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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 **AMGEN'S NOTICE OF MOTION AND MOTION FOR AN INJUNCTION PENDING APPEAL** **REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED** Date: April 30, 2015* Time: 10:00 AM Location: Courtroom 3, 17th Floor * Expedited briefing requested in accompanying Stipulated Request

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TO ALL PARTIES AND THEIR COUNSEL: PLEASE TAKE NOTICE that on March 24, 2015, Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, "Amgen") pursuant to Federal Rule of Civil Procedure 62(c) and Federal Rule of Appellate Procedure 8(a), move this Court for a motion for an injunction pending appeal of this Court's Order dated March 19, 2015 (the "Order"), based on the Federal Rules, the Local Rules of this District, this memorandum, the record of this proceeding, and any matters of which the Court takes judicial notice.[1] Per Local Rule 7-2(a) the noticed hearing date is April 30, 2015, but the parties have agreed to an expedited briefing schedule under which briefing will be complete by April 2, 2015. Amgen respectfully requests that, should the Court deem a hearing necessary, the Court set the date for such hearing as soon after April 2nd as the Court's schedule will allow.

ISSUE TO BE DECIDED AND RELIEF SOUGHT

On March 19th, the Court denied Amgen's motion for a preliminary injunction, and granted judgment on the pleadings as to two of Amgen's claims and five of Sandoz's counterclaims. In a separate motion, the parties today jointly requested that the Court enter a final judgment as to those claims and counterclaims pursuant to Fed. R. Civ. P. 54(b). (Dkt. No. 106.) Pursuant to the parties' joint motion, Amgen will notice an appeal to the Federal Circuit from the Court's denial of its motion for a preliminary injunction and, if the Court enters a Rule 54(b) final judgment, from that judgment as well. The parties have agreed to expedite appellate briefing and to request an early date for oral argument, ideally in the Federal Circuit's June calendar. And Sandoz has agreed to refrain from launching its Zarxio product until the earlier of May 11, 2015 or a decision by the Federal Circuit on Amgen's application for an injunction pending appeal, in order to give both this Court and, if need be, the Federal Circuit time to consider Amgen's application for an injunction pending appeal. Even with expedited treatment,

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

however, the Federal Circuit will not have an opportunity to rule on the merits of Amgen's appeal before that May 11, 2015 date, thus necessitating this application to this Court pursuant to Fed. R. Civ. P. 62(c) for an injunction pending appeal.

The questions presented on this application for an injunction pending appeal are: 1. Given the imminence of Sandoz's launch, the significant legal issues raised by this case and the Court's Order, the short period of the requested injunction, the irreparable harm that Amgen faces, the balance of the equities strongly favoring Amgen, and the public interest in an injunction should the Federal Circuit construe the BPCIA differently than this Court did, should the Court grant a temporary injunction pending appeal? 2. In the alternative, if the Court is not inclined to grant a temporary injunction for the entirety of Amgen's appeal, should the Court grant a temporary injunction lasting until the Federal Circuit itself rules on Amgen's motion for a temporary injunction pending appeal?

PRELIMINARY STATEMENT

Amgen recognizes that the Court has denied its request for a preliminary injunction, on both likelihood-of-success and irreparable-harm grounds. Amgen nevertheless respectfully requests that the Court grant an injunction restraining Sandoz from launching its biosimilar filgrastim product, Zarxio, until the Federal Circuit resolves an expedited appeal from this Court's Order. As the Court recognized, the words of the BPCIA "lend[] support to Amgen's reading" of the statute (Dkt. No. 105 ("Order") at 9), and while the Court ultimately found Sandoz's overall interpretation of the statute to be more persuasive (*id.*), the issue warranted resolution in a nineteen-page opinion after scores of pages of briefing and several hours of oral argument. Amgen's appeal raises serious legal questions. Most of those questions have never been presented to, and none have been decided by, the Federal Circuit. The outcome of this appeal will decide—for the entire industry—whether biosimilar applicants must follow the patent-exchange procedures of the BPCIA, thus serving an important public interest. The balance of equities also favors a limited injunction that gives the Federal Circuit the brief time it needs to consider an expedited appeal. If the Federal Circuit reverses, Amgen will be irreparably

harmed by Sandoz's having launched. If the Federal Circuit affirms, Sandoz's harm, if any, will be only having to wait a brief period beyond the May 11, 2015 date to which it has already agreed to wait.

To that end, Amgen is not seeking here an order compelling Sandoz to comply with the terms of the BPCIA. Rather, Amgen seeks an injunction against Sandoz's launch of Zarxio until the Federal Circuit decides Amgen's appeal. In the alternative, if the Court denies Amgen's motion for an injunction pending appeal, Amgen seeks an injunction lasting only until the Federal Circuit itself can decide Amgen's subsequent application for an injunction pending appeal, which the parties have stipulated Amgen will file within two business days of a denial by this Court. (*See* Dkt. No. 106-1 at ¶ 3.)

STATEMENT OF FACTS

Procedural Posture

Amgen filed its complaint against Sandoz on October 24, 2014, asserting violations under the California Unfair Competition Law (Cal. Bus. & Prof. Code § 17200 et seq.), conversion under California common law, and infringement of U.S. Patent No. 6,162,427.

On January 6, 2015, Amgen moved for partial judgment on the pleadings on its interpretation of the BPCIA (Dkt. No. 35), and Sandoz cross-moved for the same (Dkt. No. 45). Amgen moved for a preliminary injunction (Dkt. No. 56), seeking to compel Sandoz to comply with the BPCIA and to put the parties in the position they would have been in had Sandoz timely done so. The Court conducted oral argument on the parties' cross motions for judgment on the pleadings and Amgen's motion for preliminary injunction on March 13, 2015. The Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction on March 19, 2015.

As the Court recognized in its Order, the disputes presented in the now-decided motions "exclusively concern[] questions of law." (Order at 3.) Rather than burdening the Court with a repetition of the underlying facts regarding the BPCIA, Sandoz's and Amgen's discussions of Sandoz's non-provision of its BLA and manufacturing information, and the other facts addressed

in the parties' briefing, Amgen simply refers the Court to the factual presentations at pages 6 to 8 of its motion for judgment on the pleadings (Dkt. No. 35), pages 1 to 6 of its reply in support of that motion and in opposition to Sandoz's cross-motion (Dkt. No. 57), pages 8 to 12 of its motion for a preliminary injunction (Dkt. No. 56), and pages 1 to 7 of its reply in support of that motion (Dkt. No. 83-4).

The Pending Motions and Proposed Appeal

Today, Amgen and Sandoz filed a joint motion requesting that the Court enter final judgment under Fed. R. Civ. P. 54(b) with regard to Amgen's First and Second Causes of Action and Sandoz's First through Fifth Causes of Action. (Dkt. No. 106.) If the Court enters a Rule 54(b) judgment as to those claims and counterclaims, Amgen will appeal from that judgment along with appealing from the Court's denial of Amgen's motion for a preliminary injunction. If the Court declines to enter a Rule 54(b) judgment, Amgen will appeal from only the denial of the preliminary injunction.

Either way, the appeal will be expedited: Amgen and Sandoz also filed today a joint scheduling stipulation calling for completion of appellate briefing and filing of the joint appendix by April 30th, in hopes of being calendared for Federal Circuit argument in June. Once Amgen files a notice of appeal, it will also file an emergency, unopposed motion in the Federal Circuit to expedite the appeal.

Amgen now, by this motion, seeks a temporary injunction pending appeal pursuant to Fed. R. Civ. P. 62(c). The parties have agreed to accelerate this motion too, with Sandoz's opposition due within five business days, and Amgen's reply due within two business days thereafter.

ARGUMENT

Federal Rule of Civil Procedure 62(c) allows this Court to issue an injunction pending appeal from an interlocutory order or final judgment "that grants, dissolves, or denies an injunction." Fed. R. Civ. P. 62(c). The filing of a notice of appeal is no bar to such relief: "The district court retains jurisdiction during the pendency of an appeal to act to preserve the status

quo." *Natural Res. Def. Council, Inc.* v. *Sw. Marine Inc.*, 242 F.3d 1163, 1166 (9th Cir. 2001). To determine whether to deny or grant an injunction pending appeal, district courts within the Ninth Circuit consider: (1) whether "the movants established a strong likelihood of success on the merits;" (2) whether "the balance of irreparable harm favor[s] the movants;" and (3) whether "the public interest favor[s] granting the injunction." *Warm Springs Dam Task Force* v. *Gribble*, 565 F.2d 549, 551 (9th Cir. 1977). As this Court recognized, however (Order at 16-17), the Ninth Circuit—the law of which applies and will be applied by the Federal Circuit to issues not unique to patent law—also recognizes that the first requirement can be satisfied by showing the existence of difficult legal questions and that an injunction is warranted if there is also a balance of hardships tipping sharply toward the movant, irreparable harm, and public interest in an injunction. *Alliance for the Wild Rockies* v. *Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). In particular, courts have found serious legal questions may be raised when those legal issues explore new ground. *See Am. Trucking Ass'ns, Inc.* v. *City of Los Angeles*, Civ. No. 08-4920 CAS, 2010 WL 4313973, at *2 (C.D. Cal. Oct. 25, 2010); *Protect Our Water* v. *Flowers*, 377 F. Supp. 2d 882, 884 (E.D. Cal. 2004) ("An injunction is 'frequently issued where the trial court is charting a new and unexplored ground and the court determines that a novel interpretation of the law may succumb to appellate review.'" (citations omitted)).

I. Amgen's Appeal Raises Serious Questions

Amgen respectfully submits that its appeal raises serious legal questions about the interpretation of a new statute that has important implications for the biopharmaceutical industry well beyond the dispute between the parties. That the Court denied Amgen's motion for a preliminary injunction for having failed to succeed on the merits does not preclude it from entering a temporary injunction pending appeal here. As the court in *American Trucking* concluded, "[a]lthough the Court does not doubt the correctness of its own findings and legal conclusions; it recognizes that the interpretation and application of the market participant doctrine in this case present substantial and novel legal questions. Accordingly, the Court finds that the first criterion of Rule 62(c) is satisfied. . . ." *Am. Trucking Ass'ns, Inc.* v. *City of Los*

Angeles, Civ. No. 08-4920 CAS, 2010 WL 4313973, at *2 (C.D. Cal. Oct. 25, 2010).

The Federal Circuit has not yet addressed whether the provisions within 42 U.S.C. § 262(l) are mandatory or optional. The parties' dispute turns around interpretation of provisions of § 262(l) that use the term "shall" to describe the obligations of the biosimilar applicant and the reference product sponsor. While ultimately ruling for Sandoz, the Court recognized that the statute's use of "shall" and the statute's characterization of noncompliance as a "fail[ure]" "lend[] support to Amgen's reading" that the actions described are mandatory. (Order at 9.) Nevertheless, the Court determined that "[i]t 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.'" (*Id*.)

Amgen contends, and will contend on appeal, that this reading of "shall" renders the obligations illusory and does not distinguish between the statute's use of "shall" and "may." Canons of statutory construction compel a reading of the statute that treats different terms differently. *See, e.g.*, *S.E.C.* v. *McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003) ("It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words. . . . Congress's explicit decision to use one word over another in drafting a statute is material.").

The Court relied on *County of Ramsey* v. *MERSCORP Holdings, Inc.*, 962 F. Supp. 2d 1082 (D. Minn. 2013), for the proposition that "shall" is not always mandatory, because "failure to comply with a provision containing 'shall' [is] not unlawful, where the statute contemplate[s] and provides[s] for such a scenario." (Order at 10.) Amgen respectfully submits that *County of Ramsey* is not so broad. The statute at issue in that case imposed no duty to record mortgages; it simply informed a mortgagee how to record a mortgage to protect it against subsequent purchasers. (*See* Dkt. No. 83-4 at 8 n.2 (Amgen's Reply).) Sandoz concedes that a biosimilar applicant must follow the procedures of the BPCIA. It simply argues that the BPCIA contemplates two optional, parallel procedures.

For all of the reasons set forth in Amgen's prior briefing and at oral argument, Amgen respectfully submits that the Federal Circuit, applying a *de novo* review standard, might reach a different conclusion than did this Court. At a minimum, Amgen submits that it has raised sufficient questions about the meaning of the statute to warrant a temporary injunction pending appeal.

II. Amgen Would Be Irreparably Harmed If Sandoz Launches Zarxio Prematurely

The injunction Amgen seeks will be brief, but the harm it faces in that brief period is significant and irreparable.

A. Amgen's Neupogen® Market Will Be Irreversibly Changed by the Launch of Sandoz's Biosimilar Product

At the time that Amgen moved for a preliminary injunction, publicly available information suggested that Sandoz intended to price Zarxio at parity with Amgen's Neupogen® in at least some circumstances. "Publicly available information" indeed understates the situation: Sandoz told the FDA precisely that. At the time that Amgen submitted its declarations in support of its preliminary injunction motion, that was all that its Vice President and General Manager of Oncology, Robert Azelby, knew about Sandoz's pricing plans. He therefore discussed what harms Sandoz might cause to Amgen depending on how Sandoz priced its product.

While Mr. Azelby himself has not seen any of the confidential documents that Sandoz produced in discovery, Sandoz's counsel and the Court have, as permitted by the protective order. Those documents make clear that [redacted]

[redacted]

Thus, the price erosion that Mr. Azelby (and Dr. Philipson, Amgen's economist) said might occur—the conditional nature of their testimony being that Sandoz's pricing plans were not known to them at the time—is now certain to happen. The market for filgrastim is price-sensitive and, because there is no unmet clinical need (that is, there is no evidence that a significant number of patients needing filgrastim currently do not receive it, either through Amgen's Neupogen® or Teva's Granix® product), sales of Zarxio will come at the expense of Neupogen® to which it is biosimilar. (*See* Dkt. No. 56-2 ¶¶ 15, 16 (Azelby Decl.).) [redacted] As Dr. Philipson explained, in the subjunctive because he did not yet know the true facts, "Amgen's primary response to Sandoz's unlawfully premature sales would be to reduce prices . . . which again leads to a downward price and reimbursement spiral . . . ." (Dkt. No. 56-5 ¶ 78 (Philipson Report)); *see also* [redacted]

The erosion of Neupogen®'s price will begin immediately upon Zarxio's launch at a

lower price and will be irreparable. If Zarxio's launch is not enjoined but the Federal Circuit ultimately reverses this Court's Order and Sandoz exits the market until it has followed the terms of the BPCIA's patent-exchange and 180-day notice provisions, Amgen will not be able to restore its prices to the level they were at before Sandoz entered. As Amgen's Robert Azelby testified, if Amgen were forced to lower Neupogen® prices to compete with Zarxio "it would be very difficult if not impossible for Amgen to simply raise its prices back to what they were before Zarxio competition." (Dkt. No. 56-2 ¶ 23 (Azelby Decl.)) Courts have long recognized such examples of price erosion as irreparable harm. *See Abbott Labs.* v. *Sandoz Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008); *Sanofi-Synthelabo* v. *Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006); *Purdue Pharma L.P.* v. *Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001).

B. Amgen Would Be Harmed by Irreparable Damage to Consumer Relationships and Goodwill

Likewise, without an injunction pending appeal, Sandoz's later exit from the market in order to comply with the law would cause Amgen irreparable harm to its reputation, consumer relationships, and goodwill. (*See* Dkt. No. 56-5 ¶¶ 93, 97 (Philipson Report).) Because of Medicare reimbursement rules, any rapid attempt to rehabilitate Neupogen®'s price would put customers under water (that is, their acquisition cost would exceed their reimbursement) and a slower attempt to rehabilitate Neupogen®'s price would likely mean the effects of the price erosion would persist longer. (*See* Dkt. No. 56-2 ¶ 23 (Azelby Decl.).) Moreover, because there is already one alternative G-CSF product on the market, Granix®, and others expected this year, price rehabilitation may not be possible at all. Market reaction to Sandoz's entry and withdrawal could also unfairly taint Amgen for enforcing its legal rights. Moreover, the market's negative impression of Amgen, and the resulting loss of goodwill, would likely extend to Amgen's other products in this area including the newly launched on-body injector.

C. Sandoz's Launch Would Force Amgen to Divert Its Sales Force

The division of Amgen's Oncology Salesforce responsible for Neupogen® is also

responsible for supporting sales of several other oncology products, including Neulasta® and Vectibix®. The same salesforce is also responsible for supporting the launch of Amgen's new on-body injector for Neulasta®. [redacted] If Sandoz launches Zarxio before the Federal Circuit can rule on Amgen's appeal, Amgen will be irreparably harmed as it will be forced to divert its salesforce from supporting Neulasta®, Vectibix®, and the newly launched on-body injector to defending Neupogen® in the market. As Amgen's Vice President and General Manager of Oncology, Robert Azelby, testified, "if biosimilars launch and they're aggressive on price, that will take up an enormous amount of time in—in our customers' heads and talking with our representatives, and it will definitely take time, a significant portion of time away from selling of the on-body injector and Vectibix." *See* Baxter Decl. Ex. D at 269:4-15 (Azelby Dep. Tr.). Amgen will not be able to avoid the diversion of its sales force by hiring new salespeople. As Amgen's Mr. Azelby testified, it takes Amgen six months even to train a sales representative, and another six months until that representative is able to operate independently. (*See* Dkt. No. 83-23 at 277:10-278:18 (Azelby Dep. Tr.).) There thus would not be enough time to hire and deploy new salespeople during the period that Sandoz would be on the market.

III. The Balance of Hardships Favors Amgen and a Brief Injunction

Sandoz has agreed to remain off the market until as late as May 11, 2015 to allow this Court and, if need be, the Federal Circuit to rule on Amgen's motion (or motions) for an injunction pending appeal. [redacted] If Sandoz is enjoined from launching its Zarxio product until the Federal Circuit decides Amgen's appeal, Sandoz faces at most a brief period of delayed sales. Such harm can be ameliorated by a bond, and would not be an

irreparable harm. *See Glaxo Grp. Ltd.* v. *Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003) (unpublished) ("[W]ithout the preliminary injunction, Glaxo would lose the value of its patent while Apotex would only lose the ability to go on to the market and begin earning profits earlier. Additionally, Apotex's loss of profit is secured by the issuance of the bond . . . ."). [redacted]

On the other hand, as set forth above, Amgen will be severely harmed if Sandoz is allowed to launch Zarxio during the appeal. It faces immediate and irreversible price erosion, injury to its consumer relationships and goodwill, and a diversion of its salesforce away from bringing new products to market. The balance of hardships thus favors a temporary injunction of Sandoz's sales of Zarxio pending this appeal.

IV. The Public Interest Favors Granting an Injunction

The public interest, too, favors the requested relief. As Sandoz has noted, a number of other companies are seeking FDA approval for their own biosimilar products, some of them copies of Amgen's Neupogen® and others copies of other biological therapeutics. If Sandoz is permitted to launch Zarxio before the resolution of this appeal, these other companies would be incentivized to behave as Sandoz has done, something that—apparently—none of them previously thought the BPCIA allowed them to do. If indeed Amgen is right about the statute, allowing Sandoz to launch its product in violation of that statute does harm to the public interest. On the other hand, if the Federal Circuit affirms this Court's Order, the public interest will still have been served by an injunction lasting just long enough to allow the appellate court to rule. The public interest harm that Sandoz touts, that of allowing price competition, is the far lesser consideration, given the brevity of the proposed injunction and the fact that currently all patients who need Neupogen® are getting it. (*See* Dkt. No. 56-2 at ¶ 15 (Azelby Decl.).)

CONCLUSION

For the foregoing reasons, and on the record and arguments developed on its motion for a preliminary injunction and the cross-motions for judgment on the pleadings, Amgen respectfully requests that the Court enter an injunction prohibiting Sandoz from marketing, selling, offering to sell, or importing into the United States its Zarxio biosimilar filgrastim product until the Federal Circuit resolves Amgen's appeal from this Court's Order. In the alternative, if the Court denies Amgen's request for an injunction pending appeal, Amgen respectfully requests that the Court enter an injunction prohibiting Sandoz from marketing, selling, offering to sell, or importing into the United States its Zarxio biosimilar filgrastim product until the Federal Circuit can resolve Amgen's motion for an injunction pending appeal, which Amgen will file in that court within two business days of this Court's denial of this motion.

Date: March 24, 2015

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