here, Amgen) within 20 days of the FDA's acceptance of the BLA. Without that information, the reference product sponsor is in the dark about fundamental facts needed to identify and select the patents that could reasonably be asserted against the biosimilar applicant: what are the

specific and relative amounts of the biologic's formulation? How is it made? How is it purified? How is it intended to be administered?

That is why the BPCIA mandates this early disclosure, followed by an exchange of the parties' respective patent positions, negotiations, and a lawsuit—a process that concludes with a 180-day period, after the FDA approves the application, for the reference product sponsor to seek a preliminary injunction, if warranted. The entire purpose of subsection 262(l) is to drive communication, negotiation, and—in the absence of resolution—orderly litigation with time for injunction practice.

If Sandoz launches its product without giving Amgen the required notice and without participating in the required information exchanges, Amgen is harmed—irreparably—by being foreclosed from seeking preliminary injunctive relief on its patents before the exclusionary right has been infringed. To be sure, Sandoz will have to produce its BLA and manufacturing information in discovery. But that is inherently too late for preliminary injunctive relief, and it works the very harm the statute is designed to avoid.

The Court should enjoin Sandoz from launching its product until it determines whether Amgen's or Sandoz's reading of the BPCIA is correct. If Amgen is correct, then Sandoz should be compelled to follow all of the provisions of that statute prior to commencing commercial marketing of its biosimilar filgrastim product. To permit Sandoz to launch without giving Amgen the protections of the BPCIA would irreparably harm Amgen. Once a "statutory entitlement has been lost, it cannot be recaptured." *Apotex, Inc.* v. *FDA*, Civ.A. 06-0627 JDB, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006), *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006).

B. Premature Competition From Sandoz Will Harm Amgen Irreparably

The accompanying report of Tomas Philipson substantiates the irreparable harm that Amgen faces if Sandoz enters the marketplace in violation of the BPCIA. *See generally* Philipson Report ¶¶ 15-19 (summary of opinions), 20-128. The result of Sandoz's unlawful conduct is that Amgen faces each of these independent forms of irreparable harm:

1. Irreparable Harm to Research and Development

Amgen—unlike Sandoz—is an innovator. It invests substantially to develop novel, potentially life-saving products through primary research and development. Revenue for that research comes from Amgen's commercial products, including Neupogen® and Neulasta®. That research will be immediately and irreversibly harmed if Sandoz's biosimilar filgrastim draws sales from Amgen's products. *See* Philipson Report ¶¶ 20-59, 83-101. The missed opportunities in research or development of a product could not be remedied later by an injunction or an award of damages. In addition, Sandoz's entry into the market could cause Amgen to have to lay off the highly skilled research and development scientists whose projects would now go unfunded. This is irreparable harm: "[D]amage caused by a loss in personnel and the impact this would have on [a] company are indeed significant and unquantifiable." *AstraZeneca LP* v. *Apotex, Inc.*, 623 F. Supp. 2d 579, 612 (D.N.J. 2009), *supplemented*, 623 F. Supp. 2d 615 (D.N.J. 2009) and *aff'd*, 633 F.3d 1042 (Fed. Cir. 2010).

In the preliminary injunction context, the law must guard against that outcome. In *Bio-Technology Gen. Corp.* v. *Genentech, Inc*., the Federal Circuit affirmed the finding of irreparable harm based in part on Genentech's being "required to reduce its research and development activities" and because of the loss of revenue that would occur absent an injunction. 80 F.3d 1553, 1566 (Fed. Cir. 1996). Another court noted that "a significant disruption or loss of research that otherwise would have been sponsored or completed by [plaintiff] as well as a scaling back of investment in research and development which otherwise would not have occurred" are losses that cannot be "adequately compensated by a monetary payment." *Eli Lilly & Co*. v. *Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 812 (S.D. Ind. 2009). Irreparable harm has also been found in the context of a permanent injunction when "a reduction of revenue would subsequently impact [a pharmaceutical company's] ability to allocate its resources to product development." *Pozen Inc.* v. *Par Pharm., Inc.*, 800 F. Supp. 2d 789, 824 (E.D. Tex. 2011) *aff'd*, 696 F.3d 1151 (Fed. Cir. 2012).

2. Irreparable Harm to New and Emerging Products

Amgen is launching or poised to launch three new products that, like Neupogen® and Neulasta®, are all handled by Amgen's Oncology Salesforce: (i) an on-body injector for Amgen's Neulasta® product, which launched last month and will allow chemotherapy patients not to have to return to the clinic the day after chemotherapy to receive Neulasta®; (ii) Tvec, a genetically-engineered cancer-killing virus currently being studied for the treatment of melanoma and other cancers, a product that is expected to launch later this year; and (iii) Vectibix®, which received approval for first-line treatment of colorectal cancer within the past year. The sales, marketing and educational support for products at the beginning of their lifecycle is crucial to the success, revenues and profits of these products, and is handled by the same salesforce that supports Amgen's Neupogen® and Neulasta® products.

In response to unlawfully premature Sandoz sales, Amgen would have to divert sales, marketing and educational support from these products to Neupogen® and Neulasta® to mitigate the risk of share loss and additional erosion in price. The on-body injector, for example, requires in-person training of the nurses who will put the injector on chemotherapy patients, training that will be hindered by the diversion of Amgen's sales force. Tvec, too, is expected to involve significant provider training. This diversion means that the new Amgen products will not be as successful as they otherwise would have been had there been an effective launch. The harm to Amgen from reduced revenues for the new products would likely be long-lasting. And, to the extent that the diversion of support from these new products to Neupogen® and Neulasta® would result in the ineffective use of these new products, or the failure of providers to adopt these products, public health could be harmed. *See* Philipson Report ¶¶ 49, 53-59, 83-93; Azelby Decl. ¶¶ 26-28.

The outcome that Sandoz's gambit seeks to achieve is particularly perverse given the enormous expense and risk that bringing a new therapeutic to market entails. As Dr. Philipson explains, only two out of every ten approved drugs ever recoup their R&D costs; it is the "blockbuster" therapeutics, such as Neupogen®, that enable biopharma companies to fund the highly uncertain R&D to bring new products to market. Philipson Report ¶¶ 32-36. The

funding for that effort will in part come from Neupogen® revenues streams. *Id.* ¶¶ 37-43. Sandoz's proposed course of action would divert those revenue streams, just as they were about to have their most pronounced effect: to introduce new therapeutics into the market.

In short, Sandoz's use of Amgen's biological license for Neupogen® to gain an FDA license to enter the marketplace in competition with Neupogen® would reallocate Neupogen® revenue to Sandoz not only at the expense of Amgen, but at the expense of patients awaiting the innovating new therapies Amgen seeks to provide. That is not an outcome the law should encourage, particularly in the preliminary injunction context.

3. Irreparable Price Erosion

Sandoz has not publicly stated precisely how it will price its biosimilar figrastim product. If Sandoz were to price lower than Neupogen®, this pricing would raise the concerns about price erosion that courts recognize as irreparable harm where generic drugs launch in contravention of patent rights and are later enjoined. *See Abbott Labs.* v. *Sandoz Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008). *See generally* Philipson Report ¶¶ 49-105; *see* Azelby Decl. ¶¶ 14-25. But during the Advisory Committee meeting with FDA in January, FDA reportedly asked Sandoz to confirm that it would price below Neupogen® and Sandoz refused: "Sandoz would not state it would price the product, . . . below Neupogen[®]." Winters Decl. Ex. 4, at 2. Instead, Sandoz equivocated with "[w]e can't say that the price will be less because in some situation[s] the price will be at parity." Winters Decl. Ex. 1, at 5. Sandoz has elsewhere suggested that it would not make the "mistake" it has previously made pricing follow-on biologic Omnitrope below the reference innovator's therapeutic. Winters Decl. Ex 5, at 1-2.

If Sandoz intends, as it has suggested, to price its product at the level of Neupogen®'s Wholesale Acquisition Cost, or WAC price, and then offer doctors discounts or rebates from that price, Sandoz will harm the public interest and irreparably harm Amgen in the process. As Professor Philipson explains, Medicare (and most private payors') reimbursement to doctors for oncology medications is at Average Selling Price ("ASP") plus 6% rather than the WAC price. However medications newly introduced into the marketplace won't have an ASP for 6-9 months

after launch, so Medicare uses the WAC price to set reimbursement in the meantime. If the WAC price of the newly introduced product is greater that the ASP price of the incumbent, Medicare pays more for the newly introduced product.

As an illustrative hypothetical, assume that Amgen's WAC for a vial of Neupogen® is $100 and its ASP is $85. A doctor pays Amgen $85 for a vial, and the doctor is paid $90 by Medicare to reimburse the doctor (because $90 = 106% of $85), and thus profits $5. Because Sandoz's product is new to the market, however, it will have no ASP for six to nine months. In the meantime, Medicare (and most private payors) will reimburse doctors at Sandoz's listed WAC price plus 6% of Amgen's ASP. If Sandoz prices at Amgen's WAC price, the doctor will pay Sandoz $100 for a vial, and receive $105 dollars from Medicare (because $100 + (6% of $85) = $105). The doctor will thus make the same $5, but Medicare will have to pay $15 more for Sandoz's product ($105) than for Neupogen® ($90). Then, to drive sales over the crucial first six months, Sandoz could offer rebates to the doctor of, hypothetically, $10. Now the doctor pays Sandoz $100 for the filgrastim biosimilar, receives $105 from Medicare to reimburse the cost of the medicine, and gets a $10 rebate back from Sandoz. The doctor has made $15 rather than the $5 she would get for prescribing Amgen's Neupogen®, while the government and the public (in the form of Medicare) have paid $15 instead of $5, and the patient has seen no additional therapeutic benefit for the added cost to Medicare. Amgen would then have to cut its own prices on Neupogen® or risk losing sales to Sandoz.

Indeed, as Professor Philipson explains, Amgen may also have to cut its prices on Neulasta®, the long-acting form of filgrastim. Philipson Report ¶¶ 71-78. Right now, Amgen strives to provide pricing and discounts that leave healthcare providers to make choices between Neulasta® and Neupogen® based on clinical considerations. Sandoz, lacking a long-acting product, will have the incentive to price its short-acting product in a manner that draws sales from patients currently receiving Neulasta®. To counteract the risk of losing share Amgen could have to cut the price of Neulasta® as well. The price erosion for Neupogen® and Neulasta® would be permanent and irrevocable, as Professor Philipson explains. *Id.* ¶¶ 94-97.

The law recognizes this price erosion as irreparable harm to Amgen. As one court noted, "price erosion" is a "type[] of harm that traditionally [has] qualified as not easily compensable by money damages." *Antares Pharma, Inc.* v. *Medac Pharma, Inc.*, Civ.A. 14-270 SLR, 2014 WL 3374614, at *8 (D. Del. July 10, 2014) *aff'd*, 771 F.3d 1354 (Fed. Cir. 2014). Another district court elaborated on this principle by describing "irreversible effects" when the introduction of a generic product led to less favorable tier pricing, including "difficulty persuading third-party payors to restore the original tier placement." *Sanofi-Synthelabo* v. *Apotex Inc.*, 488 F. Supp. 2d 317, 342-43 (S.D.N.Y. 2006) *aff'd*, 470 F.3d 1368 (Fed. Cir. 2006).

4. Irreparable Damage to Consumer Relationships and Goodwill

Sandoz's premature entry into the market may irreparably damage Amgen's relationship with its customers and goodwill. *See* Philipson Report ¶¶ 51, 57-59, 93-105. If Sandoz launches its biosimilar filgrastim and the Court then enters an injunction, Amgen's enforcing its rights will be portrayed as taking a medicine off the market. If Amgen tries to raise its prices to their level before Sandoz's wrongful entry, Amgen's goodwill in the market will be further harmed, particularly where reimbursement rules would likely provide doctors less than full reimbursement for the new cost of Medicare after the price has been restored. In the context of patent litigation, "[t]here is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer." *Celsis In Vitro, Inc.* v. *CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Here too, there is no effective way to quantify the effect of Sandoz's entry into the market on Amgen's reputation—all the more reason to conclude the harm is irreparable.

IV. The Public Interest Favors the Entry of an Injunction

Sandoz wants to disregard a statute enacted to govern commercial behavior in an area as important to the national economy as healthcare. There is an overriding public interest in barring Sandoz from doing so that should be dispositive. *See* Philipson Report ¶¶ 106-128.

Makers of generic drugs argue that the public interest weighs against an injunction because lower priced generics are good for society. Sandoz has continued that tradition in this case by repeatedly suggesting that its biosimilar product is "lower-cost" and a "less expensive version" than Neupogen®. (Dkt. No. 45 at 1, 4, 7, 9, 20.) Courts actually reject that argument because, as the Federal Circuit observed in affirming a preliminary injunction, there is a strong public interest in encouraging investment in drug development, and that fact that a copyist may sell at a lower price does not override that important concern. *Sanofi-Synthelabo* v. *Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2006). Likewise, just as selling a lower-priced copy does not justify the disregard of the statutory ability to exclude that a patent confers, *Pfizer, Inc.* v. *Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005), selling a lower-priced copy cannot justify the wholesale disregard of the federal statutory scheme that provides the innovator with the right to assess and then assert the appropriate patents—and provides the court with the ability to assess those patent disputes in orderly fashion.

Here, though, Sandoz should not be heard to argue anything about the public interest. It has suggested publicly that it will price its biosimilar filgrastim product at or above Amgen's Wholesale Acquisition Cost for Neupogen®. Offering a biosimilar copy of an existing product at a higher cost to Medicare is not benefitting the public.

Finally, there are additional important equitable considerations in this case: Sandoz's unlawful activities threaten to impede Amgen's successful introduction of therapeutics into the market, including an on-body injector for Neulasta® which can be implanted on chemotherapy patients at the time of their chemotherapy, thus removing the need for patients to return to oncology clinics the day after chemotherapy. Surely the public interest favors the use of the Court's equitable powers to allow new therapeutics to come to market unimpeded.

V. Amgen Should Have to Post At Most a Nominal Bond

The Court has wide discretion in setting a bond amount, including no bond at all. Sandoz bears the burden of showing that it will suffer damages from a wrongfully entered preliminary injunction. *See Conn. Gen. Life Ins. Co.* v. *New Images of Beverly Hills*, 321 F.3d

878, 882-83 (9th Cir. 2003). The Ninth Circuit has recognized that in cases involving the public interest, it is appropriate to require only a nominal bond or no bond at all. *See Save Our Sonoran, Inc.* v. *Flowers*, 408 F.3d 1113, 1126 (9th Cir. 2005); *Van De Kamp* v. *Tahoe Reg'l Planning Agency*, 766 F.2d 1319, 1325-26 (9th Cir. 1985). A bond provides a remedy for defendants if an injunction is improperly issued, and the defendant's remedy is then limited to the amount of the bond.

This case involves a public interest: it is about the willful violation of federal law. The biosimilar industry is waiting to see the outcome of this case, as the Court's decisions on this motion and the co-pending 12(c) motions may affect and perhaps set strategy for that industry.

Moreover, Amgen asks for very limited relief: that Sandoz not be permitted to launch its biosimilar filgrastim product while the Court considers the co-pending 12(c) motion, and if the Court resolves those motions in Amgen's favor, thereafter until Sandoz has completed the information exchanges and commercial-marketing notice required by the BPCIA. For at least the period until the Court rules on the pending 12(c) motions, Sandoz can articulate no damages; it has not even received FDA licensure yet, nor publicly announced its selling price, nor lost so much as a single sale. For that period, then, Amgen respectfully submits that the injunction should issue without bond, or with a nominal bond. Amgen will of course be prepared to discuss a larger bond should the Court issue a longer injunction and should Sandoz demonstrate harm that would befall it from such an injunction.

CONCLUSION

The Court should grant a preliminary injunction restraining Sandoz from engaging in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of its biosimilar filgrastim product:

(1) until the Court decides the parties' motions for judgment on the pleadings and,

(2) if the Court resolves those motions in Amgen's favor, until, as set forth in detail in the accompanying Proposed Order, the parties have been placed in the position they would be in had Sandoz complied with the BPCIA.

Date: February 5, 2015

/s/ Vernon M. Winters

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

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

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

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