No. 2015-1499

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs-Appellants,

v.

SANDOZ INC.,

Defendant-Appellee.

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

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SANDOZ INC.'S STATEMENT REGARDING BOND FOR INJUNCTION PENDING APPEAL

NON-CONFIDENTIAL VERSION

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CERTIFICATE OF INTEREST

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

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

Sandoz Inc.

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

N/A

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

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

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

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

Dated: May 12, 2015 /s/ Deanne E. Maynard

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CONFIDENTIAL MATERIAL

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

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INTRODUCTION

But for this Court's injunction, Sandoz would be permitted to make its approved filgrastim drug product, Zarxio, available today to cancer patients. Sandoz incurred significant expense to obtain FDA approval of the first biosimilar filgrastim product in the United States, and the delay caused by the injunction likely will cause Sandoz substantial injury. These injuries will include losses due to: immediate lost sales, duplicated investments in the commercial infrastructure needed to market Zarxio, and the entry of additional competitors into the United States market. A substantial bond should be required to ensure that Sandoz can be fully compensated if it later is determined that the injunction was improvidently granted. Specifically, the Court should require Amgen to post a bond in a total amount that represents $460,000 per day multiplied by the maximum number of days this Court anticipates the injunction may be in place. Although Sandoz hopes a decision will issue quickly, it respectfully requests a bond amount calculated from May 11, 2015, until one year from the date of oral argument (June 3, 2016) to ensure that it is adequately protected. Such a bond would total $179.4 million. In addition, for whatever time period the Court uses to calculate the lump sum total of the bond, Sandoz requests that the Court also order that Amgen augment the bond amount by $3.22 million per week (7 times $460,000) thereafter, if the injunction remains in place beyond what the Court anticipates.

BACKGROUND

Filgrastim is administered primarily to address serious side effects from immunosuppressive chemotherapy. A58. While effective, it is very expensive, with a typical treatment costing $3,000 per chemotherapy cycle. A1017. In 2014, Amgen's sales of its filgrastim product Neupogen in the United States generated sales of $839 million with high gross and operating profit margins. A1025-A1026.

These economic returns are attracting multiple competitors. Amgen first marketed Neupogen in the United States in 1991. A5. Amgen enjoyed complete exclusivity in the short-acting filgrastim market until November 2013, when Teva launched an alternative form of filgrastim under the name Granix. A1030. Sandoz and at least two competitors plan to enter the market in 2015-2016, but Sandoz is substantially ahead of the others, which is key to market share once launched.

Sandoz has invested time and money over many years to develop its biosimilar filgrastim product, Zarxio. After passage of the Biological Price Competition and Innovation Act ("BPCIA"), Sandoz funded clinical and scientific studies and prepared its application. Sandoz succeeded in obtaining FDA approval on March 6, 2015. A1774-A1782. Others are seeking approval as well. A1061-A1063. Public announcements and both parties' internal forecasts predict the market entry of two additional short-acting biosimilar filgrastim products between the fourth quarter of 2015 and the second quarter of 2016. A1061-A1063.

In addition to developing Zarxio and working to obtain FDA approval, Sandoz has invested further to create a robust commercial infrastructure to make, market, and sell Zarxio in the United States. A1337-A1339. Sandoz manufactured and packaged inventory for sale. A1339. It hired a nationwide sales force. A1339; A1067-A1068. It invested in the people and resources needed to support doctors who will prescribe Zarxio and support reimbursement by the government and private payors. A1339; A1067-A1068. That infrastructure alone will cost Sandoz approximately [redacted] in 2015, and [redacted] in Q1 2016, even though it is enjoined. A1339; A1068. Those expenses will have to be repeated when Zarxio eventually launches. A1339; A1067-A1068.

The injunction also will cost Sandoz immediate lost sales and threatens its competitive position in the market. Sandoz will lose [redacted] in profits that it expected to earn from sales through May 2016. A1338-A1339. And Sandoz is at risk of losing the competitive advantage that it earned as the first approved biosimilar filgrastim product in the United States if it cannot launch its product in the second quarter of 2015. Uncontested expert testimony forecasts that the loss in profits from immediate sales and the change in competitive position would exceed [redacted] over the period 2015 to 2020. A1060-A1066.

Amgen has known since July 2014 of Sandoz's plan to launch Zarxio in the first half of 2015. A5; A1472-A1473. Yet Amgen waited to file suit until October

2014 and did not seek equitable relief until February 5, 2015. To permit an orderly evaluation by the courts, Sandoz voluntarily delayed its launch of Zarxio until May 11, 2015. But further delay will be very costly to Sandoz due to lost sales, stranded investments, and change in competitive dynamics described below. A substantial bond should be required to protect Sandoz against all of this potential harm in the event it later is determined that Sandoz has been wrongfully enjoined.

ARGUMENT

I. A SUBSTANTIAL BOND IS REQUIRED TO PROTECT AGAINST ALL THE HARM SANDOZ WILL SUFFER

Absent a bond large enough to cover all its potential harms, Sandoz will be without adequate recourse if it later is determined that it has been improvidently enjoined. *See Russell v. Farley*, 105 U.S. 433, 437 (1881); *W.R. Grace & Co. v. Local Union 759, Int'l Union of United Rubber, Cork, Linoleum & Plastic Workers of Am.*, 461 U.S. 757, 770 n.14 (1983) ("A party injured by the issuance of an injunction later determined to be erroneous has no action for damages in the absence of a bond."). Because a bond represents the only available relief, courts "should err on the high side" when setting the bond. *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000).

Here, the need for a substantial bond is particularly acute because of the high likelihood that Amgen's appeal – which involves no claim of patent infringement – will result in no injunctive relief and Sandoz will need to seek the bond's recourse.

First, for all the reasons given by the district court, Sandoz has not acted unlawfully by choosing a course expressly contemplated by the BPCIA. *See* Sandoz Merits Br. Parts I-II. ***Second***, even if Amgen's interpretation of the BPCIA were adopted, Amgen would be limited to that statute's exclusive recourse: an immediate suit for patent infringement. No injunctive relief is available under the BPCIA in the absence of a showing of patent infringement, which Amgen has not attempted to make. *See* Sandoz Merits Br. Part III. ***Third***, even if an injunction theoretically were available, Amgen cannot meet the standards for equitable relief. The district court twice found as fact that Amgen's alleged harms were "at best highly speculative." A18; A2080.

Finally, and most importantly, because the purpose of the bond is to protect Sandoz in the event the injunction was improvidently granted, the calculation of an appropriate bond amount must assume that Sandoz defeats any injunctive relief.

II. AN INJUNCTION WILL CAUSE SEVERE HARM TO SANDOZ

The harm to Sandoz from the injunction takes three forms: immediate lost sales, lost sales from a change in its competitive position, and stranded investments. A well-qualified economist, Professor Gordon Rausser from the University of California, Berkeley, calculated that these injuries would cause Sandoz [redacted] in damages if an injunction of up to 410 days, as originally requested by Amgen, were imposed. A1060-A1068. He based his calculation on

evidence from Amgen's and Sandoz's internal documents and information provided by Alexander Thole, an executive who leads Sandoz's commercial operations for Zarxio. A1337-A1339. Dr. Rausser's analysis is equivalent to a predicted harm of [redacted] per day.[1]

In twice briefing this issue in the district court, Amgen provided no evidence or analysis to rebut Dr. Rausser's calculations or Mr. Thole's sworn statements. Rather, Amgen proposed a "nominal" bond based on Sandoz's supposed "willful" BPCIA "violation[s]" and because the requested bond purportedly would "dwarf" those in other cases. A469; A1365. Neither argument justifies imposing on Sandoz the substantial risks of uncompensated injuries. To serve its purpose, the bond amount must assume Sandoz prevails. This Court has required substantial bonds. *E.g.*, *AstraZeneca LP v. Breath Ltd.*, No. 2015-1335 (Fed. Cir. Mar. 12, 2015), ECF No. 46 (requiring $130 million bond).

A. Sandoz Will Lose Immediate Sales In 2015 And 2016

Sandoz forecasted net sales of [redacted] in 2015 and 2016, yielding gross profit of [redacted]. A1338-A1339. Of this amount, [redacted] of the profits were forecast for the period between June 1, 2015 and May 31, 2016. Olson Decl. Ex. A. Notably, this period is *after* the end of Sandoz's voluntary

[1] [redacted] ÷ 410 days (the duration of the preliminary injunction sought by Amgen) = [redacted] per day.

deferral. Any bond should protect Sandoz for all the forecasted [redacted] in profits after June 1, 2015, because these losses are attributable to the injunction.[2]

B. Sandoz Will Lose Its Competitive Advantage

The consequences of the injunction will extend beyond 2015 and 2016, and the final losses will include but will exceed the [redacted] discussed above. Sandoz currently possesses a valuable competitive advantage because Zarxio would enter the market as the first biosimilar filgrastim product in the United States. This competitive advantage is expected to be short-lived. In February 2015, Apotex announced that it had filed an FDA application to market a second biosimilar for short-acting filgrastim, and Apotex is likely to market its biosimilar in the fourth quarter of 2015. A1061-A1063. Similarly, Sandoz and Amgen anticipate that Hospira (or another party) will enter the U.S. market in the second quarter of 2016. A1061-A1063. Thus, this Court's injunction threatens to undermine Sandoz's current, valuable market position.

Changes in the order in which products enter a market have dramatic financial implications for each participant. A1060. Zarxio's entry into a more crowded and competitive market following the end of an injunction will lead to

[2] Sandoz provided a monthly financial forecast for Zarxio (referred to as "GCSF" in the document). Olson Decl. Ex. A. The gross profit figure of [redacted] is the sum of the gross profit amounts for June 2015 through May 2016. This portion alone is the equivalent of [redacted] per day. [redacted] ÷ 366 days (June to May) = [redacted] per day.

lower sales and profits for Sandoz. A1061-A1063. Each day that Sandoz remains off the market, Zarxio loses a portion of its competitive advantage.

To identify these losses, Dr. Rausser used Sandoz's forecasts, his own independent analysis, and a well-studied academic model. A1060-A1066. He concluded that Sandoz will likely experience lost profits of [redacted], reflecting both immediate lost sales and the longer term losses from 2015 to 2020 if Zarxio entered the market after Apotex and Hospira. A1065-A1066.

C. Sandoz Will Have To Pay For Goods And Services It Cannot Use

Sandoz planned to launch Zarxio on May 11, 2015. Thus, it built a complete commercial operation and the infrastructure necessary to promote the product and support ongoing sales. A1339. While the injunction is in place, Sandoz will be forced to continue to pay these sales, marketing, regulatory, and administrative expenses related to Zarxio. A1339; A1066-A1068. But it will not be able to turn them into revenue or profits. A1339; A1066-A1068.

Equally important, these expenses cannot easily be used to support a later launch and cannot be avoided altogether. A1339; A1066-A1068. For example, a substantial percentage of the stranded costs include costs to retain the sales force that Sandoz had hired to sell Zarxio. A1339; A1067-A1068. These salespersons must wait idle or underutilized because Sandoz has no other biosimilar product to sell and no other filgrastim product to sell. A1067-A1068. Similarly, Sandoz will

incur regulatory and medical affairs costs to maintain FDA approval of the product and to respond to doctors' inquiries. A1339. But Sandoz will have to incur the same costs again once Zarxio launches. A1339. Marketing materials ready now will have to be revised or discarded. A1339; A1067-A1068.

After evaluating these issues, Mr. Thole and Dr. Rausser together determined that, through the first quarter of 2016, Sandoz's stranded investments would total [redacted]. A1339; A1068. Amgen has never offered any contrary estimate. Moreover, an extended injunction also is likely to force Sandoz to destroy [redacted]. A1339.[3]

D. The Combined Losses

In the district court, Dr. Rausser combined all the elements discussed above and concluded that Sandoz was at risk of losing [redacted] in damages for an injunction of up to 410 days, which is the equivalent of [redacted] per day. A1068.

The bond amount also should account for the fact that any forecast is inherently uncertain and that an inadequate bond risks leaving damages unrecoverable. A1068. Sandoz thus respectfully requests that this Court "should err on the high side" (*Mead Johnson*, 201 F.3d at 888) by 20% to ensure that Sandoz can be fully compensated for all losses that it later can prove resulted from

[3] These stranded expenses are the equivalent of a loss of [redacted] per day, i.e., [redacted] ÷ 366 days = [redacted].

the injunction. *See* A698. Increasing the daily rate by 20% yields [redacted] per day. For simplicity, Sandoz requests that the Court use a rate of $460,000 per day.

III. THIS COURT SHOULD ENTER A BOND TOTALING $460,000 PER DAY FOR THE EXPECTED LENGTH OF THE INJUNCTION

The Court's injunction will prevent sales of Zarxio from May 11, 2015 (the end date of Sandoz's voluntary agreement to forgo launch) until the injunction is lifted. Given the June 3 argument, Sandoz hopes a decision will issue quickly. Nonetheless, Sandoz needs sufficient protection to cover potential losses between May 11, 2015, and the as-yet-unknown date this Court lifts the injunction pending appeal. In addition, the bond order needs to specify a single lump sum, not just a daily amount, because of the practicalities of obtaining and posting supersedeas bonds. Sandoz submits that one year from argument, June 3, 2016, is a reasonable outside date for issuance of an opinion on the merits. Using that 390 days as the bond period, Sandoz respectfully requests a bond in the amount of $179.4 million.[4] Sandoz also requests that the Court order that the bond amount be augmented by $3.22 million per week (7 times $460,000) if the injunction remains beyond whatever date the Court uses to calculate the total bond amount, and that the Court require Amgen to supplement the bond if the injunction is not lifted by that date.

[4] $460,000 × 390 days = $179,400,000. Amgen cannot reasonably claim a lack of resources to provide sufficient security to protect Sandoz. Based on the sales of Neupogen and other biologics, Amgen has amassed a stockpile of cash and marketable securities totaling $27 billion. A1040.

Dated: May 12, 2015

Respectfully submitted,

/s/ Deanne E. Maynard

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No. 2015-1499

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

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DECLARATION OF ERIK J. OLSON IN SUPPORT OF SANDOZ INC.'S STATEMENT REGARDING BOND FOR INJUNCTION PENDING APPEAL

I, Erik J. Olson, hereby declare:

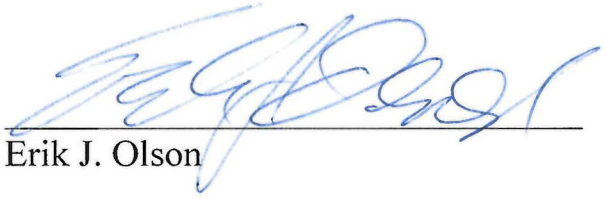
1. I am an attorney duly licensed to practice law in California, and I am admitted to practice before this Court. I am a partner with the law firm of Morrison & Foerster LLP, and counsel of record for defendant-appellee Sandoz Inc. ("Sandoz") in this action. I have personal knowledge of the facts stated herein or understand them to be true based on information provided to me by others and, if called as a witness, I could and would testify competently thereto.

2. Attached hereto as Exhibit A is a true and correct copy of a document produced by Sandoz with production numbers SDZ(56)0201443 through SDZ (56)0201444, and marked as Exhibit 20 at the deposition of Alexander Thole in the district court action. Exhibit A is a monthly financial forecast for Sandoz's biosimilar filgrastim product, Zarxio, for 2015 and 2016 and calculations regarding Sandoz's stranded costs.

3. Exhibit A contains highly confidential and competitively sensitive information regarding Sandoz's internal sales projections, cost and profit structure, and market analysis relating to Zarxio. Sandoz takes careful measures to maintain the confidentiality of this information and has consistently sought and obtained court orders in connection with this litigation to prevent its disclosure to competitors. Sandoz would suffer substantial harm if this information were disclosed to the public or Sandoz's competitors, which could use this information to Sandoz's disadvantage. For these reasons, Sandoz is submitting the publicly filed version of Exhibit A in redacted form.

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

Executed on this 12th day of May, 2015, in Palo Alto, California.



Erik J. Olson

EXHIBIT A

REDACTED IN FULL

APPENDIX TO SANDOZ INC.'S STATEMENT REGARDING BOND FOR INJUNCTION PENDING APPEAL

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Ex.	Description	Date Filed	Pages
9	Exhibit 13 to Supplemental Wu Declaration in Support of Amgen's Administrative Motion and Stipulated Request to File Supplementary Exhibit Relating to Amgen's Motion for a Preliminary Injunction: Sandoz's March 6, 2015 Letter [Dkt. No. 97-2]	3/12/2015	A1774-A1782
10	District Court's Order Denying Amgen's Motion for Injunction Pending Appeal [Dkt. No. 129]	4/15/2015	A2078-A2080

EXHIBIT 1

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

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

I. INTRODUCTION

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

permits the opposing party to commence patent litigation.

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

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

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

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

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

II. BACKGROUND

A. Relevant Provisions of the BPCIA

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

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

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

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

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

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

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

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

B. Procedural Background

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

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

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

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

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

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

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

III. LEGAL STANDARDS

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

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

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

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

IV. DISCUSSION

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

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

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

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

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

A. BPCIA: Disclosure and Negotiation Procedures

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

could not have chosen a more convoluted method of doing so. Moreover, Congress presumably could have been far more explicit had it intended for infringement suits to commence only once a biosimilar receives FDA approval. It was, therefore, not wrongful for Sandoz to give Amgen its 180 days' notice prior to first commercial marketing pursuant to subparagraph (*l*)(8)(A) in July 2014, in advance of receiving FDA approval.[8]

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

Because Sandoz's actions did not violate the BPCIA, it has committed no unlawful or wrongful predicate act to sustain Amgen's claims under the UCL and for conversion. A plaintiff may proceed under the UCL on three possible theories. First, "unlawful" conduct that violates another law is independently actionable under § 17200. *Cel–Tech Commc'ns, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999). Alternatively, a plaintiff may plead that defendants' conduct is "unfair" within the meaning of the several standards developed by the courts. *Id.* at 186–87, 83 (finding of unfairness must be "tethered to some legislatively declared policy or proof of some actual or threatened impact on competition"); *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (requiring, in consumer cases, "unfairness be tied to a 'legislatively declared' policy" or that the harm to consumers outweighs the utility of the challenged conduct). Finally, a plaintiff may challenge "fraudulent" conduct by showing that "members of the public are likely to be deceived" by the challenged business acts or practices. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009); *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 838 (2006) (elements of violation of UCL for "fraudulent" business practices are distinct from common law fraud). Amgen tethers its UCL claim to only the first theory, averring that Sandoz behaved unlawfully by violating both subsection (*l*)'s disclosure and negotiation procedures and paragraph (*l*)(8)(A)'s 180-day notice requirement. As shown above,

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

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

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

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

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

D. Sandoz's Counterclaims for Patent Noninfringement and Invalidity

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

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

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

E. Amgen's Motion for Preliminary Injunction

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

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

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

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

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

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

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

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

V. CONCLUSION

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

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

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

IT IS SO ORDERED.

Dated: March 19, 2015

RICHARD SEEBORG
United States District Judge

United States District Court
Northern District of California

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

EXHIBIT 2

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. _____ **COMPLAINT FOR PATENT INFRINGEMENT, CONVERSION, AND UNFAIR COMPETITION (CAL. BUS. & PROF. CODE § 17200)** **JURY TRIAL DEMANDED**

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

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

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

EXHIBIT 3

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 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

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.

EXHIBIT 4

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH,

Defendants.

Case No. 3:14-cv-04741-RS

SANDOZ INC.'S OPPOSITION TO AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION

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

The Honorable Richard Seeborg

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CONFIDENTIAL MATERIAL REDACTED

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

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

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

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

V. CONCLUSION

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

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

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

I, Gordon Rausser, declare as follows:

I. NATURE OF THE DISPUTE

1. This lawsuit involves the anticipated U.S. launch by Sandoz Inc. ("Sandoz") of the first biosimilar medication likely to be approved by the FDA under the terms of the Biologics Price Competition and Innovation Act ("BPCIA") which was enacted in March 2010.[1] The medication (known by the chemical name filgrastim and expected to be marketed in the U.S. under the name Zarxio) is biosimilar to a filgrastim product made by Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen"). Neupogen, referred to as "the reference product," has been sold by Amgen in the U.S. for more than 24 years and, pursuant to Amgen's repeated statements in SEC filings, Amgen's material U.S. patents for filgrastim (Neupogen) expired in December 2013.

2. I understand that the parties differ about the correct interpretation of the BPCIA. That Act sets forth a procedure by which the maker of a proposed biosimilar (applicant) and the maker of a reference drug (sponsor) can exchange information and ultimately limit the patents that may be asserted in litigation.[2] As I understand it, Amgen contends that this process (which takes a maximum of 230 days to complete) is mandatory and must precede marketing of the biosimilar. I further understand that Amgen contends a notice of commercial marketing to be

[1] Biologic therapies cover many different types of drug products including: vaccines, blood and blood components, allergenic, somatic cells, gene therapy, tissues, and recombinant therapeutic protein. According to the BPCIA, biologics are defined to be a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. §262(i)(1).
[2] These procedures are set forth in the BPCIA at 42 U.S.C. at §§262 (l)(2)-(6).

provided not later than180 days before the date of the first commercial marketing of the biosimilar, must be given *after* the biosimilar is approved by the FDA and *after* the maximum of 230 days devoted to the information exchange process discussed above. Sandoz, on the other hand, contends that the applicant does not have to use the exchange procedures stated in the statute, that the 180 day period for notice of commercial marketing can run concurrently with other time periods, and that the sponsor can bring suit on any patent that it owns if the applicant does not provide a copy of its application within 20 days of the application's acceptance by the FDA. I express no opinion about how the BPCIA should be interpreted.[3]

3. However, for purposes of the current analysis only, I presume that compliance with the BPCIA would require Sandoz to provide its application for Zarxio and that it would be a violation of the BPCIA for Sandoz to proceed with marketing for some period of time up to 410 days without following the procedures about which Amgen complains.

4. Amgen has moved for a preliminary injunction seeking to prevent Sandoz from selling Zarxio in the U.S. and requiring Sandoz to complete all elements of the exchange procedures stated above, and to give its notice of commercial marketing after FDA approval occurs and only after completion of all information exchange procedures. As I understand it, Amgen has alleged that Zarxio would infringe U.S. Patent 6,162,427 (the '427 patent), which

[3] I express no opinion about how the BPCIA should be interpreted or whether its terms have been complied with. However, I do note that the BPCIA gives twelve years of exclusivity to firms that obtain FDA approval for a new biologic product, regardless of whether they have any patent protection. 42 U.S.C. at §262 (k)(7)(A). This long period of exclusivity provides a powerful economic incentive for pharmaceutical firms such as Amgen to pursue biological drug development and addresses many of the claims regarding economic policy that Dr. Philipson makes. Dr. Philipson, however, was apparently unaware of this exclusivity period. Deposition of Tomas Philipson, February 13, 2015, at 131:4-132:1.

claims a specific method of use to treat a precisely defined condition, but does not rely on that patent as a basis for its preliminary injunction motion.

5. The motion raises numerous questions including: a) Amgen's probability of success on the merits (not addressed elsewhere in this Declaration), b) whether Amgen will suffer irreparable injury if an injunction is denied, c) whether the balance of hardships tips in favor of one party or the other, and 4) how the public interest will be affected by the grant or denial of an injunction.

6. I am an economist with considerable experience in quantifying the financial effects of competition, estimating patent infringement damages, and evaluating the pharmaceutical industry, including in the context of preliminary injunction motions. I have been retained by counsel for defendant Sandoz.

II. QUALIFICATIONS

7. I am the Robert Gordon Sproul Distinguished Professor at the University of California at Berkeley. I received a Ph.D. with Highest Honors from the University of California at Davis in 1971, and in 1972 I was awarded a Postdoctoral Fellowship in Economics and Statistics at the University of Chicago. I am an elected Fellow of the American Association for the Advancement of Science (1993), the American Statistical Association (1991), and the Agricultural & Applied Economics Association (1990). In 1987, I was a Fulbright Scholar in Australia.

8. In my academic career, I have held positions teaching economics and statistics at many universities including the University of Chicago, Harvard University, the University of California at Berkeley, University of Illinois, Iowa State University, the University of California

at Davis, and Hebrew University. I served as Dean of the College of Natural Resources at the University of California at Berkeley from 1994–2000, and have three times been selected as Chair of my academic department. I have published extensively in academic and professional journals on the application of statistical methods, market dynamics, industrial organization, environmental and resource economics, public policy, and futures and options. During my academic career, I have published more than 250 articles, books and book chapters. In addition, I have written more than 100 commissioned papers, governmental reports, and working papers. I have won 17 major awards and honors for my teaching and research.

9. I am the Editor of the Annual Review of Resource Economics. I am a past Associate Editor of the Journal of the American Statistical Association and the Journal of Economic Dynamics and Control, and a past Editor of the American Journal of Agricultural Economics. From 1986 to 1987, I was a Senior Economist at the President's Council of Economic Advisors with responsibility for finance, trade, and agriculture. While on leave from the University of California at Berkeley, I served as the Chief Economist at the Agency for International Development in Washington, D.C. from 1988 to 1990. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

10. In addition to my academic experience, I have served as an economic consultant to government agencies and private clients for more than thirty years. My work has focused on the application of economics and finance to complex legal and public policy disputes. I have extensive consulting experience in issues associated with economic damage determination, economic feasibility studies, unfair competition, market analysis, risk valuation, and statistical and econometric modeling. I often provide expert testimony in matters involving pharmaceutical products, patent infringement, commercial success, new product introduction, and damages

flowing from delayed entry or anticompetitive barriers to market entry. These engagements have included analyses of pharmaceutical pricing structures and practices, factors influencing sales success, and competition between pharmaceutical products. My work has required me to examine the economic operation of virtually every major class of drugs, including analgesics, anti-infectives, antidepressants, anti-hypertensives, cancer therapies, anti-secretory drugs, diabetes treatments, hormone replacement therapies and many others. A true and correct listing of my testimony over the last four years is attached as Exhibit B.

III. SCOPE OF ENGAGEMENT

11. I was retained by counsel for Sandoz to address from an economic perspective the following five issues:

- I was asked to review and evaluate the report submitted by Amgen's economic expert, Dr. Tomas Philipson;
- I was asked to evaluate the nature and extent of the economic injuries that may be suffered by Amgen if Sandoz has not complied with the BPCIA and sells (but should not have sold) Zarxio in the United States;
- I was asked to determine whether these economic harms, if any, could be remedied at the conclusion of the case by an award of money damages in Amgen's favor;
- I was asked to evaluate the potential economic injury to Sandoz if an injunction is issued. As part of this analysis, I was also asked to estimate the amount of a bond that would be necessary to assure Sandoz is able fully to recoup its damages in the

event an injunction is issued and Sandoz subsequently prevails in this court or on appeal;

- Finally, I was asked to evaluate whether the public interest is better served by the issuance or denial of a preliminary injunction.

12. I am being compensated for my services at the rate of $850 per hour. I have been supported in my work by the staff of OnPoint Analytics, Inc., an economic, statistical and financial consulting firm that also provides database services. The hourly billing rates of the individuals providing services range from $125 to $475, depending upon their experience and areas of expertise. No part of the compensation due or received is contingent upon the outcome of this litigation.

13. My role in this case has been to provide an economic and financial analysis, as opposed to a legal or policy analysis. In my experience, the quality of such work depends heavily upon analyzing empirical data that may prove or disprove a pre-conceived hypothesis. Accordingly, I have analyzed historical data regarding sales of filgrastim products (collectively referred to as granulocyte colony-stimulating factors, or the "G-CSF market") both here and in European countries, where the introduction of biosimilars has preceded the U.S. I have also had the benefit of reports from credible analysts evaluating the impact of biosimilar offerings. Over the last ten days, I have received and considered projections in which Amgen has modeled future sales and revenues and made forecasts regarding expected competition from biosimilars in the filgrastim market. Data on the uses of Amgen's sales force has also assisted me in evaluating the adequacy of that sales force to respond to Zarxio's planned entry. I have investigated possible price linkages between Neupogen and Amgen's long acting filgrastim product, Neulasta (also

known by its chemical name, peg-filgrastim), as well as new product introductions planned by Amgen. On the other side of the ledger, I have reviewed 2015 and 2016 projections prepared by Sandoz and compared them to my own view of what would likely transpire both with and without the proposed injunction. This quantitative data has been supplemented with reports, declarations and deposition testimony offered in this case as well as various documents (including Amgen internal business plans) produced in the course of discovery. A true and correct list of all of the information reviewed by me or my staff in the course of my analysis is attached hereto as Exhibit C.

IV. SUMMARY OF OPINIONS

14. After considering the information sources described above and conducting my own analysis, I have come to five conclusions. The basis for each of these opinions is described in detail in this Declaration and they are summarized here.

15. **Opinion 1: Evaluation of Dr. Philipson's Work.** Dr. Philipson's work on this matter is unsupported by any empirical analysis and is not tied to specific data-driven assessments of the filgrastim market, particularly how it has developed in the last 18 months and how it is likely to develop going forward. He has neither collected nor analyzed the information on which an economist would routinely rely in cases such as this. Instead, Dr. Philipson offers broad policy prescriptives that are not grounded in specific economic data. These policy recommendations, which are essential to his conclusions, ultimately reflect the view that large drug developers should be protected from competition for extended periods so they will be encouraged to generate new innovations. That policy perspective, however, is not the issue I have been asked to address and is a question that I understand Congress has already considered

and resolved in arriving at the terms of the BPCIA. My assignment was to analyze the filgrastim market and the harms Amgen or Sandoz would reasonably be expected to suffer, an exercise which must be grounded in empirical data. Dr. Philipson ignored recent market data as well as Amgen's own projections, and has performed virtually no quantitative analysis. In my opinion, his work does not meet the professional standards generally applied to an economic analysis of prospective financial harm from competition or restraints on competition.

16. **Opinion #2. Amgen will not suffer an irreparable injury**. Based on my analysis, Amgen will not suffer any form of irreparable harm from the alleged violations of the BPCIA. [redacted] A loss of revenue is by definition a harm that can be remedied by monetary compensation. Dr. Philipson, however, has offered a list of other potential injuries that are speculative and, in most cases, disproven by the empirical evidence. **First,** Dr. Philipson's estimates of possible Neupogen sales losses have no empirical or historical foundation, and depend on a self-described "guess" by one industry analyst. Further, an analysis of actual economic evidence strongly suggests that Amgen's separate product, Neulasta, would not be affected by the availability of Zarxio. To the contrary, historical experience with both products (Neupogen and Neulasta) rejects this speculation. **Second,** the losses to sales of Neupogen will not be large enough to have a significant impact on Amgen's operations and will not affect its R&D budget which could be funded entirely from existing cash resources if need be. It would be irrational to suppose that Amgen would abandon what it has otherwise deemed to be profitable research opportunities simply because it was making smaller profits on Neupogen. **Third,** the argument that Amgen sales representatives will be too distracted by Zarxio to effectively

promote Amgen's other products is unfounded. Amgen has a large sales force of professionals who respond daily to questions about competitors and must, as part of their routine responsibilities, distinguish the products they promote from other entrants. [redacted] **Fourth,** Dr. Philipson's concern that Amgen will suffer irreversible price erosion is based on speculation and disproven by historical experience. **Fifth,** the argument that Amgen will lose goodwill if Zarxio enters but is subsequently withdrawn from the market is based on conjecture. Other branded drugs that have forced generics off the market have been able to recover their market position. **Sixth,** Dr. Philipson's other forms of possible injury (which are not mentioned in Amgen's Brief in support of its motion) lack evidentiary support. These include the idea that drug developers find it difficult to raise money and, thus, their revenue streams should be specially protected. Amgen certainly has not found this to be so: its stock price has risen dramatically over the last several years, it has a market capitalization of $116.5 billion and it has one of the largest debt components among its peer group. There is no reason to believe its cost of capital will be affected by a revenue reduction from Neupogen sales. Indeed, as reflected in Amgen's own business plans and sales data, the market has long anticipated the entry of one or more biosimilar competitors for Neupogen and investors have nonetheless shown unabated enthusiasm for Amgen. Dr. Philipson similarly argues that, if an injunction is denied, Amgen's profit margins on Neupogen may decline and its operating costs may rise due to the smaller scale of corporate

operations. Given the relatively small current and expected share of Amgen revenue derived from Neupogen (less than 6% in 2014) this argument lacks financial logic. Further, makers of reference drugs often find that their costs go down and margins go up after generic (or, in this case, biosimilar) entry due to reduced expenditures on marketing the reference product. Amgen has already significantly withdrawn such support from Neupogen in hopes of shifting prescribers and patients to Neulasta before Zarxio's entry.

17. **Opinion #3. Adequacy of Money Damages.** [redacted] This is a form of injury that is measurable and compensable through an award of money damages. In addressing this issue, Dr. Philipson examines the wrong point in time. He argues that, as of *today*, there are too many unknowns to accurately estimate the future losses to Amgen. Instead, I understand the question to be whether damages will be determinable after a final judgment, once a violation of the BPCIA is proven, once patent infringement, if any, is proven, and once Zarxio has already entered the market. At that point, the history of sales reductions, market share changes and price adjustments will be fully known and recorded. The economic losses to Amgen under those circumstances would be computable. The fact that the parties may ultimately differ about the correct amount of such damages is no basis to conclude that they would be an inadequate remedy.

18. **Opinion #4. Injury to Sandoz.** Dr. Philipson fails fully to evaluate the losses that will be suffered by Sandoz in the event an injunction is issued. I understand that Sandoz expects FDA action (including possible final approval) on March 8, 2015 and has prepared to begin marketing Zarxio shortly thereafter. In the process, Sandoz has incurred large set up costs

including inventory manufacture, [redacted] In addition to the burden of such costs, Sandoz would suffer the loss of profits that it would otherwise earn during the period of the injunction as well as a portion of the profits for future periods that depend on the prior evolution of its sales, market share and customer relations. Timing for the launch of Zarxio is especially critical for Sandoz because of the likelihood that yet another biosimilar of Neupogen will soon be approved by the FDA and launched. Experience with biosimilars in Europe and small molecule generics in the U.S. teaches that the most rapid and significant price declines occur when there are multiple generics or biosimilars in the market. Sandoz will be substantially injured if an injunction is entered and it has to launch in a more crowded market. A reasonable estimate of the losses Sandoz might be expected to suffer from an injunction lasting up to 410 days is [redacted]. It would therefore be incorrect to conclude that Sandoz will not face permanent hardships, or that Amgen will suffer significantly more hardship from the denial of an injunction than Sandoz will suffer if the injunction is granted.

19. **Opinion #5. Public Interest.** The discussion of public interest in Dr. Philipson's report is disconnected from the specifics of Neupogen and, instead, depends on the assertion that the public is generally better off if new drug developers are given longer periods of immunity from competition. This general assertion has no empirical support and, in deposition, Dr. Philipson himself conceded that if all applicable patents have expired, the public interest is best

served by allowing competitive entry because that entry will reduce costs and increase consumer well-being. Public and private studies have predicted that biosimilar drugs will produce billions in U.S. healthcare savings. Filgrastim is an important tool in the medical arsenal for treating cancer patients. However, the cost is high—approximately $3,000 per chemotherapy cycle, with many patients undergoing up to four cycles. Generic and biosimilar products generally attract customers based on the costs savings they offer: because these drugs are viewed as similar (or, in the case of small molecule drugs, "equivalent") to the reference drug, their value proposition is based upon price. It is therefore to be expected that Zarxio's entry will result in price competition and that it will reduce the total cost of treatment in the U.S. using short-acting filgrastim. The meaningful savings Zarxio can be expected to provide represent a public benefit to be shared among patients, private insurers and government payers that bear these costs.

V. OPINION #1: ABSENCE OF EMPIRICAL WORK TO SUPPORT DR. PHILIPSON'S CONCLUSIONS

20. Dr. Philipson did not seek or use the business and financial data that would ordinarily be considered by an economist in evaluating prospective harm, even though the information was publicly available or easily obtainable from Amgen. For example, he did not request or review 2014 sales data from Amgen or more recent projections prepared by Amgen. Instead, he based his estimates of injury on aggregate sales figures reported in Amgen's 2013 10-K, information that is now more than thirteen months old.[4] Neupogen sales declined 28% during

[4] Dr. Philipson prepared no sales projections of his own for filgrastim products. Deposition of Tomas Philipson, February 13, 2015, at 18:11-22.

2014 (prior to Zarxio's entry) a fact that Dr. Philipson neither knew nor investigated.[5] [redacted]

[redacted] Dr. Philipson also assumes there is switching between Neupogen and Neulasta based upon price, but he analyzes no data to determine whether this is true. Because Granix (a competing product offered by Teva which is also known by its chemical name, tbo-filgrastim) captured approximately 14% of Neupogen sales in 2014, Dr. Philipson assumes that the entire filgrastim market is price sensitive, but the data shows that Granix had no effect on Neulasta and a much smaller than expected effect on Neupogen.

21. Dr. Philipson's methods are not reflective of reliable economic analysis. For example, because Dr. Philipson identifies a correlation between total annual revenue and research and development expenditures, he concludes that the former causes the latter and that a decline in revenue will therefore necessarily result in reduced research spending. Basic course work in economics warns that such causal inferences cannot be made based on the mere fact that two data sets are correlated. Further, Dr. Philipson failed to evaluate financial data to determine whether Amgen has the resources to pursue all of its research objectives even if Neupogen sales revenue is reduced. Economic principles dictate that Amgen will act rationally in making its business decisions, pursuing those projects that it believes are most likely to be profitable and discarding those that are not. Instead, Dr. Philipson assumes that Amgen will irrationally discontinue promising research and development projects that it has ample resources to fund. In the same vein, Dr. Philipson assumes that Amgen's sales force will be unable adequately to promote the company's new products following Zarxio's entry, but he undertakes no analysis of

[5] Amgen 2014 Form 10-K, at p. 44. "The increase in U.S. product sales for 2014 reflects growth across the portfolio except for NEUPOGEN®, which declined 28%."

the size or deployment of that sales force and fails to consider the fact that Amgen has been voluntarily transferring sales representatives away from Neupogen and Neulasta leading up to the Zarxio launch, something it would not rationally do if those resources were necessary to prevent an irreparable harm.

22. Dr. Philipson must have known that public data sources and Amgen information could be obtained to more reliably evaluate the effects of Zarxio's entry and of a possible injunction. Amgen reports its sales publicly each quarter, including information on U.S. sales of Neupogen and Neulasta. Dr. Philipson's only estimates of possible Neupogen losses were based on sales data from 2013. This error is especially troubling given that 2014 (which Dr. Philipson ignores) was the first year in which Amgen faced competition from another short-acting filgrastim, Granix. When asked in deposition why he had chosen to examine old data, thus missing both the decrease in Neupogen sales and increase in Neulasta sales occurring in 2014, Dr. Philipson responded that he "wanted just a rough number" for his estimate of potential Neupogen losses and that "[f]or the purpose of this argument, I didn't find [2014 Neulasta sales data] relevant."[6] When informed that Neupogen sales had fallen "from $1.2 billion to a number in the $800s [million]" in 2014, Dr. Philipson stated that decrease was not significant to the opinions expressed in his report.[7]

23. Amgen is a sophisticated corporation which prepares plans, projections, forecasts, and reports on the performance of its products. However, Dr. Philipson made no effort to obtain or analyze any of this internal information. For example, he speculates that Neupogen prices will

[6] Deposition of Tomas Philipson, February 13, 2015, at 89:12-90:11, 92:17-21; 93:8-94:18; 102:8-103:13.
[7] Deposition of Tomas Philipson, February 13, 2015, at 92:17-21.

erode without looking at Amgen business plans that instead project price increases.[8] Indeed, Dr. Philipson did not request or consider *any* of the following in forming his conclusions:

- Amgen's sales of Neupogen and Neulasta in 2014 and the beginning of 2015;[9]
- Amgen's projections of future sales of its products[10]
- Amgen's pricing of Neupogen and Neulasta in 2014[11]
- Data on Granix's market share since its introduction in November 2013[12]
- Data on distribution of Neupogen prescriptions across each of the five indications for which it is approved[13]
- IMS data on unit sales, revenue share, or pricing[14]
- Evidence to support his statement that "Sandoz is a bigger threat" to Amgen than Teva in this market[15]
- Data showing Amgen's return on investment for Neupogen or Neulasta[16]
- Data showing the relationship between Neupogen revenue and Amgen R&D spending[17]
- Information indicating other companies attempting to enter this market and their possible entry dates[18]
- Substitutability of Granix for Neulasta[19]
- Data showing whether and to what extent switching has occurred between Neupogen and Neulasta[20]
- Price differences between Zarzio and Neupogen in Europe.[21]

[8] Deposition of Tomas Philipson, February 13, 2015, at 100:18-101:9; 119:22-120:2; Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶49, p. 19; ¶74, p. 27.
[9] Deposition of Tomas Philipson, February 13, 2015, at 89:12-90:11, 92:17-21; 93:8-94:18.
[10] Deposition of Tomas Philipson, February 13, 2015, at 100:18-101:9.
[11] Deposition of Tomas Philipson, February 13, 2015, at 122:1-14 ("I didn't find it relevant for the opinion of the report.").
[12] Deposition of Tomas Philipson, February 13, 2015, at 107:7-16; 118:5-119:2.
[13] Deposition of Tomas Philipson, February 13, 2015, at 108:15-19; 109:25-110:11; 110:17-20.
[14] Deposition of Tomas Philipson, February 13, 2015, at 116:9-117:4; 117:20-25; 118:5-119:2.
[15] Deposition of Tomas Philipson, February 13, 2015, at 123:12-124:7.
[16] Deposition of Tomas Philipson, February 13, 2015, at 133:14-134:4.
[17] Deposition of Tomas Philipson, February 13, 2015, at 134:18-135:24.
[18] Deposition of Tomas Philipson, February 13, 2015, at 149:17-24; 150:15-151:3.
[19] Deposition of Tomas Philipson, February 13, 2015, at 161:1-11.
[20] Deposition of Tomas Philipson, February 13, 2015, at 151:4-25; 153:17-154:12; 155:8-17; 156:1-6; 157:22-158:3; 158:10-19; 159:6-14; 160:1-21.
[21] Deposition of Tomas Philipson, February 13, 2015, at 218:3-16. Zarxio is marketed under the name "Zarzio" in Europe.

24. Nor did Dr. Philipson do anything to validate a key assumption, that Amgen holds any enforceable patents protecting Neupogen.[22] I understand from counsel that Amgen's motion includes no evidence that a particular patent is infringed and Amgen does not rely on such infringement as the basis for seeking an injunction. I am informed by counsel that, because the list exchange process of the BPCIA was not invoked by Sandoz, Amgen has had the legal ability to bring suit on any patent in its portfolio since at least August 2014.

25. Amgen has been providing investors with information about its filgrastim patents for more than a decade. Starting in at least 2003, its annual Form 10-K filings with the SEC have included a table for each of Amgen's major products listing material patents and their expiry dates.[23] Amgen has for many years been informing the investment community that Neupogen would lose its material U.S. patent protection in December 2013. For example, the table from Amgen's 2003 10-K contained the information reproduced as Table 1 below:

Table 1. Amgen U.S. Material Patents for Filgrastim[24]

Product	General Subject Matter	Expiration
Filgrastim	Methods for recombinant production of G-CSF (issued in 1998)	8/23/2005
	Analogs of G-CSF (issued in 1999)	8/23/2005
	Pharmaceutical Compositions Comprising G-CSF (issued in 2002)	8/23/2005
	DNA, vectors, cells and processes relating to recombinant G-CSF (issued in 1989 and 1991)	3/7/2006
	G-CSF polypeptides (issued in 1996)	12/3/2013
	Methods of treatment using G-CSF polypeptides (issued in 1996)	12/10/2013

[22] Dr. Philipson conducted no investigation to determine whether there may be valid Amgen patents infringed by Zarxio – he was asked by counsel to assume this was true. The only patent he specifically identifies is the '427 patent. He has no opinion as to whether the '427 patent is in fact infringed by Zarxio, but was instructed by counsel to assume it is. Deposition of Tomas Philipson, February 13, 2015, at 21:13-22:6; 33:1-33:6.
[23] Amgen 2003 Form 10-K, at p. 17.
[24] Amgen 2003 Form 10-K, at p. 17.

26. No additional patents were added to the table in the years after 2003 and, starting in 2012, Amgen's public filings actively warned investors that expiration of the final patents in December 2013 would subject Neupogen to competition with a potentially material adverse effect on Neupogen sales.[25] Given the interest that investors have in patent expiration, Amgen would have been motivated to disclose all relevant patents in these discussions. However, no other patents were added to the table. In its 2014 10-K, Amgen stated: "Our material U.S. patents for filgrastim (NEUPOGEN®) expired in December 2013. We face competition in the United States which could have an impact over time on future sales of NEUPOGEN® and, to a lesser extent, Neulasta®."[26]

27. At his deposition, Dr. Philipson explained his failure to obtain data by the fact that the process was rushed.[27] He started work on January 27, 2015 and he signed his report nine days later on February 5, 2015.[28] Dr. Philipson explained that Amgen did not feel it needed to pursue an injunction until January 2015 when an FDA panel recommended approval.[29] By its preliminary injunction motion, Amgen is requesting serious relief with significant consequences for Sandoz and for patients and purchasers of filgrastim. I am not aware of any circumstances

[25] Amgen 2013 Form 10-K, at p. 40: "Additionally, certain of the existing patents on our principal products — including NEUPOGEN ®, EPOGEN®, Neulasta® and Aranesp® — recently expired or will expire over the next few years, and we expect to face increasing competition from competitive products including biosimilars." *See also* Amgen 2013 Form 10-K, at p. 42; Amgen 2012 Form 10-K, at p. 63.
[26] Amgen 2014 Form 10-K, at 46.
[27] Deposition of Tomas Philipson, February 13, 2015, at 126:18-128:1.
[28] Deposition of Tomas Philipson, February 13, 2015, at 126:14-20.
[29] Deposition of Tomas Philipson, February 13, 2015, at 129:5-21.

that would have prevented it from allocating the time and resources necessary to conduct a professionally acceptable economic analysis.

VI. OPINION #2: POTENTIAL HARM TO AMGEN

A. Dr. Philipson's illustration of possible Amgen losses in sales and profits is unrealistic and unsupported.

28. Dr. Philipson offers little specific discussion about the reduction in profits Amgen might expect to experience as a result of sales lost to Zarxio. He does, however, provide two brief "illustrations" of profits that might be lost from Neupogen and he argues that Neulasta sales might be adversely impacted as well. These illustrations are based upon a false assumption, and the conclusion regarding Neulasta is controverted by historical data.

29. Dr. Philipson concluded there was no need to attempt an actual estimate of lost profits, as long as the reduction in revenue would be "substantial," a term he defined as meaning "I would guess hundreds of millions."[30] This is well below the level of precision required for professional economic analysis. Further, he contends that even if there was little or no revenue loss at all (i.e., Zarxio failed meaningfully to penetrate the market or took sales only from Granix) Amgen would *still* suffer irreparable injury because its sales force would be disrupted[31] and the investment community would lose confidence generally in the value of patents.[32] He offers no explanation as to why Amgen would be wasting sales resources to fight an entirely unsuccessful competitor, how price erosion could occur if Zarxio sales were trivial, and why the investment community would be disquieted by the alleged patent holder having preserved its

[30] Deposition of Tomas Philipson, February 13, 2015, at 162:3 -163:1; 170:14-23.
[31] Deposition of Tomas Philipson, February 13, 2015, at 166:7-11.
[32] Deposition of Tomas Philipson, February 13, 2015, at 166:12-167:3.

market share. Dr. Philipson goes so far as to state that patents in general will be devalued if a biosimilar applicant violates the BPCIA, even if the reference drug maker has no valid patents.[33] There is neither economic logic nor evidence to support this opinion.

1. Dr. Philipson's estimates of the potential impact on Neupogen are based on the wrong data and are greatly overstated.

30. Dr. Philipson included in his report what he described at deposition as an "illustration" regarding the revenues or profits Amgen *might* lose.[34] This illustration is based on 2013 revenues multiplied by a speculative market share figure multiplied by an approximate contribution margin figure. Dr. Philipson admits that he is not confident in the result of his computations and emphasized that they are merely an illustration.[35] His approach could never pass muster as a lost profits analysis in any professional damages analysis, as the critical components are based on either speculation or unrepresentative data.

31. Dr. Philipson takes his "market share" figure solely from one analyst's comment that "I'm guessing that in the US in five years, Sandoz will be at least half the market."[36] Despite the fact that the quote is a self-described "guess," that the word "half" is imprecise in this context, and that the statement refers to the *end* of a five-year period, Dr. Philipson treats the statement as evidence that Amgen would lose half of its Neupogen sales (i.e., a 50% loss of the expected sales) on an immediate basis. Loss of market share is something that occurs gradually, over time, and not all at once.

[33] Deposition of Tomas Philipson, February 13, 2015, at 168:18-22.
[34] Deposition of Tomas Philipson, February 13, 2015, at 79:6-10; Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶50, p. 19.
[35] Deposition of Tomas Philipson, February 13, 2015, at 87:15-88:21.
[36] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶50, p. 19.

32. Dr. Philipson applies the 50% guess to the 2013 Neupogen sales figures reported in Amgen's 10-K. That data is stale, already 13 months old. Even in that document, Amgen acknowledged that its 2013 Neupogen U.S. sales were boosted by a one-time government purchase.[37] More importantly, Amgen's 2014 sales of Neupogen (which were available but not considered by Dr. Philipson) were down by approximately 28% from 2013, decreasing from $1.2 billion to $839 million.[38] [redacted] Dr. Philipson had access to Mr. Azelby and other finance professionals at Amgen but did not seek or obtain Amgen's more recent data or its best estimate of future sales. Dr. Philipson explained away his use of old data and his incorporation of the 50% guess into his illustration of potential damage to Amgen by pointing out that, in his view, "these issues are…not highly relevant to . . . my report, because I'm not hanging my report on this estimate being accurate."[41]

33. Given that two of the three inputs were unreliable or wrong, no reasonable weight can be given to Dr. Philipson's illustration of any harm to Amgen's revenues or profits.

[37] Amgen 2013 Form 10-K, at p. 42.
[38] Amgen 2013 Form 10-K, at p. 42; Amgen 2014 Form 10-K, at p. 45.
[39] AMG-NEUP-00002616—683, at -634.
[40] Deposition of Robert Azelby, February 15, 2015, at 91:6-15.
[41] Deposition of Tomas Philipson, February 13, 2015, at 96:17-97:2; 98:7-20.

2. There is no reason to believe that Amgen's separate product, Neulasta, would be significantly affected by the availability of Zarxio.

34. Dr. Philipson speculates that "some portion of its Neulasta® sales could also be lost to Zarxio" and if Zarxio's entry "resulted in only a 10% reduction in Neulasta® sales, Amgen would lose over $280 million in addition."[42] Once again, there is no analysis or evidence to support the assumption that 10% – or, indeed, any amount – of Neulasta sales would be lost due to the availability of Zarxio. Indeed, during his deposition Dr. Philipson confirmed that the 10% figure was unsupported and was merely "a guess."[43]

35. Despite this, Dr. Philipson repeatedly lumps Neupogen and Neulasta together,[44] and in many cases only reports sales for the two products combined.[45] This creates the appearance that the revenue stream potentially threatened by Zarxio is much larger than it actually is. Zarxio is a short-acting product sharing the same dosing schedule with Neupogen. Zarxio and Neupogen are different from Neulasta, which is a long-acting product based on a different G-CSF that is dosed only once in a chemotherapy cycle.[46] Neupogen's revenue is much smaller than that of Neulasta and (unlike Neulasta) Neupogen sales have been declining,

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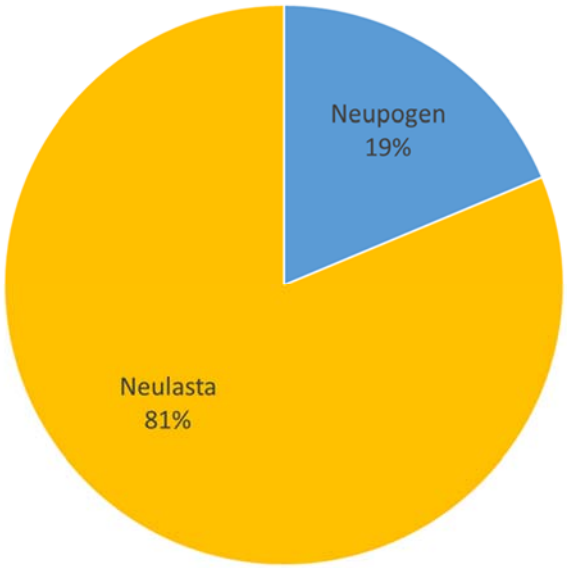
[42] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶50, p. 19.
[43] Deposition of Tomas Philipson, February 13, 2015, at 102:8-103:13; 104:8-105:4.
[44] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶47, p. 18: "Neupogen® and Neulasta® are highly successful and profitable products"; "Neupogen® and Neulasta® are Amgen's best-selling products, accounting for 32% of total product sales in 2013"; "the contribution margins on Neupogen® and Neulasta® are significant." Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶49, p. 19: "unlawfully premature Zarxio sales would directly harm Amgen's revenues and profits from lost sales of Neupogen® and Neulasta®"; "unlawfully premature Zarxio sales would result in the erosion of the prices Amgen receives from its sales of Neupogen® and Neulasta®."
[45] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶47, p.18: "sales of Neupogen® and Neulasta® were $5.8 billion."
[46] Neupogen Label, at pp. 1 and 5; U.S. Food and Drug Administration, "Neulasta (pegfilgrastim) Approved Label," at pp. 1 and 9. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/125031s082lbl.pdf.

particularly in recent years. Amgen's Executive Vice President of Global Commercial Operations notes that "Neulasta represents about 80% of the combined sales of [Neulasta and Neupogen]."[47] Figure 2 below shows that Neupogen made up only 19% of 2014 sales revenue for Amgen's G-CSF products, while Neulasta accounted for the remainder.

Figure 2. Share of Amgen 2014 Filgrastim Sales Revenue by Product

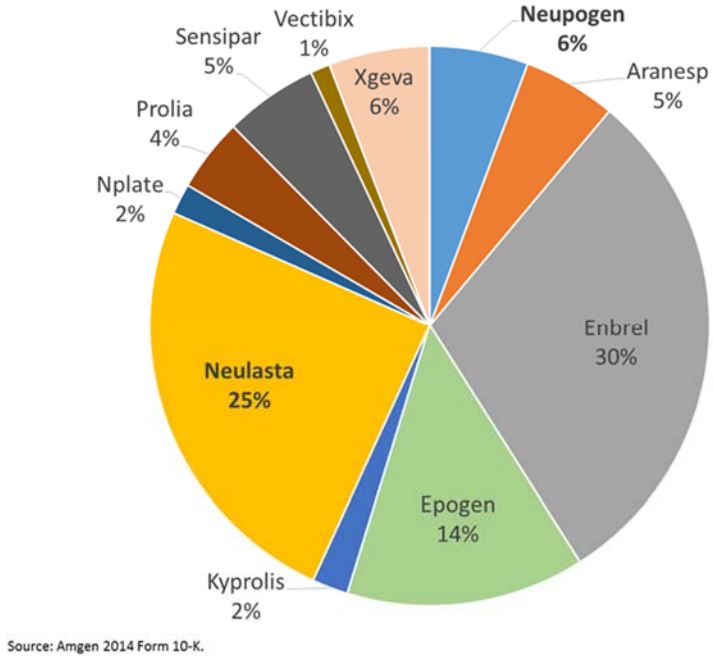


Source: Amgen 2014 Form 10-K.

36. As a share of all Amgen's products, Neupogen contributed less than 6% of total 2014 sales revenue as illustrated in Figure 3.

[47] Seeking Alpha, "Amgen FQ3 2013 Earnings Call Transcript," July 30, 2013, at p. 4. Accessed February 12, 2015. http://seekingalpha.com/article/1762302amgensceodiscussesq32013resultsearningscalltranscript.

Figure 3. Share of Amgen 2014 Sales Revenue by Product



37. Dr. Philipson assumes Zarxio will take sales away from Neulasta rather than empirically examining that question. The basis for his assumption is two-fold. First, he alludes to an October 2010 incident related to him in a discussion with Mr. Azelby.[48] As Dr. Philipson describes it, "smaller clinics had been moving away from Neulasta due to reimbursement concerns, i.e., doctor margins were driving substitution. When Amgen switched to unitary pricing, doctors moved back to the product."[49] On this basis, Dr. Philipson concludes that "a relatively small change in the relative net acquisition costs of Neupogen® and Neulasta® results in providers switching between the two products."[50] Second, he concludes, without any

[48] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶70, p. 25.
[49] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶70, p. 25.
[50] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶70, p. 25.

examination, that the U.S. experience with Granix supports his view regarding possible losses to Neulasta.[51]

38. Dr. Philipson attributes the evidence of the first incident entirely to his conversation with Mr. Azelby. [redacted]

39. [redacted] Dr. Philipson presented no information regarding the price of Neupogen

[51] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶70, pp. 25-26.
[52] Deposition of Robert Azelby, February 15, 2015, at 253:10-257:25.
[53] Deposition of Robert Azelby, February 15, 2015, at 255:9-256:12 and 257:8-25.
[54] Deposition of Robert Azelby, February 15, 2015, at 255:18-25.
[55] Deposition of Robert Azelby, February 15, 2015, at 255:9-22.
[56] Deposition of Robert Azelby, February 15, 2015, at 256:8-12; 255:18-25.
[57] Deposition of Robert Azelby, February 15, 2015, at 253:25-254:10 and 256:2-7.

during this same period, information that would be essential to any economist in determining whether there was substitution between the two products based on their relative prices. The incident on which Dr. Philipson relies provides no meaningful information about the cross-price elasticity of demand for Neupogen and Neulasta and cannot be used to infer that there would be product switching so long as customers are not required to take a loss by buying either product.

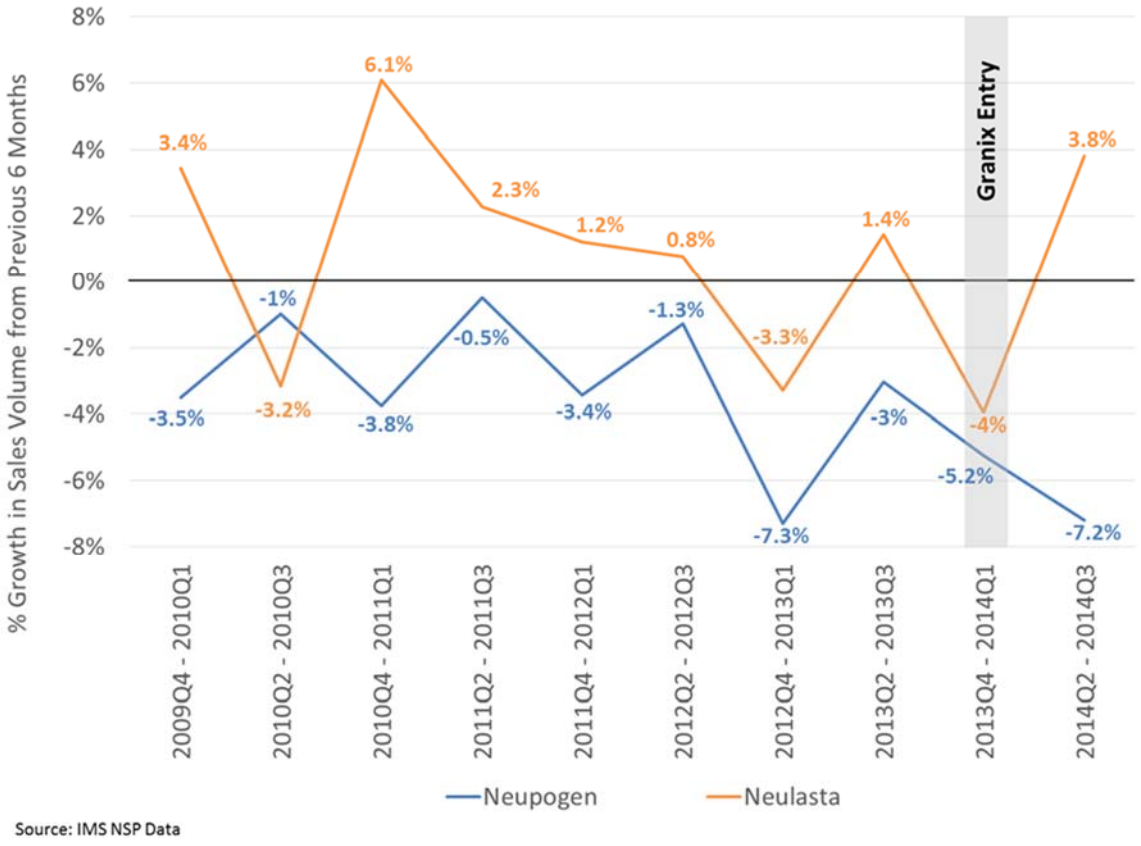
40. The second reason Dr. Philipson offers for assuming possible losses of Neulasta sales is the market experience with Granix, another short-acting filgrastim product offered by Teva in the U.S. beginning in November 2013. Granix has been sold at a discount to Neupogen and Dr. Philipson reports that it "acquired roughly 14% of filgrastim sales in the first fourteen months after launch."[58] This statement is incorrect: Granix acquired 14% of short-acting (i.e., Neupogen) sales and not 14% of the total filgrastim sales (including Neulasta). Indeed, actual sales data demonstrates that Granix had little if any impact on Neulasta, thus disproving Dr. Philipson's opinion.

41. [redacted] Equally important are the actual results reflected in Amgen's sales figures following Granix's introduction in November 2013. After Granix entered at a discount to both products in November 2013, Amgen raised its prices for Neulasta; it reported that net sales of Neulasta rose in 2014 primarily because of those price increases. Figure 4 and Figure 5 below

[58] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶70, p. 26.

graph the changes in sales volume (Figure 4) and sales dollars (Figure 5) for both Neupogen and Neulasta. Following Granix's entry, Neupogen experienced significant declines but Neulasta sales volume and dollars both increased.

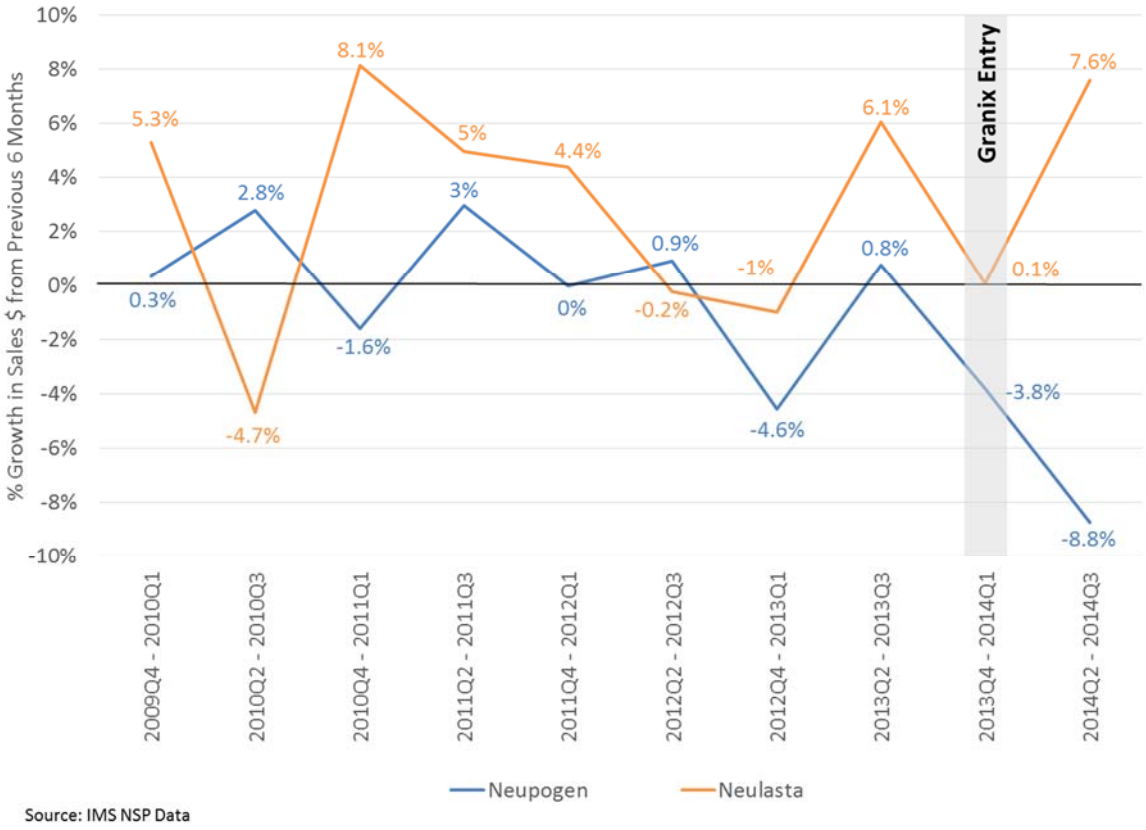
Figure 4. Change in Sales Volume for Neupogen and Neulasta at Granix Entry



Source: IMS NSP Data

42. The data for sales dollars is even more dramatic than the volume changes reported in Figure 4, showing that Neupogen sales dollars fell by 8.8% during the two quarters after Granix entry, while Neulasta sales dollars grew by 7.6% during that same period. In short, there is simply no basis to infer that introduction of a lower priced short-acting filgrastim product (such as Zarxio) would have any meaningful impact on Neulasta sales.

Figure 5. Change in Sales $ for Neupogen and Neulasta at Granix Entry



43. The introduction of Granix also provides a separate and competing explanation for why Neupogen sales may decline in 2015 and after. Despite knowing Granix had taken 14% of Neupogen sales in 2014, Dr. Philipson did nothing to examine how Granix will affect Neupogen's pricing or volume going forward. Any credible analysis of the market needs to account for Granix and the market share, volume and pricing changes that have already occurred in the wake of its entry.

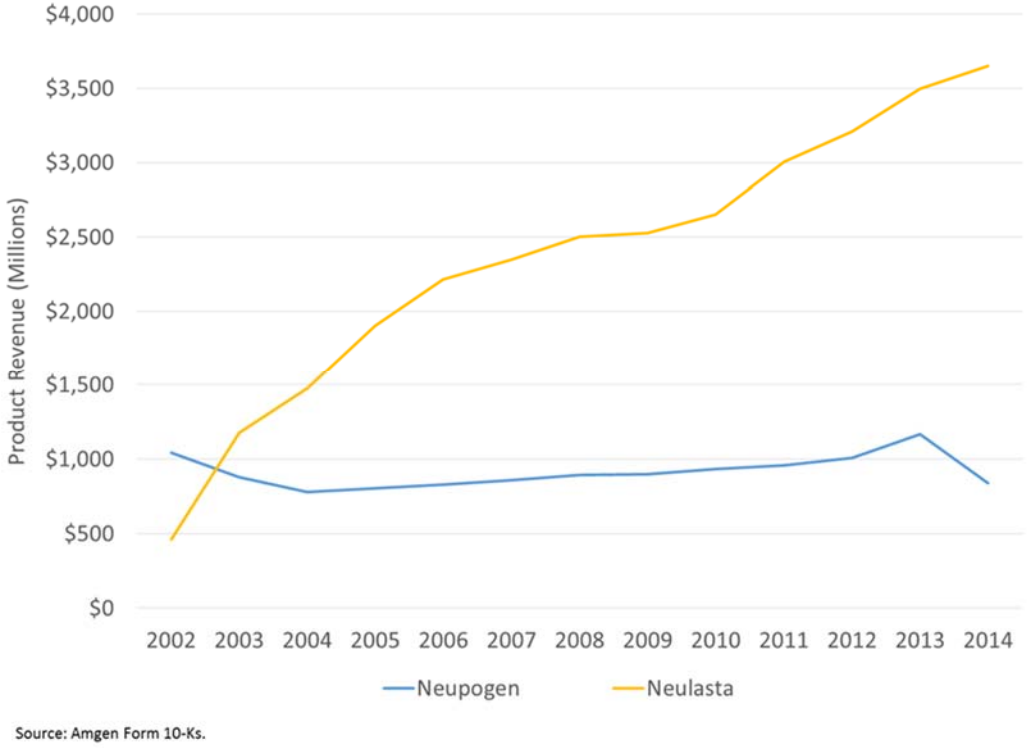
3. Neupogen sales losses resulting from Zarxio's entry would be small in proportion to Amgen's total revenue.

44. As the foregoing examination makes clear, Zarxio's introduction will likely affect the quantity of Neupogen that is sold but not the quantity or price for sales of Neulasta, and

Neupogen represents a relatively small and already declining share of Amgen's product revenue. Figure 6 below shows U.S. revenue for Neupogen and Neulasta from 2002, when Neulasta was introduced, through 2014. Annual Sales of Neulasta have dramatically increased over this time period from a start of $464 million to its current high of $3.649 billion.[59] In contrast, Neupogen sales declined with the introduction of Neulasta, and have exhibited little overall growth. Neupogen sales in 2002 were $1.042 billion, and in 2014 they totaled $839 million.[60] In 2015, Amgen anticipated that they would be less than $600 million.[61] The slight jump in 2013 Neupogen sales which is visible in Figure 6 was "driven by a $155-million order from the U.S. government [Strategic National Stockpile]."[62]

[59] Amgen 2004 Form 10-K, at p. 31; Amgen 2014 Form 10-K, at p. 45.
[60] Amgen 2004 Form 10-K, at p. 31; Amgen 2014 Form 10-K, at p. 45.
[61] AMG-NEUP-00002616--683, at -634.
[62] Amgen 2013 Form 10-K, at p. 42 and F-7.

Figure 6. Amgen US Product Revenue – Neupogen and Neulasta

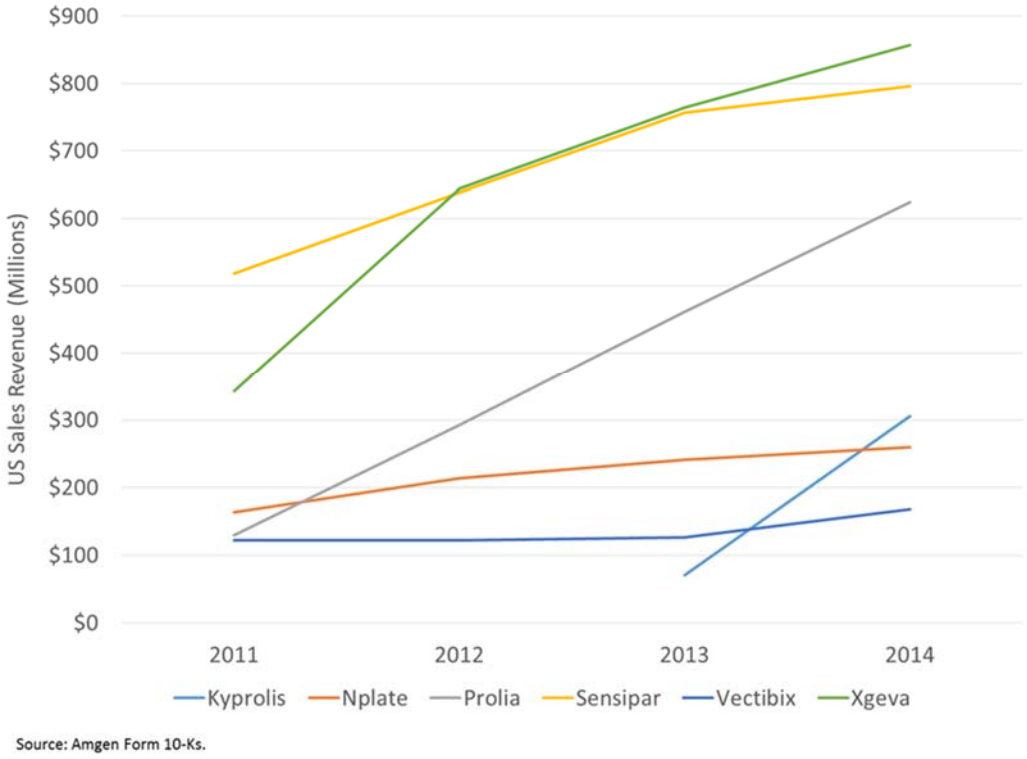


Source: Amgen Form 10-Ks.

45. Regardless of any anticipated decline in Neupogen sales, industry analysts expect Amgen to rely more heavily on its other drugs in 2015, which are expected to increase in growth sufficiently to more than compensate for losses to Neupogen. One analyst has concluded: "Amgen's big money maker Neulasta/Neupogen…has been a bit inconsistent in recent quarters regarding growth. This is expected to continue into 2015 due to the drug being a mature product. But other blockbusters like Enbrel, Epogen, and Aranesp remain solid mid-single digit growth drugs for the company. Not to mention, Xgeva is well on its way to becoming one of, if not Amgen's best-selling drugs with growth exceeding 20% annually, thereby easily accounting for the losses with Neulasta/Neupogen. Based on these numbers, Amgen's outlook is likely tied more so to these products, along with the addition of some revenue with new drug launches in

2015."[63] Amgen already has several recent product introductions that are being assimilated by the market and are growing at a rapid pace. Figure 7 below shows sales revenue from Amgen's newer products and the growth in that revenue over the last three years.

Figure 7. Amgen Newer Product Sales Revenue



Source: Amgen Form 10-Ks.

46. Given these facts, it is not surprising Amgen itself has stated it expects to succeed in the face of competition from biosimilars, noting that "we have been relatively successful outside the U.S. and we will be applying the same type of tactics."[64]

[63] Seeking Alpha, "Why I Am Building A Healthcare Portfolio Around Amgen In 2015," February 3, 2015.
Accessed February 13, 2015. http://seekingalpha.com/article/2880546-why-i-am-building-a-healthcare-portfolio-around-amgen-in-2015.
[64] Seeking Alpha, "Amgen FQ2 2013 Earnings Call Transcript," October 22, 2013, at p. 12. Accessed February 12, 2015.
http://seekingalpha.com/article/1586622amgensceodiscussesq22013resultsearningscalltranscript.

B. Neupogen sales losses would not affect Amgen's R&D budget.

47. Dr. Philipson argues that "the profits Amgen would lose due to Sandoz's unlawfully premature sales would have a lasting and recurring impact on its R&D investment."[65] He assumes that a decrease in Neupogen sales would translate to a decrease in overall revenues for Amgen, and states that lower revenues would cause Amgen to reduce its spending on research and development. The only support he offers for his opinion that Amgen would forgo potentially valuable R&D is a correlation analysis comparing changes in overall revenue and changes in R&D spending. From this correlation, Dr. Philipson incorrectly infers that there is a causal relationship between Neupogen revenues and Amgen R&D investment. The analysis is deeply flawed. Dr. Philipson makes no attempt to determine empirically how potential losses of Neupogen revenue would affect Amgen's overall revenue.[66] He also makes no attempt to determine why or how revenue changes may have affected R&D changes, the degree of their impact, how long any research cutbacks would last or how large they would be.

48. Dr. Philipson relies on a simplistic correlation calculation as his basis to claim that Amgen's revenues determine the amount of its R&D spending. He compares changes in Amgen's overall revenue in a given year with changes in its R&D spending for that same year. He finds that the two numbers are correlated at 0.8, meaning that they tend to move up and down together over time with about 80% association. He then infers from that correlation that the

[65] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶87, p. 31. *See also* Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶40, p. 14; ¶52, p. 20; ¶57, p. 21; and, ¶83, p. 30.

[66] Deposition of Tomas Philipson, February 13, 2015, at 134:12-135:24: "The Neupogen [revenue] is, by definition, part of . . . aggregate revenue, and since I knew aggregate revenue would take a hit, I knew aggregate R&D would take a hit. So [looking at the relationship between Neupogen revenues and R&D spending] [i]s not relevant in that respect."

revenue figures must be the *cause* of the R&D figures.[67] Having drawn this inference, Dr. Philipson concludes that a reduction in overall revenue will necessarily result in a reduction in R&D spending.

49. This exercise is deeply flawed and unsuitable to support the type of conclusion Dr. Philipson seeks to reach. First, it examines changes in *aggregate* revenue from all products and not changes in revenue from a single product such as Neupogen. Dr. Philipson has done nothing to examine whether Amgen's *aggregate* revenue will in fact rise in 2015 and 2016 as a result of success with other products, in spite of Zarxio's entry. Dr. Philipson does not attempt to control for (and does not even discuss) the numerous other factors that may affect Amgen's R&D spending including research discoveries, clinical trial successes or failures, market demand, entry or exit of competing products, changing regulatory conditions and others. He compares *same year* revenue and R&D, failing to take into account the fact that research budgets are typically set well in advance.[68] All of these facts make his correlation coefficient a meaningless number for the current purposes.

50. It is well recognized in the field of economics that mere correlation is insufficient to infer causation. This is true in part because two highly correlated metrics may both be caused by a third metric that is not being studied, or each of them may be driven by separate causal variables that are closely correlated with each other. It is easy to demonstrate that unrelated datasets can still be highly correlated by performing an exercise similar to Dr. Philipson's. Table 8 provides examples of correlations between Amgen's R&D expenses and other datasets. Each

[67] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶40, p.14: "The correlation between changes in revenues and changes in R&D expenditures is 0.80."
[68] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006, at p. 19.

of these is more highly correlated with changes in Amgen's R&D than was the change in Amgen revenue that Dr. Philipson tested. Using Dr. Philipson's logic, each of these figures would likely be a cause of the changes in Amgen's R&D, a position demonstrating the plain error in his approach.

Table 8. Correlations between Amgen R&D and Unrelated Datasets[69]

Series	Time Period	Correlation
US GDP	1991 - 2014	98%
US CPI	1991 - 2014	97%
Percentage of US Adult Non-Smokers	1995 - 2010	92%
CDC Website Page Views	2004 - 2014	83%

51. As his only other evidence that changes in revenue affect Amgen's R&D spending, Dr. Philipson mentions a 2007 corporate restructuring undertaken in response to the rapid decline of Amgen's Aranesp product.[70] As a result of this restructuring, Amgen decreased R&D expenses by about $400 million and reduced personnel by 2,200-2,400.[71] [redacted] Amgen has undertaken equally significant restructurings recently, without any specific link to actual or anticipated revenue losses, and with the stated objective to "invest in continuing innovation and the launch of our new pipeline molecules, while improving our cost structure."[73] This most recent restructuring,

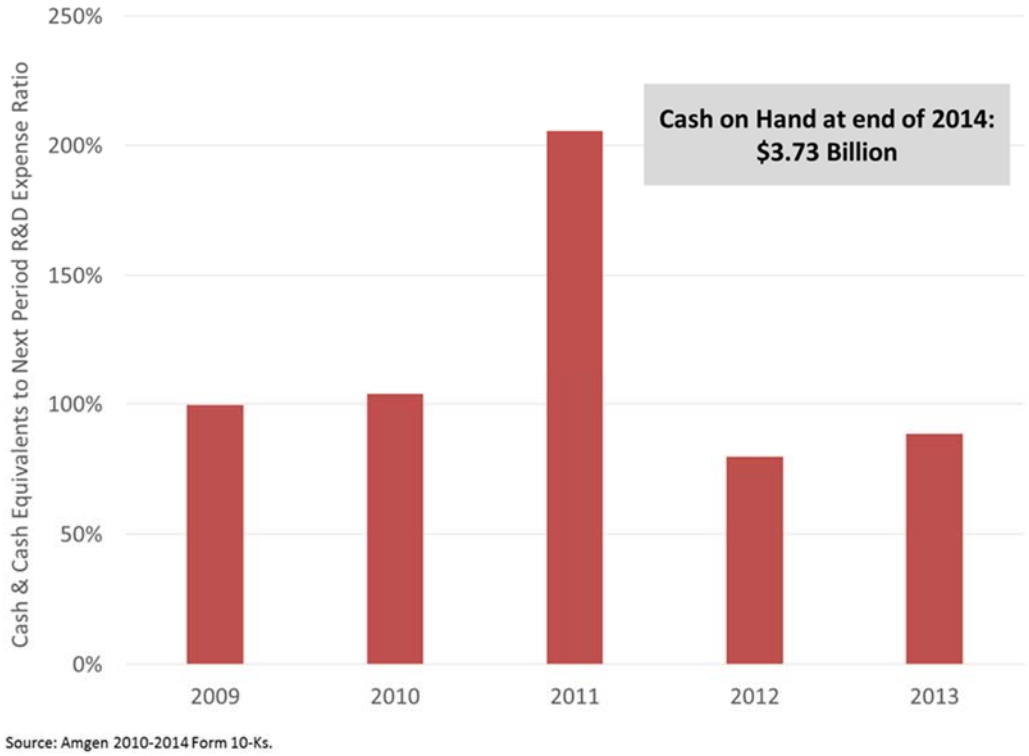
[69] "National Economic Accounts: GDP," *Bureau of Economic Analysis*; "Consumer Price Index," *U.S. Bureau of Labor Statistics*; "BRFSS Prevalence and Trends Data: Tobacco Use," *Center for Disease Control*; "Monthly Page Views of CDC.gov," *Center for Disease Control*; Amgen Inc. Income Statement, S&P Capital IQ, 1991 - 2014.
[70] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶41, p. 15.
[71] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶41, p. 15.
[72] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶41, p. 15; Amgen 2014 Form 10-K, at p. 45.
[73] Amgen 2014 Q3 Form 10-Q, at p. 6.

announced on July 29, 2014, involves plans to lay off 3,500-4,000 employees. Nonetheless, Amgen's R&D spending went up in 2014 despite the restructuring and despite a nearly $300 million decline in Neupogen revenues.

52. Even if Amgen's aggregate revenue does decline in 2015 and 2016, the company has more than enough cash on hand to make up any shortfall and keep its research and development programs intact. Indeed, in its 2014 Form 10-K filed February 19, 2015, Amgen said: "We believe that existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our needs for working capital; capital expenditure and debt service requirements; our plans to pay dividends and repurchase stock; and other business initiatives we plan to strategically pursue, including acquisitions and licensing activities."[74] Figure 9 shows that Amgen has consistently held large amounts of cash and cash equivalents, typically approximating a full year's worth of R&D spending for the entire company. As of December 31, 2014, Amgen had on hand cash and cash equivalents of approximately $3.73 billion.[75] Under these circumstances, it is irrational to suppose that Amgen would jettison what it otherwise deemed to be worthwhile, promising R&D opportunities, thus inflicting upon itself an unnecessary harm.

[74] Amgen 2014 Form 10-K, at p. 52.
[75] Amgen 2014 Form 10-K, at p. F-4.

Figure 9. Amgen Cash as % of Next Year R&D



53. As of December 31, 2014, Amgen reported that it had worldwide cash, cash equivalents and marketable securities (i.e., securities with maturities of less than one year) totaling $27 billion.[76] Although there may be tax reasons why the portion of these funds generated from foreign operations would not be repatriated for use in U.S. operations, cash is fungible and these monies could theoretically be used for foreign research or for other purposes that would reduce the demand on U.S. sales revenue. Amgen could also borrow funds in the United States, using its overseas cash as collateral. Further, Amgen has demonstrated the ability to raise money through the capital markets when it chooses, and could readily do so if it did not want to use its cash reserves. There is no economic reason why Amgen cannot pursue the R&D projects that it believes are economically valuable over the long term.

[76] Amgen 2014 Form 10-K, at p. 51.

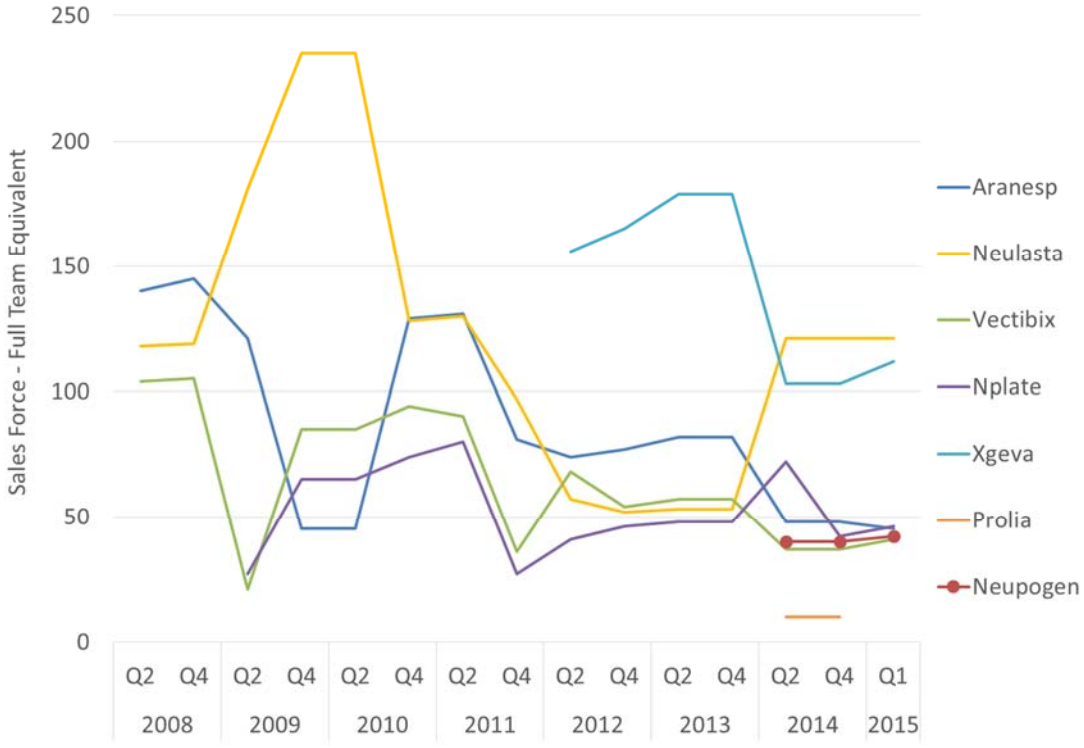
C. If sales representatives are diverted away from Amgen's new products, this will not be a result of Zarxio.

54. Dr. Philipson also concludes that Amgen will suffer irreparable harm due to the diversion of "fixed" sales resources, resulting in inadequate attention to other products.[77] But this claim is not supported by any analysis and is disproved by the facts.

55. Amgen has a large sales force. Within the oncology sector, most of these sales representatives have been dedicated to promoting Xgeva and Neulasta in recent years. Figure 10 graphs Amgen's sales force by oncology product, illustrating that Neupogen is a relatively low corporate priority. In fact, the sales force allocation data show that Amgen did not actively promote Neupogen for the six years leading up to 2014, when a small portion (approximately 10%) of its oncology sales resources were directed to the product. If Amgen viewed Neupogen as a product to be salvaged through sales efforts, it would rationally have allocated greater sales resources to its promotion. However, there is no evidence that Amgen would benefit by dedicating more resources to Neupogen following a Zarxio launch, and any such decision would be contrary to the marketing and sales decisions it has previously made for this product.

[77] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶54, pp. 20-21; ¶88, p. 32.

Figure 10. Amgen Oncology Sales Force



Source: PharmaForce Deployment Analyzer, Oncology Data

PharmaForce Analyzer reports that Amgen had an Oncology Sales Force of approximately 400 full time equivalents with only minor variation in Q2 2009 through Q2 2011. That same sales force was estimated to be 431 in Q2 2014, but dropped to 401 in the Q4 of that same year, following the announcement that the FDA had accepted Sandoz's BLA for Zarxio. This action would be irrational if, as Dr. Philipson speculates, greater sales force would be needed to respond to Zarxio's entry.

56. Dr. Philipson's only support for his "distracted sales force" theory is his belief that sales resources are "fixed" (i.e., can not be expanded for a period of time) and that current staffing levels are inadequate simultaneously to support Amgen's new and existing products and respond to Zarxio's presence in the market. The sole justification offered for this view is the

conversation he had with Mr. Azelby.[78] On that basis alone, Dr. Philipson argues that more sales people will be required to support Neupogen following Zarxio's launch and that there is inadequate time to hire and train them. In deposition, Dr. Philipson stated that he understood a complete year is required to train and deploy sales people (six months training and six months supervision in the field) and, yet, there was no reason to expect Amgen would hire or train these sales people until Zarxio was actually launched.[79]

57. [redacted] Therefore, even if additional sales resources were an appropriate response to Zarxio's entry, there was ample time and sufficient resources for Amgen to obtain them before Sandoz's launch. [redacted]

[78] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶53, p. 20; Deposition of Tomas Philipson, February 13, 2015, at 182:6-15.
[79] Deposition of Tomas Philipson, February 13, 2015, at 162:15-164:22; 179:1-21; 180:14-181:5; 183:2-12.
[80] Deposition of Robert Azelby, February 15, 2015, at 224:5-18.
[81] Deposition of Robert Azelby, February 15, 2015, at 230:2-8.
[82] Deposition of Robert Azelby, February 15, 2015, at 243:15-17.
[83] Deposition of Robert Azelby, February 15, 2015, at 243:21-244:6.

58. Dr. Philipson concedes that Amgen knew Sandoz's application had been accepted by the FDA in July 2014, but says "Amgen is waiting to see what the FDA—they wouldn't do anything unless the FDA approved the drug, and after that decision, it becomes more likely and that's when they started ramping up."[84] Elsewhere he says that final FDA approval "would be a necessary condition…." to increased hiring.[85]

59. Given that Dr. Philipson contends the shortage of sales staff will result in permanent, irreparable injury, possibly putting the safety of patients in jeopardy,[86] he was asked at deposition why Amgen would make the choice to delay hiring. "Q. Is it your belief as an economist, sir, that if someone is facing the probability of irreparable harm, they will do things as fast and as well as they can to try to avoid it? A. I'm not forming an opinion on that in this report. Q. Well, just as an economist, do you expect that people will do what they can do to avoid irreparable harm? A. Again, I'm not -- it's irrelevant to my opinion in this -- Q. It's irrelevant to your opinion as to whether or not people will try to avoid doing things that will cause them irreparable harm? A. I took Azelby's timeline as given." [87] When asked whether hiring in the second quarter of 2014 could have been used to avoid the possible injury, Dr. Philipson responded: "I have not been asked to opine on that and I didn't look into it, so I'm not going to speculate on it."[88]

60. Amgen's demonstrated actions are inconsistent with its claims that it will suffer irreparable harm. [redacted]

[84] Deposition of Tomas Philipson, February 13, 2015, at 185:20-186:23.
[85] Deposition of Tomas Philipson, February 13, 2015, at 192:21-193:17.
[86] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶ 54, pp. 20-21.
[87] Deposition of Tomas Philipson, February 13, 2015, at 184:22-185:14.
[88] Deposition of Tomas Philipson, February 13, 2015, at 189:25-190:7.

[redacted] This again reflected a conscious business decision to use cash and resources in other areas. This is not a choice Amgen would rationally make if it believed additional promotion of Neupogen would be needed to prevent an irreparable harm following Zarxio's launch. It reflects, instead, a business decision about where to invest funds for maximum return.

61. Finally, Dr. Philipson is plainly wrong in concluding that Amgen's new product, T-Vec, will suffer due to the excess demands on sales force created by Zarxio's launch.

[redacted]

D. Dr. Philipson's concern that Amgen will suffer irreversible price erosion is unfounded.

62. Dr. Philipson speculates that Neupogen may suffer from price erosion for two reasons. First, he speculates that Amgen may lower Neupogen's price to compete with Zarxio.

[89] Deposition of Robert Azelby, February 15, 2015, at 235:5-8.
[90] Deposition of Robert Azelby, February 15, 2015, at 225:6-20; 230:10-231:12.
[91] Deposition of Robert Azelby, February 15, 2015, at 233:9-23.
[92] Deposition of Robert Azelby, February 15, 2015, at 59:22-60:11.
[93] Deposition of Robert Azelby, February 15, 2015, at 240:7-10.

[redacted] Second, he points out that Medicare Part B reimbursements are based on the Average Selling Price of the reference and biosimilar drugs, combined, and he suggests that Zarxio's discount will significantly drag down that reimbursement. Any price erosion taking place over 410 days would be minimal and easily quantifiable. [redacted] I note at the outset that in deposition Dr. Philipson characterized the likelihood of price erosion as "highly uncertain."[94] Further, price erosion, if it occurred, could be remedied by an award of money damages.

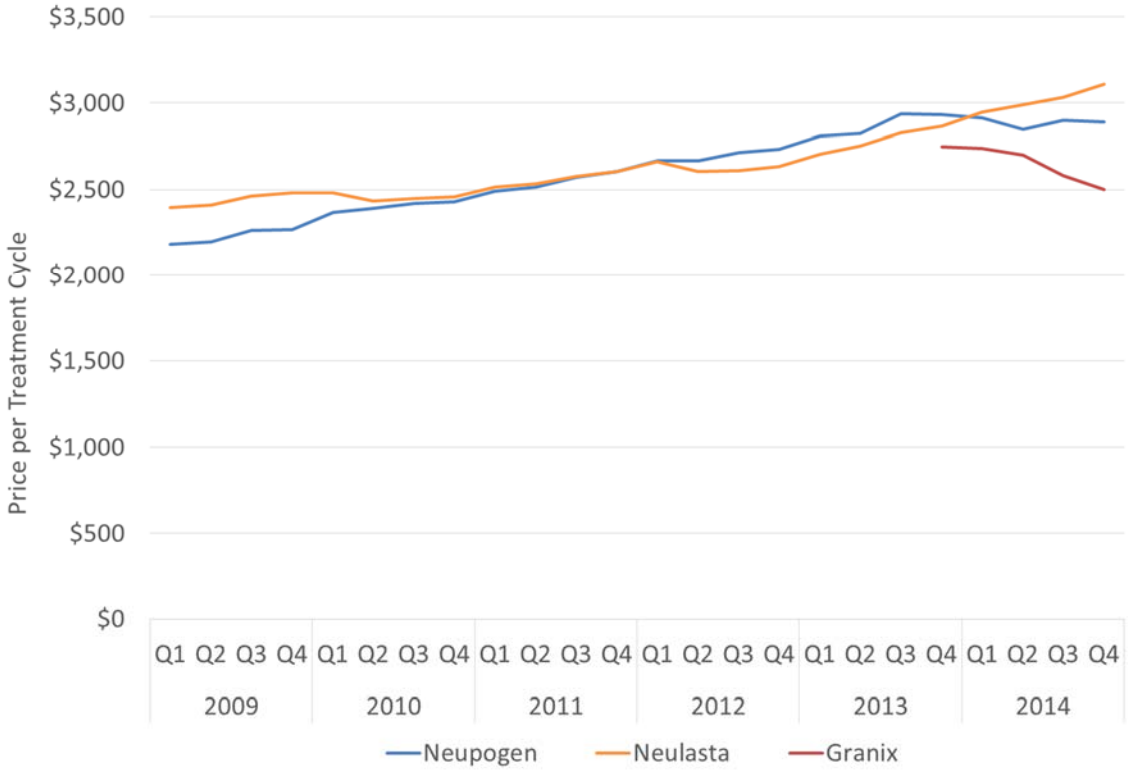
63. Equally important, as discussed above, the prices of Neupogen and Neulasta did not decrease in response to Granix's market entry. Amgen has instead been increasing the prices of Neulasta and, to a lesser extent Neupogen, in spite of Granix's entry. [redacted]

64. Figure 11 shows the price per chemotherapy treatment cycle for Granix, Neupogen, and Neulasta. While Neupogen prices remained flat after Granix's entry, the price of Neulasta increased. Although Neulasta is dosed just once in a chemotherapy cycle, Neupogen and Granix are dosed daily. I understand that the average number of Neupogen injections per chemotherapy cycle is approximately 8.7.[96] As a result, in preparing this figure I have multiplied the cost of a single syringe of Neupogen or Granix by 8.7 to make them comparable to Neulasta.

[94] Deposition of Tomas Philipson, February 13, 2015, at 119:22-120:5.
[95] Deposition of Robert Azelby, February 15, 2015, at 213:22-214:5.
[96] Sandoz Inc., "FDA Oncologic Drugs Advisory Committee Meeting: Zarxio® (filgrastim)," Sandoz Advisory Committee Briefing Materials, January 7, 2015, at figure 32.

CONFIDENTIAL MATERIAL REDACTED

Figure 11. Average Quarterly Price per Treatment Cycle for Granix, Neupogen, and Neulasta



Source: IMS NSP Data; Sandoz Inc., "FDA Oncologic Drugs Advisory Committee Meeting: Zarxio® (filgrastim)," Advisory Committee Briefing Materials, January 7, 2015, at figure 32.

65. [redacted]

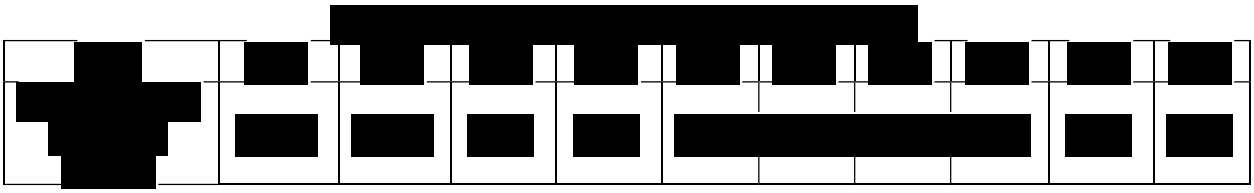
[redacted]

[redacted]

[redacted]

[97] AMG-NEUP-00002697 – 746, at -712 (Amgen U.S. G-CSF 2014 LRP, April 23, 2014).

66. [redacted]



67. Given the data on Amgen's experience with Granix, [redacted], and Dr. Philipson's own admission that the prospect of price erosion is quite uncertain, the risk of this alleged harm does not appear to be significant or irreparable.

E. There is no basis for Dr. Philipson's assertion that Amgen will lose goodwill if Zarxio enters and later is removed from the market.

68. Dr. Philipson theorizes that if Sandoz entered the market and was later prevented from selling due to Amgen's patent protection, the removal of Sandoz's product could be seen as "Amgen's fault…Amgen faces the risk of lasting harm to its goodwill."[99] Amgen has a long history of raising Neupogen prices in the past without apparent fear of losing goodwill.[100]

69. Amgen would not be the first pharmaceutical manufacturer that has forced a second entrant off the market. For example, the case of Plavix shows that a brand can very

[98] AMG-NEUP-00002697 – 746, at -723 (Amgen U.S. G-CSF 2014 LRP, April 23, 2014).
[99] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶93, p. 33.
[100] "The increase in U.S. sales of Neulasta®/NEUPOGEN® for 2010 was driven principally by an increase in the average net sales price". Amgen 2010 Form 10-K, at p. 74. "The increase in U.S. sales of Neulasta® /NEUPOGEN® for 2011 was driven principally by an increase in the average net sales price and Neulasta® unit growth." Amgen 2011 Form 10-K, at p. 73. "The increase in U.S. NEUPOGEN ® sales for 2012 was driven by an increase in the average net sales price." Amgen 2012 Form 10-K, at p. 63.

quickly recover after a generic leaves the market. Plavix is a brand drug used to prevent blood clots. On August 8, 2006, Apotex launched a generic version of Plavix.[101] Three weeks later, on August 31, 2006, Sanofi and Bristol Myers were granted an injunction, which barred further sales of Apotex's generic version but did not force a recall of supplies that had already been shipped.[102] In those three weeks, Apotex's generic Plavix had already flooded the market and generated $884 million in sales.[103] Although Plavix suffered substantial losses in the short term, it recovered quickly once the generic product was exhausted.[104] By January 2007, its market share in the U.S. already exceeded that of Apotex's generic, as available supplies of the generic ran out.[105] Despite facing almost $900 million in generic sales, within a year branded Plavix fully recovered its prior growth trajectory in prescriptions as illustrated in Figure 14.

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[101] Bristol-Myers Squibb Company, "Preliminary Injunction Ordered in Plavix® Patent Infringement Case; Apotex to Halt Sales of Unauthorized Generic," August 31, 2006. Accessed February 23, 2015. http://www.sec.gov/Archives/edgar/data/14272/000119312506185268/dex991.htm.

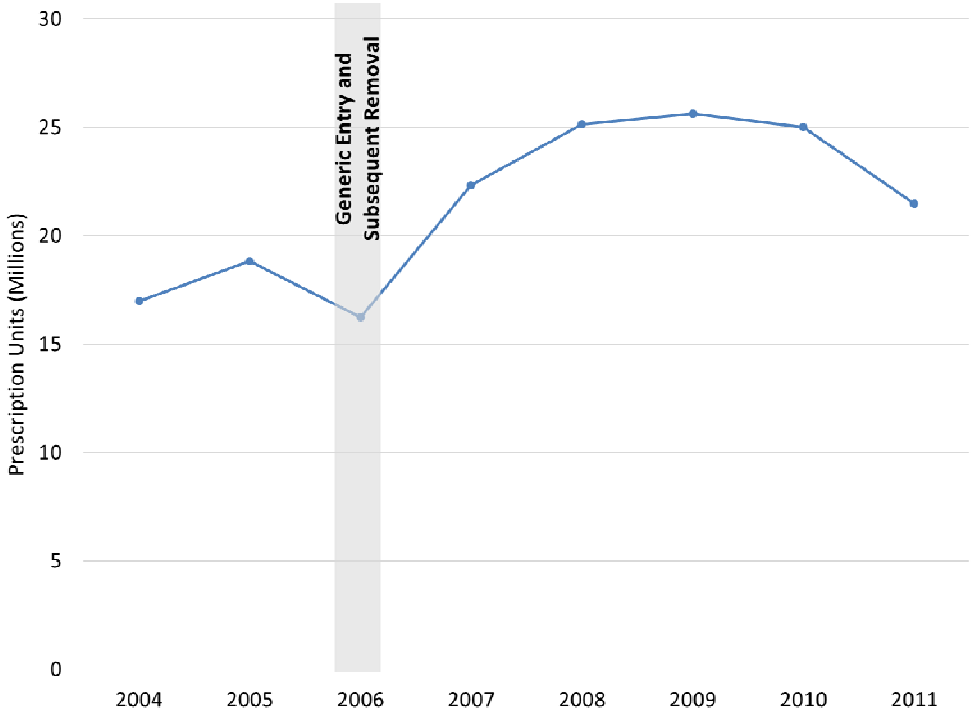
[102] Bristol-Myers Squibb Company, "Preliminary Injunction Ordered in Plavix® Patent Infringement Case; Apotex to Halt Sales of Unauthorized Generic," August 31, 2006. Accessed February 23, 2015. http://www.sec.gov/Archives/edgar/data/14272/000119312506185268/dex991.htm.

[103] Generics and Biosimilars Initiative, "Apotex Clopidogrel At-Risk Launch Costs US$442 Million," February 3, 2012. Accessed September 11, 2014. http://gabionline.net/Generics/News/Apotex-clopidogrel-at-risk-launch-costs-US-442-million; Stanton, Tracy, "Court Upholds $442M Plavix Judgment Against Apotex," *FiercePharma*, October 19, 2011. Accessed February 20, 2015. http://www.fiercepharma.com/story/court-upholds-442m-plavix-judgment-against-apotex/2011-10-19.

[104] Stanton, Tracy, "Court Upholds $442M Plavix Judgment Against Apotex," *FiercePharma*, October 19, 2011. Accessed February 20, 2015. http://www.fiercepharma.com/story/court-upholds-442m-plavix-judgment-against-apotex/2011-10-19; Laforte, Marie-Eve, "Plavix regaining US market share over generic drug, report," *FirstWord Pharma*, January 11, 2007. Accessed February 20, 2015. http://www.firstwordpharma.com/node/120012#axzz3DdnYwuz7.

[105] Laforte, Marie-Eve, "Plavix regaining US market share over generic drug, report," *FirstWord Pharma*, January 11, 2007. Accessed February 20, 2015. http://www.firstwordpharma.com/node/120012#axzz3DdnYwuz7.

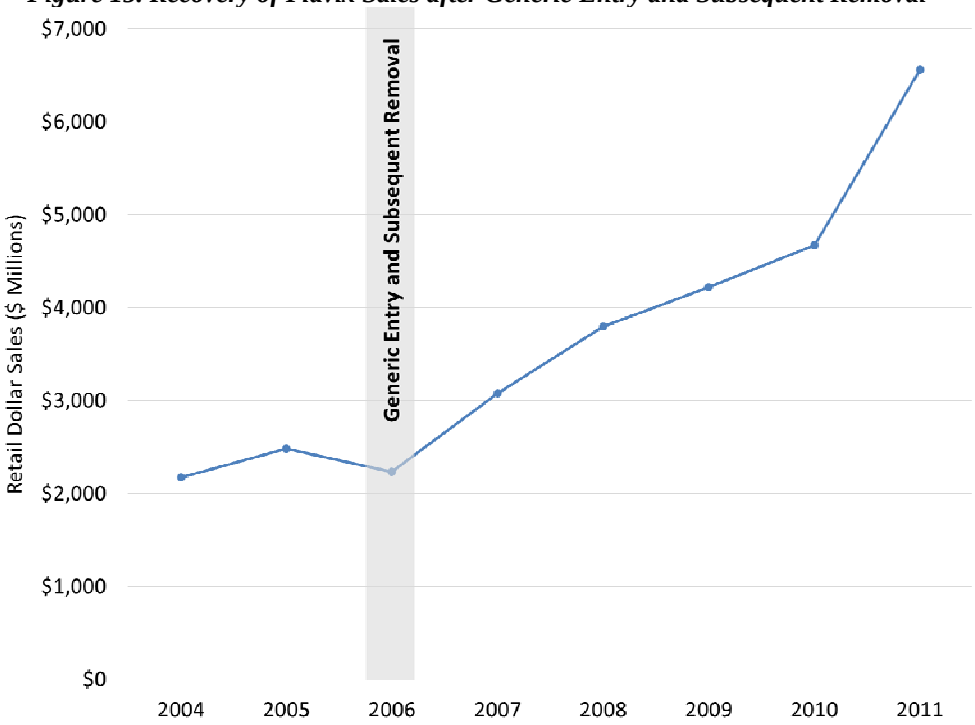
Figure 14. Recovery of Plavix Prescriptions after Generic Entry and Subsequent Removal[106]



70. Figure 15 shows that Plavix was also able to recover its growth trajectory in retail dollar sales. This indicates that Plavix did not suffer from any persistent price erosion.

[106] Drugs.com, "U.S Pharmaceutical Sales" by Prescription Units and Year, 2004-2011. Accessed February 20, 2015. http://www.drugs.com/top200_units_2004.html

Figure 15. Recovery of Plavix Sales after Generic Entry and Subsequent Removal[107]



71. This experience suggests that any potential harm to goodwill is a speculative rather than real concern.

F. Dr. Philipson's other forms of possible injury lack factual support.

72. Dr. Philipson included a broad list of other alleged harms not mentioned in Amgen's Brief. I address them separately and briefly in this section.

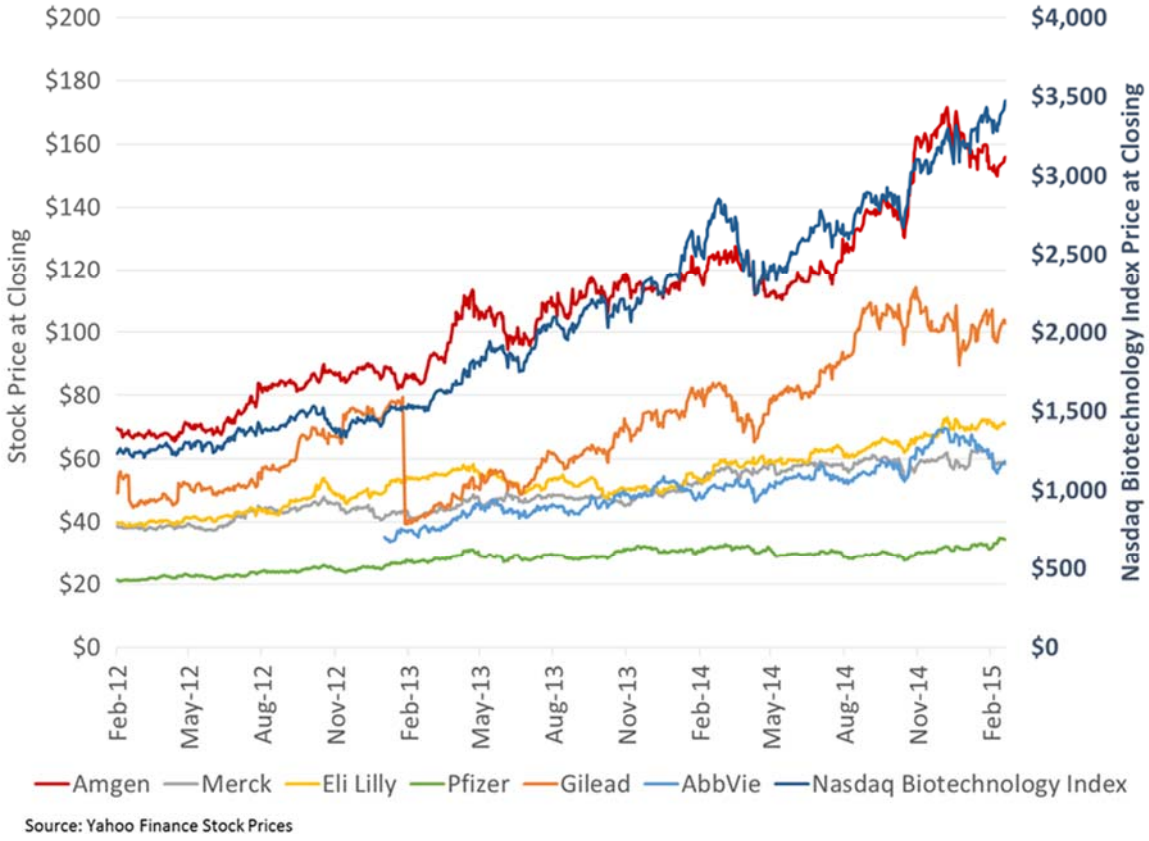
73. Dr. Philipson's assertion that drug developers find it difficult to raise money is both incorrect and inapplicable to Amgen. Amgen's stock has performed extremely well and has offered large dividends:[108] the company's market capitalization is approximately $116.5

[107] Drugs.com, "U.S Pharmaceutical Sales" by Retail Dollar Sales and Year, 2004-2011. Accessed February 20, 2015. http://www.drugs.com/top200_2004.html

[108] Dividends on Amgen stock rose from $0.56 per share in 2011, to $1.44 in 2012, $1.88 in 2013, and $2.44 in 2014. Amgen 2014 Form 10-K, at p. 41.

billion.[109] As Figure 16 shows, Amgen's stock price (appearing in red) has more than doubled over the last three years, and it has outperformed many of its competitors in the pharmaceutical sector. Included in this graph for purposes of comparison is the NASDAQ biotechnology index (appearing in dark blue).

Figure 16. Amgen and Pharmaceutical Market 3 Year Stock Price History[110]



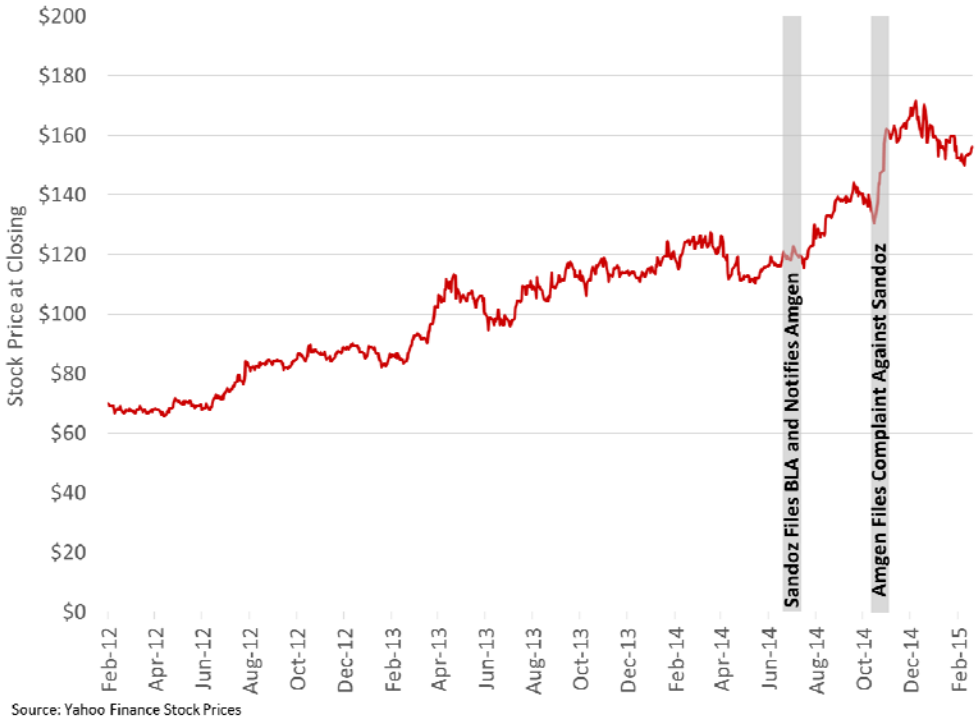
74. Furthermore, Figure 17 shows that Amgen's stock did not react unfavorably to the notice that Sandoz had filed its Neupogen biosimilar a BLA; instead, the stock exhibited a steep

[109] NASDAQ.com, "Amgen Inc." Accessed February 2, 2015. http://www.nasdaq.com/symbol/amgn.

[110] Note that Gilead's stock price drop in early 2013 is due to a two-for-one stock split; Gilead Sciences, Inc., "Gilead Board Approves Two-for-One Stock Split," December 10, 2012. Accessed February 18, 2015. http://www.gilead.com/news/press-releases/2012/12/gilead-board-approves-twoforone-stock-split.

climb in value. This shows that investors did not act as Dr. Philipson theorized and confirms that they were already prepared for and unconcerned by biosimilar competition with Neupogen. Amgen's stock continued its climb until December 2014 when there was a broad-based shakeout in the biotechnology sector. Amgen's stock was reported to have suffered especially because "Amgen and Regeneron [went] head to head on pricing for cholesterol products."[111] In other words, the decline had nothing to do with Neupogen or fears about the upcoming Zarxio launch.

Figure 17. Amgen 3 Year Stock Price History

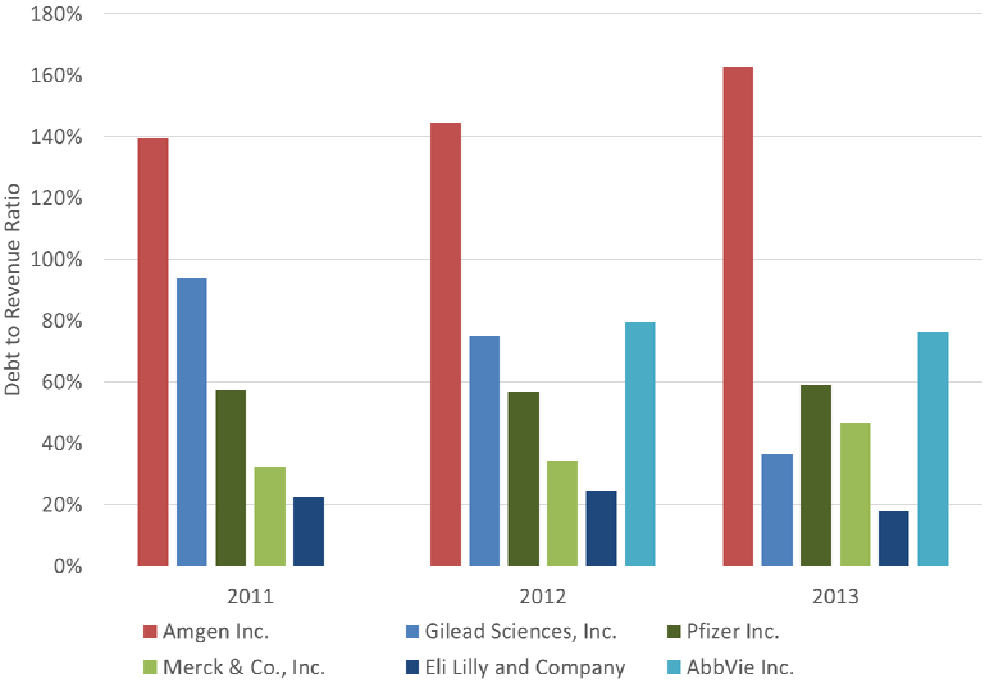


[111] Seeking Alpha, "I'm Waiting Till the Carnage in Biotech Stocks Subsides to Buy Amgen." December 26,
2014, at p. 3. Accessed February 13, 2015. http://seekingalpha.com/article/2781105-im-waiting-till-the-carnage-in-biotech-stocks-subsides-to-buy-amgen. *See also* Silverman, Ed, "The Hepatitis C Price Wars Begin: What the Express Scripts Move Means," *Wall Street Journal*, December 22, 2014. Accessed February 23, 2015. http://blogs.wsj.com/pharmalot/2014/12/22/the-hepatitis-c-price-wars-begin-what-the-express-scripts-move-means/.

75. Although Dr. Philipson has argued outside investors would be reluctant to finance Amgen's R&D due to uncertain outcomes and information asymmetries, [112] Amgen actually has a large amount of debt, indicating that it has no difficulty accessing "outside funding." Figure 18 illustrates that Amgen's long term debt to revenue ratio is usually over 100%, and has always been significantly higher than that of major competitors. Amgen is also considered a "low default risk" with an A credit rating by Morningstar, Inc.[113] In July 2014, Amgen renewed its $2.5 billion unsecured, syndicated, revolving credit facility obtained through Citibank, further confirming the significant "outside" resources available to it.[114]

[112] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶38-39, pp. 13-14.
[113]Morningstar, "AMGN Amgen Inc debt, bond, rates, credit – Morningstar." Accessed February 23, 2015. http://quicktake.morningstar.com/StockNet/bonds.aspx?Symbol=AMGN&Country=usa; Morningstar, "Morningstar's Approach to Rating Corporate Credit," at p. 1. Accessed February 23, 2015. http://news.morningstar.com/pdfs/corp_credit_rating.pdf.
[114] Amgen 2014 Form 10-K, at p. 53.

Figure 18. Long Term Debt as a % of Revenue for Amgen and Branded Pharmaceutical Companies



Source: Company 2012 and 2013 Form 10Ks

76. In his deposition, Dr. Philipson argued that even if non-revenue funding sources were available, this would be irrelevant because Amgen historically has not used them to boost R&D spending in periods of revenue decline.[115] It is impossible for Dr. Philipson to know this without first examining borrowing activity, securities offerings, cash and cash equivalent balances, and free cash generated from operations to determine whether they were, in fact, drawn down by Amgen for research purposes in periods of reduced revenue. There is no suggestion that Dr. Philipson has looked at *any* of this evidence before arriving at his unfounded conclusion.

77. Dr. Philipson insists that "there is uncertainty about the precise impact of Zarxio's unlawfully premature sales on Amgen"[116] and that "[t]he magnitude of losses that Sandoz's unlawfully premature sales would cause to Amgen's business over time cannot be determined

[115] Deposition of Tomas Philipson, February 13, 2015, at 139:3-17.
[116] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶85, p. 31.

with reasonable certainty *in advance*."[117] [redacted]

[redacted]

78. Dr. Philipson also argues that, after Zarxio's entry, Amgen's profit margins on Neupogen may decline and its operating costs may rise due to the smaller scale of corporate operations. However, in the case of small molecule drugs, the makers of reference drugs often find their costs decrease and profit margins increase after generic entry due to a decrease in

[117] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶86, p. 31 (emphasis added).
[118] AMG-NEUP-00002747 – 820, at -765.

marketing support. Amgen has already withdrawn marketing support from Neupogen in an effort to switch patients to Neulasta prior to Zarxio's entry. In October 2012, Amgen began telling investors that "in the U.S., we haven't actively promoted NEUPOGEN for 8, 9 years. All our focus is obviously around Neulasta."[119] [redacted] This is a standard practice among branded pharmaceutical firms that are anticipating generic competition for one of their products. Where a patented follow-on version of the drug has been developed (such as a long-acting formulation) it is in the branded drug maker's economic interest to convert as much of its sales base as possible before the generic enters the market.

VII. OPINION #3: ADEQUACY OF MONEY DAMAGES

79. In his report, Dr. Philipson says that he was asked to analyze five questions. The third of these was "Whether money damages adequate to compensate Amgen for the harms that Sandoz's unlawfully premature, and possibly patent-infringing sales are likely to cause to Amgen can be determined with reasonable certainty *at this time*."[121] In his Summary of Opinions, Dr. Philipson concludes that "Monetary damages would be inadequate and difficult to estimate with reasonable accuracy."[122] Throughout his deposition, Dr. Philipson stated that the

[119] Seeking Alpha, "Amgen FQ3 2012 Earnings Call Transcript," October 23, 2012, at p. 9. Accessed February 12, 2015
2015. http://seekingalpha.com/article/944111-amgen-management-discusses-q3-2012-results-earnings-call-transcript.
[120] AMG-NEUP-00000358 – 429, at -408.
[121] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶12(iii), p. 4 (emphasis added).
[122] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶19, p. 6.

injury to Amgen would be "hard to monetize."[123] I disagree with this conclusion. As discussed throughout this Declaration, the injury to be compensated would consist of lost profits from sales of Neupogen.

80. [redacted]

As a matter of economics, this is a form of harm that is readily addressed through an award of money damages. The other forms of injury posited by Dr. Philipson are purely speculative and, in most cases, are already undermined by the empirical evidence.

81. Dr. Philipson is not well-suited to opine on the adequacy of money damages. At his deposition, he testified that he has never prepared a patent damages calculation for legal purposes, whether for lost profits, price erosion or as a reasonable royalty.[125] He also conceded that he does not know the scope and nature of the monetary remedies that would be permitted if Amgen ultimately could identify a valid patent and prove its infringement.[126] As a result, it

[123] Deposition of Tomas Philipson, February 13, 2015, at 70:19-71:7; 72:23-73:22, 119:22-120:2; 121:12-20.
[124] Deposition of Robert Azelby, February 15, 2015, at 224:1-18. (emphasis added; objection omitted)
[125] Deposition of Tomas Philipson, February 13, 2015, at 64:21-65:19.
[126] Deposition of Tomas Philipson, February 13, 2015, at 65:20-66:6.

would presumably be difficult for him to determine whether this harm from patent infringement can be adequately remedied through an award of money damages.

82. Dr. Philipson's position on money damages appears to be based on this view that, at this point in time, it is not possible with precision to foresee how the market for filgrastim will unfold in the United States. Although the future is to some degree uncertain, this is the wrong focus. The question is not whether damages can be accurately computed *now*, but whether they will be calculable on an *ex post* basis, after Zarxio has launched and if the product is found to have infringed a valid and unexpired patent held by Amgen.

83. At that point in time, fact witnesses and experts for each party should have access to historical third party data that reliably reports on a monthly basis the units of each filgrastim product sold in the U.S., the aggregate dollars paid for those purchases grouped by each manufacturer and product, the distribution of sales by setting (hospital, clinic, or retail pharmacy), Medicare reimbursement rates based on Average Selling Price, and the treatment accorded by private formularies to each of these products. Proprietary information on sales adjustments such as discounts or rebates, costs, and profit margins likely will be available through the litigation discovery process. In the normal course, information of this type makes it possible to compute with reasonable certainty the lost sales and profits, if any, experienced by one pharmaceutical product as a result of competition posed by another. Economists often measure the effects of competition using such data sources and there is no reason to suppose that this cannot be done later in this case if infringement is found. The likelihood of disputes regarding the amount and nature of the damages, which are to be expected and common in litigation, does not make the availability of damages an inadequate remedy.

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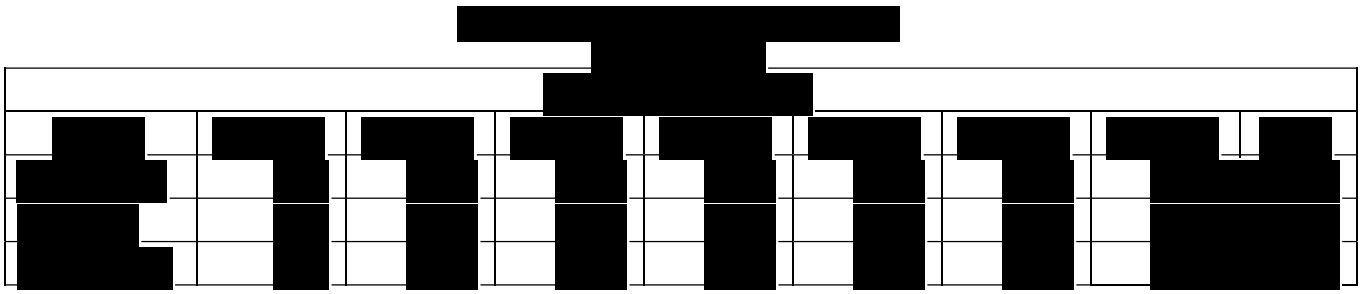
VIII. OPINION #4: SANDOZ WOULD SUSTAIN SIGNIFICANT ECONOMIC LOSSES IF ZARXIO'S LAUNCH WERE DELAYED

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

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

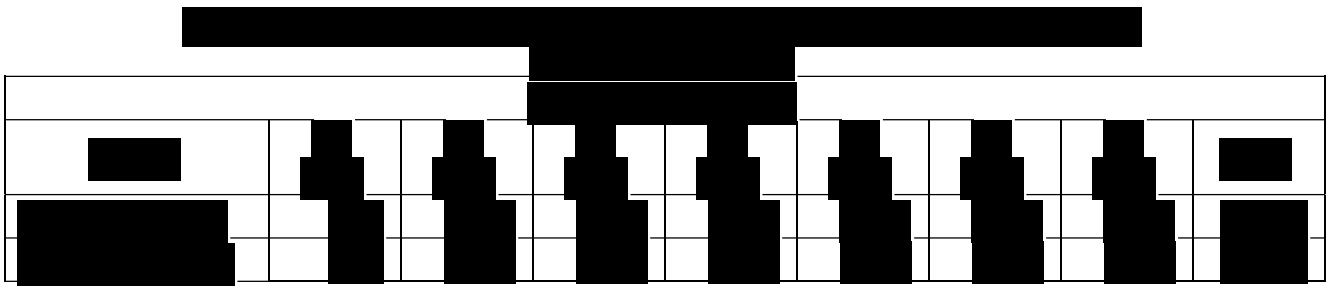
85. To evaluate Sandoz's likely losses, I studied the experience of biosimilar filgrastim products in Europe and the line-up of companies currently pursuing such products in the U.S. [redacted]

[redacted]



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

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



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

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

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

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

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

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

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

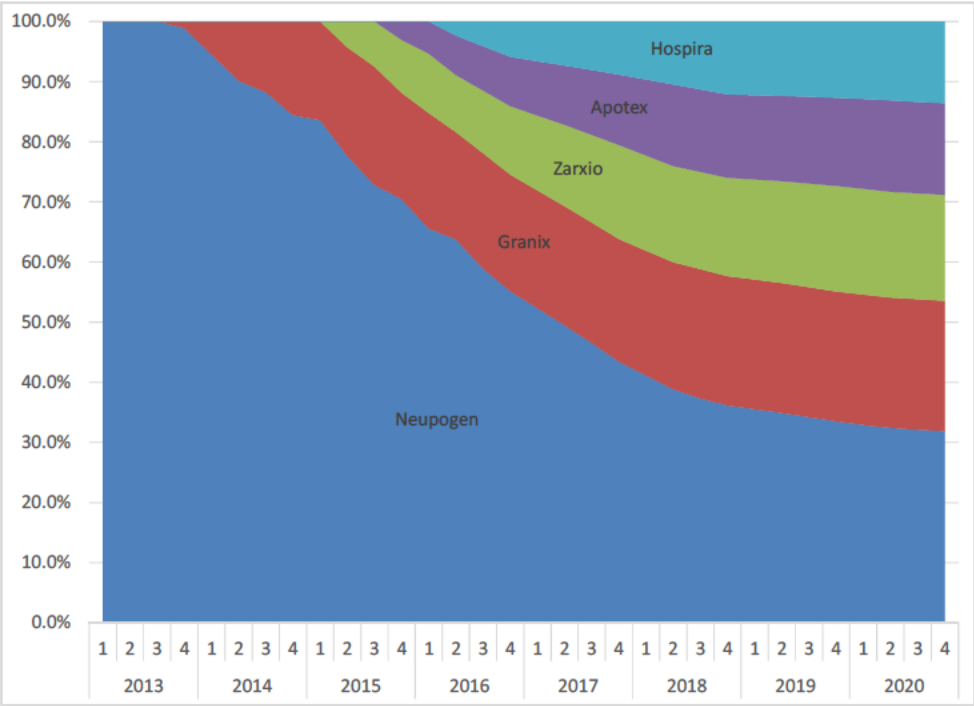
d. I assumed that price discounts will increase as the number of biosimilar competitors grows. In my model, I have evaluated these price discounts off of the contemporaneous price for Neupogen.

e. [redacted]

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

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

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



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

[redacted]

91. [redacted]

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

93. [redacted]

B. Inventory losses.

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

C. Losses from unrecoverable planned expenses.

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

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

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

96. [redacted]

97. [redacted]

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

[redacted]

98. [redacted]

[redacted]

D. Bond amount.

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

134 [redacted]

IX. OPINION #5: PUBLIC INTEREST

100. Dr. Philipson claims that an injunction would benefit the public interest. I disagree. Notably, Dr. Philipson's discussion of public interest is not related to Neupogen specifically, but instead focuses on the alleged overall benefit from innovation and the reasons why society should provide substantial economic returns to companies that innovate to create new medicines. He asserts that if Sandoz's interpretation of the BPCIA is accepted, there would be a "reduction in the incentives to invest in R&D and innovate throughout the industry."[135] Dr. Philipson does not provide any sort of analysis to support this theory, nor does his discussion explain why biotechnology firms would rationally decide not to invest in an otherwise promising product based solely on the availability of no more than 410 days of added exclusivity in situations where they hold no enforceable patent rights. The difference is not, on its face, meaningful and Dr. Philipson does no specific analysis to isolate the effect that specific periods provided in the BPCIA would have on the incentives to invest.

101. Dr. Philipson suggests that, rather than benefitting consumers, the result of Zarxio's entry would "largely [be] a reallocation of revenues from Amgen to Sandoz… [which] would not serve the public interest."[136] Instead, he argues, the real public benefit comes from encouraging innovation, and that giving greater protection from competition to new drug developers will serve this purpose.[137] This argument should depend on the existence of an enforceable patent applicable to Neupogen, but no such patent has been identified.[138]

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[135] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶82, p. 30.
[136] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶124, p. 43.
[137] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at §D.5, pp. 36-44.
[138] Dr. Philipson has no opinion as to whether Amgen would suffer irreparable harm if it no longer has any enforceable patents pertaining to filgrastim or its manufacturer. Deposition of Tomas Philipson, February 13, 2015, at 34:13-35:22.

102. Dr. Philipson presents in his report two figures (Figures 5) purporting to illustrate changes in consumer welfare, neither of which is based on real data and neither of which is intended to represent the actual change that would be experienced with Zarxio entering the market.[139] In deposition, Dr. Philipson conceded that these were merely conceptual illustrations: "Q. And it's also a hypothetical illustration; correct? A. Correct. Q. Meaning that none of the numbers we're plotting here come from actual data in the market? A. Correct."[140] Dr. Philipson went on to confirm that "the demand curve is not estimated off real data, so that we're trying to make a point by using a figure. Q. So there's no real data about the Filgrastim market that is defining how you – how you wrote or plotted that demand curve; correct? A. Correct."[141] Although he argues that the top priority should be protecting the innovator, in deposition Dr. Philipson acknowledged that "[o]nce the patent period has expired on all patents relevant to this Neupogen – it's not just a molecule patent, but manufacturing patents as well – it's all those are – have been expired, then, yes, lower prices [resulting from biosimilars] are better."[142] Put simply, absent a valid patent right, competition and lower prices benefit consumers and society.

103. Neupogen entered the market in 1991 and Amgen has already enjoyed 24 years of exclusivity for the product. It told investors that its material patents on the product have expired. After this long period of exclusivity, the public interest is better served by increasing access to life-saving filgrastim while reducing costs. Although not mentioned by Dr. Philipson, the cost of Neupogen is large – Neupogen's price is approximately $3,000 per chemotherapy

[139] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at pp. 40, 42.
[140] Deposition of Tomas Philipson, February 13, 2015, at 234:15-24.
[141] Deposition of Tomas Philipson, February 13, 2015, at 230:23 - 231:14.
[142] Deposition of Tomas Philipson, February 13, 2015, at 237:5-10.

cycle,[143] and most oncology patients go through 1-4 cycles. Industry experts point out that "[b]ecause Neupogen (the old drug) costs over $300 per dose, copays can be significant and are potentially limiting."[144] In fact, all "[b]iologic drug innovations…are expensive. As examples, annual treatment for breast cancer with the biologic drug Herceptin can cost $48,000 and the annual treatment for rheumatoid arthritis with Remicade can cost approximately $20,000. Indeed, in 2007, Americans spent $286.5 billion for prescription drugs, $40.3 billion of which was for biologic drugs."[145] In order to combat these high prices, patients in the U.S. urged the FDA Oncologic Drugs Advisory Committee to consider approving Sandoz's Zarxio because of the cost benefits it would bring to patients.[146]

104. Industry experts have also expressed unease over the lack of competition in the biologics market, noting that "[i]t is of particular concern that biologics typically do not face generic competition after their original patent protection has expired, thus extending high prices indefinitely."[147] In light of this competition problem, the entry of authorized biosimilars to the

[143] IMS National Sales Perspective Data, Sales Dollars ($) and Volume ("Sales_Amgen_Teva_NSP_1_Feb-09-2015.xlsx" and "Eaches Volume_Amgen_Teva_NSP_1_Feb-09-2015.xlsx"); "Neupogen – Prices, Coupons, and Information." *GoodRx*. Accessed February 18, 2015. http://www.goodrx.com/neupogen.
[144] Schattner, Elaine, "Why the FDA Panel's Nod to Sandoz's Filgrastim (Zarzio) Is Good News for Patients," *Forbes*, January 7, 2015. Accessed February 23, 2015. http://www.forbes.com/sites/elaineschattner/2015/01/07/the-fdas-approval-of-zarzio-is-good-news-for-patients/.
[145] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, at p. i.
[146] "'We have talked this morning about the elephant in the room — about cost,' said Amye Leong, who identified herself as a patient. 'I know that the F.D.A. is not supposed to be talking about this, but it is the cost that we patients daily must deal with.'" Tavernise, Sabrina, "For First Time, F.D.A. Panel Approves Generic Copy of Costly Biologic Drug," *New York Times,* January 7, 2015, at p. 3. Accessed February 23, 2015. http://www.nytimes.com/2015/01/08/science/fda-panel-vote-biologics.html?_r=0.
[147] Mulcahy, Andrew, Predmore, Zachary, and Soeren Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," *RAND Corporation Perspective*, 2014, 1-16, at p. 2.

market holds a particular importance, as "[t]he advent of a U.S. biosimilar approval pathway and market can affect health care spending through two mechanisms: (1) [d]ecreased unit cost… (2) [i]ncreased volume."[148]

105. Dr. Philipson suggests that Zarxio may not provide significant cost savings because it could be priced at parity with Neupogen.[149] Although he points to a media interview as support for this possibility, his excerpts provide a misleading picture.[150] He ignores the fact that the quoted Sandoz executive went on to say, in no uncertain terms, "[t]he cost [of Zarxio]…would be less for consumers, payers and the health care economy."[151] Sandoz is understandably reluctant to publicize Zarxio's expected pricing structure prior to launch, and the vagueness of its remarks to the media is understandable.

106. Generic and biosimilar drugs are, by definition, comparable to their reference drugs in all significant respects other than the price. Because they are not differentiated from the reference drug, lower prices represents the value proposition generics or biosimilars bring to the market and which enables them to compete. As a result, I find it extremely unlikely that Zarxio would be brought to market without offering a meaningful price savings when compared to Neupogen. [redacted]

[148] Mulcahy, Andrew, Predmore, Zachary, and Soeren Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," *RAND Corporation Perspective*, 2014, 1-16, at p. 4.
[149] Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶73, pp. 26-27.
[150] Dr. Philipson reports news that "[Zarxio] **could** be priced at parity with Neupogen" although Sandoz spoke of this only as one possible pricing option. Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶73, p. 27 (emphasis added). In addition, Dr. Philipson reports that Sandoz "can't say that the price [of Neupogen] will be less because in some situation [sic] the price will be at parity." Expert Report of Tomas Philipson, Ph.D., February 5, 2015, at ¶73, p. 26.
[151] Firth, Shannon, "FDA Advisory Committee Endorses Neupogen Biosimilar," *Public Health & Policy*, January 8, 2015, at p. 4. Accessed February 23, 2015. http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/49427.

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[redacted]

107. The availability of lower cost biosimilar filgrastim would be a significant benefit to patients, third party payers, and government programs that bear these costs. Industry experts predict that "biosimilars will lead to a $44.2 billion reduction in direct spending on biologic drugs from 2014 to 2024, or about 4 percent of total biologic spending over the same period, with a range of $13 billion to $66 billion."[153] The FTC found that biosimilar entrants are likely to price at a discount to the reference biologic's price of "between 10 and 30 percent."[154] The FTC explains the implications of this discount, stating "[a]lthough not as steep a discount as small-molecule generic drugs, a 10 to 30 percent discount on a $48,000 drug product represents substantial consumer savings."[155] As noted by one industry expert in connection with the FDA's approval of Zarxio, "[b]iosimilars have the potential to significantly reduce the costs of modern health care for people with all kinds of illness…so this decision should be of interest, and concern, to everyone."[156]

[152] Interview with Alex Thole and other Sandoz representatives on February 17, 2015.
[153] Mulcahy, Andrew, Predmore, Zachary, and Soeren Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," *RAND Corporation Perspective*, 2014, at p. 1.
[154] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, at p. v.
[155] Federal Trade Commission, "Emerging Health Care Issues: Follow-on Biologic Drug Competition," June 2009, at p. v.
[156] Schattner, Elaine, "Why the FDA Panel's Nod to Sandoz's Filgrastim (Zarzio) Is Good News for Patients," *Forbes*, January 7, 2015, at p. 2. Accessed February 23, 2015. http://www.forbes.com/sites/elaineschattner/2015/01/07/the-fdas-approval-of-zarzio-is-good-news-for-patients/.

108. [redacted]

109. Plainly, Amgen understands the importance and opportunity of biosimilar drugs. It is currently developing nine of its own biosimilar products, six of which have been identified in documents supplied through discovery and are listed in the table below. Amgen expects five of its biosimilars to launch by 2019.

[157] AMG-NEUP-00002827 – 3026, at -869.
[158] AMG-NEUP-00002827 – 3026, at -869.
[159] AMG-NEUP-00002827 – 3026, at -951.

Table 24. Amgen Biosimilars Under Development[160]

Active Substance	Brand Name	Manufacturer
1. Adalimumab	HUMIRA	AbbVie Inc.[161]
2. Trastuzumab	Herceptin	Genentech, Inc.[162]
3. Bevacizumab	Avastin	Genentech, Inc.[163]
4. Infliximab	REMICADE	Janssen Biotech, Inc.[164]
5. Rituximab	Rituxan	Genentech, Inc.[165]
6. Cetuximab	Erbitux	ImClone LLC[166]

110. In a Q2 2011 earnings call, Amgen's CEO, Kevin Sharer, was asked "in terms of the biosimilars in the U.S., do you think that their pricing impact would be similar to what you have seen in the EU?"[167] His response demonstrates that Amgen expects biosimilars in the U.S. to command higher returns than small molecule generics in light of their larger investment.

> Certainly, we'll have a robust biosimilar environment in the United States, hard to predict exactly when, hard to predict how many. But I'd like to just reiterate that the biosimilar environment commercially is nothing like the generic pill situation.

[160] Foraker, Scott, "Biosimilars," *Amgen*, October 28, 2014, at p. 3.
[161] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Humira," at p. 52. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125057s367lbl.pdf.
[162] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Herceptin," at p. 35. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103792s5311lbl.pdf.
[163] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Avastin," at p. 35. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125085s305lbl.pdf.
[164] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Remicade," at p. 15. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/103772s5370lbl.pdf.
[165] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Rituxan," at p. 34 Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103705s5432lbl.pdf.
[166] U.S. Food and Drug Administration, "Highlights of Prescribing Information – Erbitux," at p. 8. Accessed February 18, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125084s242lbl.pdf.
[167] Seeking Alpha, "Amgen FQ2 2011 Earnings Call Transcript," July 29, 2011, at p. 7. Accessed February 20, 2015. http://seekingalpha.com/article/283246-amgens-ceo-discusses-q2-2011-results-earnings-call-transcript

> Companies have to invest in clinical trials, they have to invest in manufacturing, they have to actually sell the product, they have to have regulatory capability, et cetera, et cetera. So this is a competitive environment. I expect that the players will be commercially rational and that our shareholders will demand that they earn a good return. And so I think it will be kind of like a normal business, if you will, where there are multiple competitors. We have experience in this. We will be smart, tenacious and I believe effective competitors in the United States just as we have been in Europe. I'd rather not try to speculate at this moment on exactly what the prices are. But I think we can see and characterize from sort of a general business theory way what likely will be the competitive landscape, and Amgen will be ready.[168]

111. Indeed, a presentation on Biosimilars prepared by Scott Foraker, Amgen's Vice President and General Manager, "Biosimilars", concludes that they have more in common with branded biologics than with small molecule generics, including long periods of development, high levels of scientific and manufacturing difficulty, large up-front costs, and the need to provide extensive marketing and sales support.[169] These investments, described by Mr. Foraker and Mr. Sharer, are precisely the investments that Sandoz has already had to make to prepare Zarxio for market. In light of the fact that discovery is ongoing, I reserve the right to revise my opinions based upon any new or additional information that becomes available.

I declare under penalty of perjury under the laws of the United States that the foregoing statements are true and correct to the best of my knowledge and that this Declaration was executed on February 24, 2015 in Berkeley, California.

Gordon Rausser

Gordon Rausser, Ph.D.

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[168] Seeking Alpha, "Amgen FQ2 2011 Earnings Call Transcript," July 29, 2011, at p. 7. Accessed February 20, 2015. http://seekingalpha.com/article/283246-amgens-ceo-discusses-q2-2011-results-earnings-call-transcript

[169] Foraker, Scott, "Biosimilars," *Amgen*, October 28, 2014, at p. 5.

EXHIBIT 6

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SANDOZ INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH,

Defendants.

Case No. 3:14-cv-04741-RS

DECLARATION OF ALEXANDER THOLE IN SUPPORT OF SANDOZ INC.'S OPPOSITION TO AMGEN'S MOTION FOR A PRELIMINARY INJUNCTION

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

The Honorable Richard Seeborg

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

I, Alexander Thole, declare:

1. I am Executive Director, Oncology Sales & Marketing. I submit this declaration in support of Sandoz Inc.'s Opposition to Amgen's Motion for a Preliminary Injunction. I am personally knowledgeable about the statements set forth in this declaration and could competently testify to them.

2. I have responsibility for significant aspects of Sandoz's efforts to successfully launch and commercialize a biosimilar for filgrastim in the United States. Amgen's name for the reference product for filgrastim is Neupogen. Sandoz expects to launch its biosimilar product under the name Zarxio. My responsibilities include the sales and marketing of Sandoz oncology biosimilars in the United States.

Sandoz's Plans to Launch the First Biosimilar into the United States Market.

3. Sandoz has invested significant time and effort to prepare for the launch of Zarxio as the first biosimilar product in the United States. This has included significant efforts to prepare a biosimilar application for submission to the FDA, to create a commercial organization to manage and sell the product, and to create a broader administrative, compliance and financial organization to support these efforts. The manufacture, preparation and approval of a biosimilar are complex business and scientific enterprises. They require considerable technical skill, considerable expertise, and the investment of substantial funds in development. The likelihood that Zarxio will be the first biosimilar product approved in the United States is a testament to and a reflection of Sandoz's expertise and efforts.

4. On July 7, 2014, the FDA accepted Sandoz's biosimilar application. Under the BSUFA guidelines, Sandoz anticipates a decision from the FDA regarding whether to grant approval at or around March 8, 2015.

5. Currently, there are two short acting filgrastim products on the market, Neupogen (filgrastim), which was introduced in 1991 and Granix (tbo-filgrastim), which was introduced in late 2013. Neupogen and Granix are used to increase the number of neutrophils, which are a form of white blood cells, in the body. They are both short acting filgrastim products that require daily injections, starting the day after an infusion of chemotherapy and lasting until certain clinical end

points are met. While they can be used for multiple medical purposes, the predominant use of these products is to address the suppression of neutrophils in connection with certain forms of chemotherapy in cancer patients. Zarxio will be a third short acting filgrastim product approved, and Sandoz anticipates that Zarxio will be approved for the same indications that Neupogen is approved for.

6. Amgen also markets a long acting PEG-filgrastim product called Neulasta, which was introduced in 2002. It is dosed just once per chemotherapy treatment cycle, the day after an infusion of chemotherapy, avoiding the need for the patient to return to a clinic for additional shots, where applicable.

7. As a consequence of the positive Advisory Committee opinion and the BSUFA guidelines, it is likely that the FDA will approve Zarxio as biosimilar to Neupogen in March 2015 and it is likely to approve it for use in the same indications as Neupogen. If this occurs, Zarxio will be the first product approved as a biosimilar under the provisions of the Biologics Price Competition and Innovation Act or BPCIA.

8. Zarxio has already been a very successful product after it was introduced as a biosimilar in Europe (where it is sold under the name Zarzio). After a number of years on the market, Zarzio has become the most frequently used short acting filgrastim product in Europe.

9. To successfully convince customers to purchase a new pharmaceutical product, they must believe that it offers an advantage in its performance or its price. Because Zarxio is a biosimilar, it has essentially the same overall effectiveness, the same overall safety profile, and the same overall pharmacology profile as Neupogen. As a result, Zarxio needs to compete based in significant measure on value.

10. [redacted]

The Permanent, Long-Term Competitive Harm That a Delay Would Impose on Sandoz.

11. If approved, Sandoz would initiate commercial activity in March 2015 to sell

Zarxio in the United States and would compete directly with Neupogen and Granix. Entry this spring and the opportunity to market Zarxio as the first biosimilar is a significant competitive advantage compared to later entry. This advantage was obtained through significant efforts and expense by Sandoz.

12. Sandoz (and market analysts) anticipates that at least two additional products that are biosimilar to Neupogen will launch in the United States in the next five quarters. On February 17, 2015, Apotex announced that the FDA accepted its biosimilar application for filgrastim. As a result and if the biosimilar is approved, Sandoz anticipates that Apotex will be in a position to launch its product in the period between October 2015 and June 2016. Further, Hospira is likely to introduce another biosimilar short-acting filgrastim product into the U.S. market around April 2016.

13. Thus, if an injunction was entered for a year or more, Sandoz's product would enter the market at the same time as or after the entry of both Hospira's and Apotex's products. I believe that this would have a severe negative impact on the expected sales and returns for Zarxio. Entry as the fourth or fifth competing short acting filgrastim product or at the same time as one or two other filgrastim biosimilars would reduce Sandoz's ability to build market share, would increase the probability of more severe price discounts, would increase the amount that Sandoz has to spend as a percent of revenue to promote the product, and would reduce the profits and cash flow from the products. Sandoz would achieve a lower immediate share of the market and a lower long-term share of the market at a lower realized price. These economic and market share losses are highly likely to be permanent and cannot be made up in light of the material change in the nature of the market that would occur after multiple biosimilars have entered.

<u>The Immediate Economic Loss that a Delay Would Impose on Sandoz.</u>

14. Sandoz anticipates starting commercial activity to sell Zarxio in the United States soon after it is approved by the FDA. If that occurs, Sandoz has projected that it will have the net sales, cost of goods sold and gross profits in 2015 and 2016 as shown in the following table (dollar figures in millions):

CONFIDENTIAL MATERIAL REDACTED

[redacted]

15. Sandoz has incurred and will incur a number of sales, marketing, regulatory and administrative costs relating to Zarxio in 2015. If Zarxio is not launched, Sandoz will still incur a significant portion of these types of costs that it would incur with a product launch, but it will not be able to offset those costs with revenues from sales of the product. These costs cannot easily be used to support a later launch, such as in 2016, nor can they be avoided altogether and thus I refer to them as "stranded" costs. For example, sales people will sit idle for a period, certain regulatory costs will be incurred even though the product is not being sold, and marketing and promotional material that has been prepared will need to be destroyed and revised in light of a different market a year or more from now.

16. Using our current projections regarding the total functional costs for Zarxio, I have worked with the Sandoz U.S. finance staff to project the stranded costs that Sandoz will incur if the Zarxio launch is delayed. That analysis results in expected losses of [redacted]

17. If the launch of Zarxio were delayed for a year or more, the inventory that Sandoz has prepared for launch will become unusable. Based on our current forecasts, Sandoz would lose at least [redacted]

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

Alexander Thole

EXHIBIT 7

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Alexander D. Baxter (SBN 281569)
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AMGEN INC.
Wendy A. Whiteford (SBN 150283)
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One Amgen Center Drive
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wendy@amgen.com

Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **AMGEN'S REPLY IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION** **REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED** Date: March 13, 2015 Time: 10:00 AM Location: Courtroom 3, 17th Floor

CONFIDENTIAL MATERIAL REDACTED

VII. Sandoz's Request for the Largest Bond Ever Is Unwarranted

Despite downplaying the potential harm to Amgen, [redacted] Sandoz asks for what would, to our knowledge, be the largest bond this Court has ever entered: [redacted] That amount would span the entire 410-day period, which would be at issue only if the Court had concluded that Sandoz was likely wrong on the law and that it should have been complying with the BPCIA since last year. Indeed, if the Court rules in Amgen's favor on the pending Rule 12(c) motions, entering judgment that Sandoz has violated the BPCIA and has been doing so since July of 2014, then the injunction is more like a permanent injunction after a decision on the merits, which requires no bond at all. In any event, a [redacted] bond would dwarf even the bond in the *Apple/Samsung* case, which was only $98.2 million where Apple sought $2.2 billion in damages at trial. *See Apple, Inc.* v. *Samsung Electronics Co., Ltd.*, Civ. 11-01846 LHK, 2012 WL 2401680, at *5 (N.D. Cal. June 26, 2012); *Apple, Inc.* v. *Samsung Electronics Co.*, 877 F. Supp. 2d 838, 918 (N.D. Cal. 2012), *rev'd on other grounds*, 695 F.3d 1370 (Fed. Cir. 2012). Preliminary injunctions in patent cases in this Court regularly result in bonds orders of magnitude below the amount Sandoz seeks. *See, e.g.*, Baxter Decl. Ex. F (*Blackberry Ltd.* v. *Typo Prods. LLC*, Civ. 14-00023 WHO (N.D. Cal. Apr. 15, 2014)) ($500,000); *eBay, Inc.* v. *Bidder's Edge, Inc.*, 100 F. Supp. 2d 1058, 1073 (N.D. Cal. 2000) ($2,000,000). There is no basis in fact or law for Sandoz's extravagant number.

CONCLUSION

For the reasons set forth above, in Amgen's opening brief, and in the briefing on Amgen's motion for judgment on the pleadings, the Court should enter a preliminary injunction in the form set forth in Amgen's Proposed Order.

EXHIBIT 8

SANDOZ

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

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

July 8, 2014

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

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

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

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

Dear Sirs:

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

In recognition that the BPCIA patent resolution framework:

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

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

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

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

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

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

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

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

Very truly yours,

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

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

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

EXHIBIT 9

SANDOZ
a Novartis company

Markus Hartmann
Vice President &
North American Counsel

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

By EMAIL: wendy@amgen.com

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

March 6, 2015

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

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

Dear Ms. Whiteford,

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

We would be grateful if you could acknowledge receipt.

Yours faithfully,

Markus Hartmann
Vice President & North American Counsel

Julia Pike
Head, Global IP Litigation

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125553

BLA APPROVAL

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

Dear Mr. Pakulski:

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

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

LICENSING

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

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

MANUFACTURING LOCATIONS

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

DATING PERIOD

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

FDA LOT RELEASE

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

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

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

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

CONTENT OF LABELING

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

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

The SPL will be accessible via publicly available labeling repositories.

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

CARTON AND IMMEDIATE CONTAINER LABELS

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

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

REQUIRED PEDIATRIC ASSESSMENTS

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

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

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

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

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

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

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

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

We remind you of your postmarketing commitments:

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

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

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

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

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

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

Final Report Submission: 05/2016

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

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

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

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

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

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

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

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

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

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

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

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

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

Final Report Submission: 05/2016 Annual Report

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

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

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

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

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

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

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

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

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

PROMOTIONAL MATERIALS

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

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

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

REPORTING REQUIREMENTS

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

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

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

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

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

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

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

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

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

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

Sincerely,

{See appended electronic signature page}

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

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

EXHIBIT 10

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AMGEN INC., et al.,

Plaintiffs,

v.

SANDOZ INC., et al.,

Defendants.

Case No. 14-cv-04741-RS

ORDER DENYING MOTION FOR INJUNCTION PENDING APPEAL

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

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

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

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

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

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

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

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

IT IS SO ORDERED.

Dated: April 15, 2015

RICHARD SEEBORG
United States District Judge

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

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on May 12, 2015.

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

Dated: May 12, 2015 /s/ Deanne E. Maynard