

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

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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.

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

9 **PRELIMINARY STATEMENT**

10 Amgen brings this motion for a preliminary injunction to prevent Sandoz from entering
11 the U.S. market with a biosimilar filgrastim product, which could happen as soon as March
12 8th. Because Sandoz's market entry will be unlawful and will irreparably harm Amgen, and
13 because the public interest and the equities favor an injunction to stop that unlawful entry and
14 prevent that irreparable harm, the Court should enter an injunction. That injunction should last
15 until the Court decides the parties' pending motions for judgment on the pleadings, set to be
16 argued along with this motion on March 2nd, and should continue thereafter if the Court agrees
17 with Amgen's reading of the plain text of the applicable law.

18 This case is about what may be the first FDA approved "biosimilar," roughly akin to a
19 generic but for a biologic product, not a small-molecule drug. Sandoz's estimated FDA
20 approval date for its biosimilar filgrastim product is March 8th, and Sandoz has said it will enter
21 the U.S. market—and compete directly with Amgen's Neupogen® (filgrastim) product—as
22 soon as it obtains FDA approval. The law forbids this. Sandoz seeks FDA licensure under a
23 new statute, the BPCIA, that created an abbreviated approval pathway for "biosimilar" copies of
24 previously licensed biologic products in which the biosimilar applicant references another's pre-
25 existing biologics license, a reference that would otherwise be impossible without the license-
26 holder's permission. *See* 42 U.S.C. § 262(k)(2)(A)(iii)(I); 21 C.F.R. 314.420. That statute
27 imposes obligations on Sandoz and protections for Amgen: contemporaneous with the start of
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1 FDA's consideration of Sandoz's application for biosimilar licensure, Sandoz was required to
2 give Amgen a copy of Sandoz's BLA and information about how it manufactures its biosimilar
3 filgrastim product, and thereafter to engage in a series of detailed exchanges to identify patents
4 that would be at issue if Sandoz were to gain licensure and commence commercial activity in
5 the U.S. *See* 42 U.S.C. § 262(1)(2)-(5). The information exchanges include detailed contentions
6 regarding infringement, validity, and enforceability, and ultimately ensure that Amgen would
7 have adequate time and information to seek a preliminary injunction after FDA licensure and
8 before commencement of commercial activity. That exchange would have proceeded,
9 concurrent with FDA's review of Sandoz's BLA, over some 230 days, culminating in a patent
10 infringement action if necessary. Even after this 230-day period, the obligation to continue the
11 exchanges for newly issued or licensed patents persists. If FDA licenses Sandoz's biosimilar
12 product, the statute affords a further 180-day period before first commercial marketing to give
13 the reference product sponsor (here, Amgen) time to seek preliminary injunctive relief. *See* 42
14 U.S.C. § 262(1)(8).

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

25 For the reasons set forth below and in the accompanying papers, the Court should enter
26 an injunction restraining Sandoz from commercially manufacturing, using, offering to sell, or
27 selling its biosimilar filgrastim product until the Court decides the parties' pending motions for
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1 judgment on the pleadings and, if the Court resolves those motions in Amgen’s favor, further
2 restraining Sandoz until the parties are in the same position they would be in had Sandoz
3 complied with the BPCIA (which steps are spelled out in detail in the accompanying Proposed
4 Order). All of the factors favor the grant of an injunction here.

5 **Likelihood of Success:** Amgen seeks this preliminary injunction based on its
6 contention that the BPCIA means exactly what it says. The information exchanges in 42 U.S.C.
7 § 262(1)(2)(A) through (1)(5) are not, as Sandoz says, optional. They are mandatory, phrased
8 repeatedly as what Sandoz “shall” do (but did not do) and what Amgen “shall” do (but could
9 not do, because Amgen was denied that opportunity when Sandoz unilaterally determined not to
10 comply with those portions of the BPCIA it found disadvantageous to it). The details of the
11 parties’ dispute are explored in the pending motions for judgment on the pleadings. In this brief
12 we merely summarize for the Court’s convenience, and address those elements of Amgen’s
13 section 17200 and conversion claims that are not addressed in those motions.

14 **Irreparable Harm:** The harm here is recognized in the BPCIA itself. Congress
15 expressly forbade biosimilar applicants from putting reference product sponsors in the position
16 in which Sandoz’s lawlessness puts Amgen: facing entry of a biosimilar into the marketplace
17 without the ability—the information and the time—to seek a preliminary injunction on the full
18 and relevant breadth of its patent portfolio. That is why the Act specifically directs the
19 disclosure of otherwise confidential information, directs the exchange of patent contentions, and
20 provides time to seek a preliminary injunction before the marketplace is changed by commercial
21 entry of the biosimilar product. As set forth in the accompanying declaration of Amgen’s Stuart
22 Watt, Amgen and its subsidiaries are the owners by assignment of more than 1,400 United
23 States patents that have issued since 1998, many of which are directed to manufacturing and
24 purification processes for recombinant proteins. Watt Decl. ¶ 3. Over 400 of Amgen’s patents
25 fall into U.S. Patent and Trademark Office’s classes and subclasses that could include patents
26 that might be relevant to the recombinant production and purification of filgrastim. *Id.* ¶ 4.
27 While not all of the 400 patents would apply to Sandoz’s biosimilar product, some of them
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1 could cover the recombinant manufacture and purification of filgrastim in bacterial cells. *Id.*
2 And there could be even more Amgen patents in other classes and subclasses that could be
3 relevant to the production of Sandoz's biosimilar product or its use. *Id.* ¶ 5. Without reviewing
4 Sandoz's BLA and manufacturing information, Amgen cannot assess which of its patents may
5 apply (including Amgen's manufacturing patents) in order to assert those patents against
6 Sandoz. *Id.* ¶ 6. That is exactly why subsection 262(1)(2)(A) required Sandoz to provide
7 Amgen with not only its BLA but also "information that describes the process or processes used
8 to manufacture the biological product that is the subject of such application." Sandoz, having
9 withheld that information from Amgen for more than six months in the face of Amgen's
10 assertion that Sandoz was in violation of the BPCIA and in the face of this lawsuit, continues to
11 seek the benefit of the abbreviated regulatory approval pathway at Amgen's expense.
12 Specifically, as alleged in Amgen's conversion claim, Sandoz is unlawfully using the safety,
13 purity, and potency determination represented in Amgen's biological license for Neupogen® to
14 gain licensure of Sandoz's own filgrastim product without Amgen's permission or compliance
15 with the BPCIA. *See* Compl. ¶¶ 87-97. If Sandoz is permitted to launch its product without
16 having provided the information and time to Amgen as the statute provides, Amgen will be
17 irreparably harmed by losing the opportunity afforded it under the BPCIA to exercise its
18 exclusionary patent rights and seek a preliminary injunction before Amgen is injured by the
19 entry of Sandoz's biosimilar product. As alleged in Amgen's Complaint, the result of Sandoz's
20 violating the BPCIA is the entry of Sandoz's biosimilar product to directly compete with
21 Amgen, which causes Amgen's injury to its business and property. *Id.* ¶¶ 77-86.

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

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

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

20 • **Price Erosion:** Sandoz's public statements about its pricing plans for its
21 biosimilar filgrastim product suggest that Sandoz plans to harm the public interest while lining
22 its own pockets, irreparably harming Amgen in the process. Sandoz may actually increase the
23 amount that Medicare and private insurance pay, but in a way that also requires Amgen to cut
24 its own prices to maintain market share. And Sandoz's pricing could cause oncologists to
25 prescribe biosimilar filgrastim rather than Amgen's long-acting filgrastim product Neulasta®,
26 causing Amgen to have to lower prices on Neulasta® as well. The price erosion for
27 Neupogen® and Neulasta® would be effectively permanent and irrevocable. If Sandoz were
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1 later compelled to leave the market to comply with the BPCIA, Amgen would be left in the
2 position to accept effectively permanent and irrevocable price erosion, or to damage Amgen's
3 ongoing relationship with its customers by taking a precipitous price increase resulting in
4 irreparable loss of goodwill. *See generally* Philipson Report ¶¶ 49-105; Azelby Decl. ¶¶ 14-25.

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

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

24 Further, Sandoz has repeatedly suggested its biosimilar product is "lower-cost" and a
25 "less expensive version" than Neupogen®. (Dkt. No. 45 at 1, 4, 7, 9, 20.) This is inconsistent
26 with how Sandoz has indicated it may price its products. In the media, Sandoz has suggested it
27 may not price biosimilar filgrastim product below Neupogen®. *See, e.g.*, Winters Decl. Ex. 1,
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1 at 5. If Sandoz prices its product at or above Neupogen®, then Sandoz will be reimbursed at a
2 higher cost to the government than Amgen’s reference product. There is no public interest to
3 lining Sandoz’s pockets at the expense of the American public.

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

12 **STATEMENT OF FACTS**

13 The parties’ pending motions for judgment on the pleadings, (Dkt. Nos. 35, 45), describe
14 in detail Sandoz’s refusal to comply with the BPCIA, beginning with Sandoz’s submission of its
15 BLA to FDA under 42 U.S.C. § 262(k), the notification by FDA of acceptance of that BLA on
16 July 7, 2014, Sandoz’s immediate proposal that Amgen accept terms other than those set forth
17 in 42 U.S.C. § 262(l) as a precondition to Sandoz providing a copy of its BLA to Amgen,
18 Sandoz’s July 25, 2014 declaration that it had opted not to provide Amgen with that BLA and
19 manufacturing information within 20 days of FDA’s notification of acceptance, as would have
20 been required by 42 U.S.C. § 262(l)(2)(A), and Sandoz’s repeated assertions that it provided
21 notice of commercial marketing to Amgen under 42 U.S.C. § 262(l)(8)(A) in the summer of
22 2014, and thus that the 180-day period under that statute had already run, even though the
23 statute provides that such notice may not be provided until the FDA has issued a license for the
24 biosimilar product, which has not yet happened. (Dkt. No. 35 at 6-7.)

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

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

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

4 • Sandoz would have provided Amgen with a copy of its BLA and manufacturing
5 information on or before **Monday, July 28, 2014**. *See* 42 U.S.C. § 262(1)(2)(A).

6 • Amgen would have reviewed that information and provided to Sandoz a list of
7 patents for which Amgen reasonably believes a claim of patent infringement could be asserted,
8 as well as a list of those patents it would be willing to license, within 60 days, or on or before
9 **Friday, September 26, 2014**. *See* 42 U.S.C. § 262(1)(3)(A).

10 • Sandoz would then have had until **November 25, 2014** to, if it chose, supplement
11 the list of patents with others it believes could reasonably be asserted against it, and to provide
12 for each patent (whether listed by Amgen or Sandoz) either a statement that it would remain off
13 the market until the patent expires or a detailed statement describing, on a claim by claim basis,
14 why the patent is unenforceable, invalid, or will not be infringed by the marketing of Sandoz's
15 biosimilar filgrastim. *See* 42 U.S.C. § 262(1)(3)(B).

16 • Amgen would then have had sixty days, or until **January 26, 2015**, to respond
17 with a claim by claim assertion of why Amgen believes that each patent will be infringed by
18 Sandoz's biosimilar product and to respond to Sandoz's statements of invalidity and
19 enforceability. *See* 42 U.S.C. § 262(1)(3)(C).

20 • Thereafter, the parties would have negotiated in good faith which listed patents,
21 if any, should be the subject of an action for patent infringement under 42 U.S.C. § 262(1)(6).
22 *See* 42 U.S.C. § 262(1)(4). If commenced immediately after the exchange above had been
23 completed, the negotiations would have ended **February 11, 2015**.

24 • If the parties agreed, then Amgen would have had to bring—the statute says
25 “shall bring”; the lawsuit is mandatory—a patent infringement suit on the agreed-on patents
26 within 30 days, or approximately **March 13, 2015** depending on the start date of negotiations.
27 *See* 42 U.S.C. § 262(1)(6)(A).
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1 • If the parties had not agreed on the list of patents to be included in the (l)(6)
2 lawsuit within fifteen days of negotiations commencing, then the parties would have followed
3 the dispute-resolution procedures of subsection 262(l)(5), and would have arrived at a list of at
4 least one patent to be included in the lawsuit within 5 additional days (**by February 16, 2015**),
5 *see* 42 U.S.C. § 262(l)(5), and Amgen would have been compelled to bring the subsection (l)(6)
6 lawsuit on the listed patents **by approximately March 18, 2015**.

7 • Once the FDA licensed Sandoz's biosimilar filgrastim, then Sandoz would have
8 given notice to Amgen 180 days before the date of first commercial marketing under 42 U.S.C.
9 § 262(l)(8)(A) and Amgen could have used that period to bring a preliminary injunction motion
10 on any patent that was included in the parties' early exchanges of patents under 42 U.S.C.
11 § 262(l)(3), as supplemented in accordance with 42 U.S.C. § 262(l)(7), but not designated for
12 inclusion in the subsection (l)(6) lawsuit. *See* 42 U.S.C. § 262(l)(8)(A), (B).

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

25 Instead, Sandoz has sandbagged Amgen. It has refused to provide its BLA and
26 manufacturing information, frustrating Amgen's ability to determine which of its many patents
27 it can assert against Sandoz. And Sandoz intends to launch its product immediately upon FDA
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1 licensure, rather than waiting the 180 days required by the law. That is why Amgen brings this
2 motion for a preliminary injunction.

3 **The Timing of Amgen’s Motion**

4 Sandoz has complained that Amgen has delayed filing this motion, and should have filed
5 the motion in 2014. The fervor of the charge is exceeded by its inaccuracy. On January 15,
6 2015, the parties submitted a Joint Case Management Statement in which Sandoz states that it
7 “expects that FDA approval of Sandoz’s biosimilar product may occur as early as March 8,
8 2015, and Sandoz anticipates launch of its biosimilar product immediately thereafter.” (Dkt.
9 No. 40 at 4.) It was only in the negotiation of that joint statement, and specifically in an email
10 the previous day, that Sandoz identified March 8th as a specific potential launch date. (Dkt. No.
11 51-1 ¶ 5.) By then, Amgen had already moved for partial judgment on the pleadings (which it
12 did on January 6, 2015, *see* Dkt. No. 35), and that motion had a hearing date of February 12,
13 2015, nearly a month before Sandoz’s proposed launch. The parties also discussed a
14 preliminary injunction application with the Court at the CMC on January 22nd, and the Court
15 expressed a desire to hear a preliminary injunction application simultaneously with the motion
16 for judgment on the pleadings. But Sandoz not only opposed Amgen’s motion on January 23,
17 2015, it cross-moved for judgment on the pleadings too (Dkt. No. 45.) The parties discussed the
18 possibility of obviating the need for preliminary injunction proceedings by Sandoz agreeing to
19 postpone the launch of its biosimilar product pending resolution of the BPCIA issues by this
20 Court. (Dkt. No. 51-1 ¶ 8.) Those efforts were unsuccessful. (*Id.*) Amgen also asked if
21 Sandoz would provide Amgen and the Court with five business days’ notice before launch so
22 that Amgen could seek emergency relief if needed. (*Id.* ¶ 11.) Sandoz did not agree.
23 Accordingly, Amgen now brings this motion, seeking in the first instance a preliminary
24 injunction until the Court can decide the parties’ motions for judgment on the pleadings, and
25 thereafter—if the Court agrees with Amgen’s reading of the BPCIA—an injunction, as set forth
26 in the accompanying Proposed Order, putting the parties where they would be had Sandoz
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1 complied with the BPCIA. The Court ordered that the parties' motions for judgment on the
2 pleadings and this motion for preliminary injunction be heard on March 2nd. (Dkt. No. 55.)

3 ARGUMENT

4 "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to
5 succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of
6 preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is
7 in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The
8 Federal Circuit applies the law of the regional circuit (here, the Ninth Circuit) in reviewing the
9 grant or denial of an injunction, which is an issue not unique to patent law. *See Allergan, Inc. v.*
10 *Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013).

11 **I. Amgen Is Likely to Succeed on the Merits of Its California Business and Professions** 12 **Code and Conversion Claims**

13 Counts One and Two of Amgen's Complaint rest in the first instance on an allegation
14 that Sandoz has violated the BPCIA, by refusing to provide its BLA and manufacturing
15 information under 42 U.S.C. § 262(1)(2)(A) and by providing notice of commercial marketing
16 not after FDA approval, as the statute requires, *see* 42 U.S.C. § 262(1)(8)(A), but when it filed
17 its BLA, rendering the 180-day notice period meaningless. *See Sandoz Inc. v. Amgen Inc.*, No.
18 C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013). The parties' briefing on the
19 cross-motions for judgment on the pleadings fully explores the statute, its plain text, and
20 Sandoz's striking argument that it is free not to comply with the law because it does not want to
21 comply. Amgen does not repeat that briefing here, and instead addresses its likelihood of
22 succeeding at the remaining elements of its section 17200 claim (Count One) and its conversion
23 claim (Count Two) if the Court agrees with Amgen's reading of the BPCIA.

24 **A. Amgen Is Likely to Succeed on its California Business and** 25 **Professions Code Claim**

26 Sandoz's unlawful refusal to provide the information called for by 42 U.S.C.
27 § 262(1)(2)(A) and premature notice of commercial marketing under subsection 262(1)(8)(A) are
28 acts of unfair competition under section 17200. Unfair competition is "any unlawful, unfair or

1 fraudulent business act or practice[.]” Cal. Bus. & Prof. Code § 17200. As described in
2 Amgen’s motion for judgment on the pleadings, the “unlawful” prong of section 17200
3 “‘borrows’ violations of other laws and treats these violations, when committed pursuant to
4 business activity, as unlawful practices independently actionable under section 17200 et
5 seq” *Farmers Ins. Exch. v. Superior Court*, 2 Cal. 4th 377, 383 (1992). “Virtually any
6 law-federal, state, or local-can serve as a predicate for a section 17200 action.” *State Farm Fire*
7 *& Casualty Co. v. Superior Court*, 45 Cal. App. 4th 1093, 1102–03 (1996) (abrogated on other
8 grounds by *Cel–Tech Commc’ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180
9 (1999)).

10 If the Court agrees with Amgen that Sandoz has violated the BPCIA and that this
11 violation is sufficient to support a section 17200 claim, Amgen will also have to demonstrate
12 standing under Cal. Bus. & Prof. Code § 17204 by proving that Amgen has “(1) suffered an
13 injury in fact and (2) lost money or property as a result of the unfair competition.” *Birdsong v.*
14 *Apple, Inc.*, 590 F.3d 955, 959 (9th Cir. 2009). Lost money or property may be shown in
15 “innumerable ways” including “hav[ing] a present or future property interest diminished” or
16 “be[ing] required to enter into a transaction, costing money or property, that would otherwise
17 have been unnecessary.” *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323 (2011). Here,
18 Sandoz has diminished Amgen’s present and future property interests and required the needless
19 expenditure of funds. Sandoz made clear that it would not provide Amgen with its BLA and
20 manufacturing information pursuant to 42 U.S.C. § 262(l)(2)(A) and said that Amgen would
21 have to file suit in order to protect its rights. Amgen then did so, incurring the cost of this
22 lawsuit, and the cost of this injunction motion, all of which would have been (and should have
23 been) avoided by Sandoz’s compliance with the law. And Amgen’s future property interests are
24 further reduced by the elements of irreparable harm (detailed below) that will befall Amgen if
25 Sandoz launches its product without giving Amgen the time and information the BPCIA affords
26 it to commence enforcement of its patents and to seek an injunction on any applicable patents
27 before first commercial marketing of Sandoz’s biosimilar filgrastim. Sandoz will harm Amgen
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1 through premature competition, price erosion, loss of goodwill, lost research & development
2 opportunities, the risk of losing uniquely qualified employees, and simply lost revenue. Any
3 one of those is sufficient to sustain Amgen's burden of proving a likelihood of success on its
4 Business and Competition Law claim.

5 **B. Amgen Is Likely to Succeed on its Conversion Claim**

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

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

22 In *Rasmussen*, the Ninth Circuit confirmed that this type of act is an act of conversion.
23 There, *Rasmussen* held a Supplemental Type Certificate (STC) that allowed "an airplane owner
24 to obtain an airworthiness certificate for a particular design modification [of an airplane]
25 without the delay, burden and expense of proving to the FAA that a plane so modified will be
26 safe." 958 F.2d at 903. The defendant, *Kalitta*, decided to modify a used passenger airplane to
27 cargo use, "a use that would be uneconomical without the modification described in
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1 Rasmussen’s STC.” *Id.* at 899. Kalitta, however, neither generated nor submitted the requisite
2 information showing that modifications to his planes were safe, nor did Kalitta license the STC
3 from Rasmussen. *Id.* at 899-900. Instead, Kalitta relied on Rasmussen’s STC in his application
4 to the FAA to secure an airworthiness certificate for itself, which the FAA then granted. *Id.*

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

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

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

1 The balance of the equities strongly favors a preliminary injunction. If Sandoz launches
2 before this Court can decide whether that launch is unlawful under the BPCIA, Sandoz will
3 have unleashed the cascade of harms that the statute was designed to avoid and that
4 Dr. Philipson details. Worse, from the perspective of the judicial system, Sandoz will have
5 deprived this Court of the ability to provide a meaningful remedy. If, on the other hand, this
6 Court grants the preliminary injunction requested but soon finds on the motion for judgment on
7 the pleadings that Amgen's interpretation of the BPCIA is wrong, then the BPCIA will no
8 longer be a bar to Sandoz launching its product. It will have been delayed to permit the Court to
9 rule, but then it will get to launch. Given that the statute itself imposes such a delay, Sandoz
10 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

13 Provided FDA licensure is obtained and maintained, Sandoz will eventually enter the
14 market. But the entire purpose of section 262(1), "Patents," is to ensure that reference product
15 sponsors like Amgen receive the information and the time they need to enforce their patent
16 rights. Sandoz has hidden from Amgen its BLA and its manufacturing information, frustrating
17 Amgen's ability to identify those patents in its portfolio that could reasonably be asserted
18 against Sandoz's manufacture, use, offer for sale, sale, or import into the U.S. of its biosimilar
19 filgrastim product. (The one patent that Amgen has asserted reads on a method of treatment,
20 and Amgen does not yet know the indications for which Sandoz's product will ultimately be
21 licensed.) The irreparable harm question here, then, is whether Amgen will be harmed by
22 Sandoz marketing its biosimilar product now, rather than after (a) the statutory periods inherent
23 in the BPCIA, which together total over 400 days, and (b) expiration of any patents that Sandoz
24 infringes and Amgen could have asserted had Sandoz provided its BLA and manufacturing
25 information.

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

16 **A. Disregarding the BPCIA Timeline Causes Irreparable Harm**

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

21 Concurrent with FDA review of a biosimilar application, the BPCIA contemplates an
22 orderly process to resolve patent disputes, starting with the subsection (k) applicant (here,
23 Sandoz) providing its BLA and manufacturing information to the reference product sponsor
24 (here, Amgen) within 20 days of the FDA's acceptance of the BLA. Without that information,
25 the reference product sponsor is in the dark about fundamental facts needed to identify and
26 select the patents that could reasonably be asserted against the biosimilar applicant: what are the
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1 specific and relative amounts of the biologic’s formulation? How is it made? How is it
2 purified? How is it intended to be administered?

3 That is why the BPCIA mandates this early disclosure, followed by an exchange of the
4 parties’ respective patent positions, negotiations, and a lawsuit—a process that concludes with a
5 180-day period, after the FDA approves the application, for the reference product sponsor to
6 seek a preliminary injunction, if warranted. The entire purpose of subsection 262(l) is to drive
7 communication, negotiation, and—in the absence of resolution—orderly litigation with time for
8 injunction practice.

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

15 The Court should enjoin Sandoz from launching its product until it determines whether
16 Amgen’s or Sandoz’s reading of the BPCIA is correct. If Amgen is correct, then Sandoz should
17 be compelled to follow all of the provisions of that statute prior to commencing commercial
18 marketing of its biosimilar filgrastim product. To permit Sandoz to launch without giving
19 Amgen the protections of the BPCIA would irreparably harm Amgen. Once a “statutory
20 entitlement has been lost, it cannot be recaptured.” *Apotex, Inc. v. FDA*, Civ.A. 06-0627 JDB,
21 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006), *aff’d*, 449 F.3d 1249 (D.C. Cir. 2006).

22 **B. Premature Competition From Sandoz Will Harm Amgen Irreparably**

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

1. Irreparable Harm to Research and Development

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

13 In the preliminary injunction context, the law must guard against that outcome. In *Bio-*
14 *Technology Gen. Corp. v. Genentech, Inc.*, the Federal Circuit affirmed the finding of
15 irreparable harm based in part on Genentech’s being “required to reduce its research and
16 development activities” and because of the loss of revenue that would occur absent an
17 injunction. 80 F.3d 1553, 1566 (Fed. Cir. 1996). Another court noted that “a significant
18 disruption or loss of research that otherwise would have been sponsored or completed by
19 [plaintiff] as well as a scaling back of investment in research and development which otherwise
20 would not have occurred” are losses that cannot be “adequately compensated by a monetary
21 payment.” *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 812 (S.D. Ind.
22 2009). Irreparable harm has also been found in the context of a permanent injunction when “a
23 reduction of revenue would subsequently impact [a pharmaceutical company’s] ability to
24 allocate its resources to product development.” *Pozen Inc. v. Par Pharm., Inc.*, 800 F. Supp. 2d
25 789, 824 (E.D. Tex. 2011) *aff’d*, 696 F.3d 1151 (Fed. Cir. 2012).

2. Irreparable Harm to New and Emerging Products

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

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

23 The outcome that Sandoz’s gambit seeks to achieve is particularly perverse given the
24 enormous expense and risk that bringing a new therapeutic to market entails. As Dr. Philipson
25 explains, only two out of every ten approved drugs ever recoup their R&D costs; it is the
26 “blockbuster” therapeutics, such as Neupogen®, that enable biopharma companies to fund the
27 highly uncertain R&D to bring new products to market. *Philipson Report* ¶¶ 32-36. The
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1 funding for that effort will in part come from Neupogen® revenues streams. *Id.* ¶¶ 37-43.
2 Sandoz’s proposed course of action would divert those revenue streams, just as they were about
3 to have their most pronounced effect: to introduce new therapeutics into the market.

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

9 3. Irreparable Price Erosion

10 Sandoz has not publicly stated precisely how it will price its biosimilar figrastim
11 product. If Sandoz were to price lower than Neupogen®, this pricing would raise the concerns
12 about price erosion that courts recognize as irreparable harm where generic drugs launch in
13 contravention of patent rights and are later enjoined. *See Abbott Labs. v. Sandoz Inc.*, 544 F.3d
14 1341, 1361-62 (Fed. Cir. 2008). *See generally* Philipson Report ¶¶ 49-105; *see* Azelby Decl.
15 ¶¶ 14-25. But during the Advisory Committee meeting with FDA in January, FDA reportedly
16 asked Sandoz to confirm that it would price below Neupogen® and Sandoz refused: “Sandoz
17 would not state it would price the product, . . . below Neupogen[®].” Winters Decl. Ex. 4, at 2.
18 Instead, Sandoz equivocated with “[w]e can’t say that the price will be less because in some
19 situation[s] the price will be at parity.” Winters Decl. Ex. 1, at 5. Sandoz has elsewhere
20 suggested that it would not make the “mistake” it has previously made pricing follow-on
21 biologic Omnitrope below the reference innovator’s therapeutic. Winters Decl. Ex 5, at 1-2.

22 If Sandoz intends, as it has suggested, to price its product at the level of Neupogen®’s
23 Wholesale Acquisition Cost, or WAC price, and then offer doctors discounts or rebates from
24 that price, Sandoz will harm the public interest and irreparably harm Amgen in the process. As
25 Professor Philipson explains, Medicare (and most private payors’) reimbursement to doctors for
26 oncology medications is at Average Selling Price (“ASP”) plus 6% rather than the WAC price.
27 However medications newly introduced into the marketplace won’t have an ASP for 6-9 months
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1 after launch, so Medicare uses the WAC price to set reimbursement in the meantime. If the
2 WAC price of the newly introduced product is greater than the ASP price of the incumbent,
3 Medicare pays more for the newly introduced product.

4 As an illustrative hypothetical, assume that Amgen's WAC for a vial of Neupogen® is
5 \$100 and its ASP is \$85. A doctor pays Amgen \$85 for a vial, and the doctor is paid \$90 by
6 Medicare to reimburse the doctor (because $\$90 = 106\%$ of $\$85$), and thus profits \$5. Because
7 Sandoz's product is new to the market, however, it will have no ASP for six to nine months. In
8 the meantime, Medicare (and most private payors) will reimburse doctors at Sandoz's listed
9 WAC price plus 6% of Amgen's ASP. If Sandoz prices at Amgen's WAC price, the doctor will
10 pay Sandoz \$100 for a vial, and receive \$105 dollars from Medicare (because $\$100 + (6\%$ of
11 $\$85) = \105). The doctor will thus make the same \$5, but Medicare will have to pay \$15 more
12 for Sandoz's product (\$105) than for Neupogen® (\$90). Then, to drive sales over the crucial
13 first six months, Sandoz could offer rebates to the doctor of, hypothetically, \$10. Now the
14 doctor pays Sandoz \$100 for the filgrastim biosimilar, receives \$105 from Medicare to
15 reimburse the cost of the medicine, and gets a \$10 rebate back from Sandoz. The doctor has
16 made \$15 rather than the \$5 she would get for prescribing Amgen's Neupogen®, while the
17 government and the public (in the form of Medicare) have paid \$15 instead of \$5, and the
18 patient has seen no additional therapeutic benefit for the added cost to Medicare. Amgen would
19 then have to cut its own prices on Neupogen® or risk losing sales to Sandoz.

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

1 The law recognizes this price erosion as irreparable harm to Amgen. As one court noted, “price
2 erosion” is a “type[] of harm that traditionally [has] qualified as not easily compensable by
3 money damages.” *Antares Pharma, Inc. v. Medac Pharma, Inc.*, Civ.A. 14-270 SLR, 2014 WL
4 3374614, at *8 (D. Del. July 10, 2014) *aff’d*, 771 F.3d 1354 (Fed. Cir. 2014). Another district
5 court elaborated on this principle by describing “irreversible effects” when the introduction of a
6 generic product led to less favorable tier pricing, including “difficulty persuading third-party
7 payors to restore the original tier placement.” *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp.
8 2d 317, 342-43 (S.D.N.Y. 2006) *aff’d*, 470 F.3d 1368 (Fed. Cir. 2006).

9 **4. Irreparable Damage to Consumer Relationships and Goodwill**

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

23 **IV. The Public Interest Favors the Entry of an Injunction**

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

1 Makers of generic drugs argue that the public interest weighs against an injunction
2 because lower priced generics are good for society. Sandoz has continued that tradition in this
3 case by repeatedly suggesting that its biosimilar product is “lower-cost” and a “less expensive
4 version” than Neupogen®. (Dkt. No. 45 at 1, 4, 7, 9, 20.) Courts actually reject that argument
5 because, as the Federal Circuit observed in affirming a preliminary injunction, there is a strong
6 public interest in encouraging investment in drug development, and that fact that a copyist may
7 sell at a lower price does not override that important concern. *Sanofi-Synthelabo v. Apotex, Inc.*,
8 470 F.3d 1368, 1383-84 (Fed. Cir. 2006). Likewise, just as selling a lower-priced copy does not
9 justify the disregard of the statutory ability to exclude that a patent confers, *Pfizer, Inc. v. Teva*
10 *Pharm., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005), selling a lower-priced copy cannot
11 justify the wholesale disregard of the federal statutory scheme that provides the innovator with
12 the right to assess and then assert the appropriate patents—and provides the court with the
13 ability to assess those patent disputes in orderly fashion.

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

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

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

25 The Court has wide discretion in setting a bond amount, including no bond at all.
26 Sandoz bears the burden of showing that it will suffer damages from a wrongfully entered
27 preliminary injunction. *See Conn. Gen. Life Ins. Co. v. New Images of Beverly Hills*, 321 F.3d
28

1 878, 882-83 (9th Cir. 2003). The Ninth Circuit has recognized that in cases involving the public
2 interest, it is appropriate to require only a nominal bond or no bond at all. *See Save Our*
3 *Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1126 (9th Cir. 2005); *Van De Kamp v. Tahoe Reg'l*
4 *Planning Agency*, 766 F.2d 1319, 1325-26 (9th Cir. 1985). A bond provides a remedy for
5 defendants if an injunction is improperly issued, and the defendant's remedy is then limited to
6 the amount of the bond.

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

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

20 CONCLUSION

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

24 (1) until the Court decides the parties' motions for judgment on the pleadings and,
25 (2) if the Court resolves those motions in Amgen's favor, until, as set forth in detail
26 in the accompanying Proposed Order, the parties have been placed in the position they would be
27 in had Sandoz complied with the BPCIA.

1 Date: February 5, 2015

2 /s/ Vernon M. Winters

3 Vernon M. Winters (SBN 130128)
4 SIDLEY AUSTIN LLP
5 555 California Street, Suite 2000
6 San Francisco, CA 94104
7 Telephone: (415) 772-1200
8 Facsimile: (415) 772-7400
9 vwinters@sidley.com

10 *Attorneys for Plaintiffs Amgen Inc. and*
11 *Amgen Manufacturing, Limited*

12 OF COUNSEL:

13 Nicholas Groombridge (*pro hac vice*)
14 Eric Alan Stone (*pro hac vice*)
15 Jennifer H. Wu (*pro hac vice*)
16 Jennifer Gordon
17 Peter Sandel (*pro hac vice*)
18 Michael T. Wu (*pro hac vice*)
19 PAUL, WEISS, RIFKIND, WHARTON
20 & GARRISON LLP
21 1285 Avenue of the Americas
22 New York, NY 10019
23 Telephone: (212) 373-3000
24 Facsimile: (212) 757-3990
25 ngroombridge@paulweiss.com

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