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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 REPLY IN SUPPORT OF
ITS MOTION FOR AN INJUNCTION
PENDING APPEAL**

**REDACTED VERSION OF DOCUMENT
SOUGHT TO BE SEALED**

Date: TBD [Dkt. No. 113]

Time:

Location: Courtroom 3, 17th Floor

1 Sandoz’s opposition brief is fighting the last battle, not this one. Sandoz directs its
2 arguments to an injunction that would span the entire 410-day period under the BPCIA, rather
3 than the very limited relief that Amgen is actually seeking. To be clear, Amgen seeks an
4 injunction against Sandoz making, using, selling, offering to sell, or importing Zarxio only while
5 the Federal Circuit considers Amgen’s appeal from the Court’s denial of preliminary injunction
6 in its March 19, 2015 Order (the “Order”) and March 25, 2015 Judgment pursuant to Rule 54(b)
7 (the “Rule 54(b) Judgment”). (Amgen Br. at 12). If the Court denies this request, Amgen seeks,
8 in the alternative, an injunction only until the Federal Circuit itself can decide a motion for an
9 injunction pending appeal. (*Id.*) Amgen is not now seeking again the same preliminary
10 injunction that this Court already denied.

11 **I. Sandoz Misstates the Law to be Applied to this Motion**

12 Sandoz spends much of its brief attacking the injunction standard that Amgen cited,
13 contending that the “serious legal questions” approach employed by the Ninth Circuit is “not the
14 right standard.” (Sandoz Br. at 3). But Sandoz does not have the courage of its convictions. It
15 also suggests that “the Ninth Circuit itself applies the Supreme Court’s *Winter* standard in some
16 cases.” (*Id.* at 3 n.1 (emphasis added)). If Sandoz is suggesting that the “serious questions”
17 injunction analysis has been overruled, Sandoz is wrong. As this Court recognized in its March
18 19, 2015 Order, the Ninth Circuit evaluates likelihood of success on a sliding scale, and the
19 “serious questions” approach has been expressly found to be valid in light of *Winter*. (Order at
20 16-17; *see also Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011)
21 (holding that the “serious questions” approach survives *Winter v. Natural Res. Def. Council*, 555
22 U.S. 7 (2008)).

23 Sandoz also suggests that Federal Circuit, rather than Ninth Circuit, law should apply
24 here to Amgen’s motion, because the provisions of the BPCIA are at issue on appeal. (Sandoz
25 Br. at 4). That argument conflates the underlying subject matter of the appeal with the
26 procedural requirements of a preliminary injunction. As the Federal Circuit has repeatedly held,
27 “The Federal Circuit applies its own law with respect to issues of substantive patent law and
28

1 certain procedural issues pertaining to patent law, but applies the law of our sister circuits to non-
2 patent issues.” *Research Corp. Techs. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (Fed. Cir. 2008).
3 Because preliminary injunctions are not unique to patent cases, the Federal Circuit applies the
4 law of the regional circuit—here, the Ninth Circuit. *See, e.g., Trebro Mfg. v. FireFly Equip.*
5 *LLC.*, 748 F.3d 1159, 1165 (Fed. Cir. 2014) (applying Ninth Circuit law); *Aevoe Corp. v. AE*
6 *Tech Co.*, 727 F.3d 1375, 1381 (Fed. Cir. 2013) (same); *Jacobsen v. Katzer*, 535 F.3d 1373, 1
7 (Fed. Cir. 2008) (same); *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894-95
8 (Fed. Cir. 1998) (same).

9 Thus, the Federal Circuit will apply its own law to interpreting the BPCIA, but the Ninth
10 Circuit standard applies to Amgen’s motion for a temporary injunction pending appeal.

11 **II. Sandoz Fails to Address Irreparable Harm For the Period of this Injunction**

12 The merits of Sandoz’s opposition are merely a recapitulation of its argument in
13 opposition to Amgen’s now-denied motion for a preliminary injunction. The arguments do not
14 translate without modification, however, and Sandoz improperly argues at length about the harm
15 it would face from a 410-day injunction, which Amgen is not seeking. Indeed, Sandoz seeks a
16 bond in exactly the same amount it sought in opposition to Amgen’s preliminary injunction
17 motion.

18 The Federal Circuit granted Amgen’s motion to expedite the parties’ appeal, which
19 included expediting briefing and oral argument pursuant to the parties’ agreed-upon schedule.
20 Baxter Decl. Ex. F (Order Granting Amgen’s Unopposed Motion to Expedite Briefing Schedule
21 No. 15-1499, Dkt. No. 19 (Fed. Cir. Mar. 27, 2015)). Indeed, Amgen’s appellate opening brief is
22 due tomorrow. *Id.* Briefing will be concluded by the end of April, and the parties have
23 requested an oral hearing in June. Sandoz notes that no date has been calendared for oral
24 argument but omits that the Federal Circuit granted Amgen’s motion in its entirety, and not in
25 part. The fact that oral argument will be scheduled by subsequent order does not mean that the
26 Federal Circuit denied Amgen’s unopposed request to schedule oral argument for June. Thus,
27 assuming that the Federal Circuit renders a decision on an expedited basis, which would be
28

1 consistent with prior practice involving expedited appeals, the length of the injunction Amgen
2 seeks will defer Sandoz's launch by a couple of months, not the 410 days, or almost 14 months,
3 that the Court previously rejected and to which Sandoz refers.

4 Nowhere in its opposition brief does Sandoz squarely address the relative harms or
5 balance of the harms that would occur over the period of this injunction as opposed to the 410
6 days of the injunction the Court already rejected. Nor does Sandoz fairly address the irreparable
7 harm to Amgen as set forth in the motion before the Court. For example, regarding price erosion
8 Sandoz largely relies on documents and testimony about Neulasta®, but the price erosion that
9 Amgen identified in its motion here was with regard to Neupogen®. And to the extent that
10 Sandoz discusses Neupogen®, it refers to wholesale pricing, not net price. As was made clear in
11 Amgen's opening brief, [REDACTED]
12 [REDACTED]. (See Amgen Br. at 8.) Indeed, documents produced by Amgen and provided in
13 support of its motion show [REDACTED]
14 [REDACTED]. (See Dkt. No. 107-10, at AMG-NEUP-
15 0002636, 0002638 (OBU Q4 14' QBR Review); Dkt. No. 107-12 at AMG-NEUP-00002723
16 (U.S. G-CSF 2014 LRP)). Sandoz's arguments regarding loss of goodwill and diversion of sales
17 force similarly fail to account for the shortened period of the requested injunction.

18 Sandoz claims that it will be harmed by "*any* delay of Sandoz's launch." (Sandoz Br. at
19 10 (emphasis in original).) But its only argument in this regard is that it may lose its head start
20 on other biosimilar entrants that it estimates may launch "later this year or in early 2016." (*Id.*)
21 But those biosimilar products will not launch before the appeal is complete; indeed, there has
22 been no public disclosure that the BLA for one of them has even been filed with the FDA. If
23 Sandoz prevails it will not lose its head start on those products.

24 **III. Sandoz's Attempts to Limit the Scope of Injunction Should Be Rejected**

25 Finally, Sandoz argues that, any injunction should be limited to conduct occurring in
26 California, and to "shipping product in commercial quantities" rather than "marketing, selling,
27 offering for sale, or importing." Neither argument has merit.

1 First, Sandoz suggests that Amgen has somehow agreed that any injunctive relief would
2 be limited to California, citing a portion of Amgen's reply in support of its Rule 12(c) motion
3 and opposition to Sandoz's Rule 12(c) motion. (Sandoz Br. at 11 (citing Dkt. No. 57, at 19)).
4 But Amgen's preliminary injunction motion was clear that Amgen sought nationwide relief, in
5 Amgen's moving brief and proposed order. (*See* Dkt. Nos. 56 at 25 and 56-12 at 1.) Sandoz
6 ignores that brief, and instead focuses on a brief that is not even seeking injunctive relief. The
7 page of Amgen's Rule 12(c) brief that Sandoz cites discusses only Amgen's claims under
8 California Business & Professions Code § 17200 et seq. (the "UCL") and responds to Sandoz's
9 argument that Amgen's UCL claims should be dismissed because the UCL is available only in
10 California. (*See* Dkt. No. 57, at 19.) On the very next page of Amgen's brief, Amgen discussed
11 its conversion claim which Amgen has always contended is not limited to California.

12 Second, Sandoz attempts to limit the scope of an injunction by redefining the term
13 "launching" to mean "shipping its product to customers in commercial quantities." (Sandoz Br.
14 at 11.) Amgen's requested injunction is not limited to merely shipping product. Indeed,
15 Amgen's proposed order on this Rule 62(c) motion seeks an injunction prohibiting commercial
16 manufacture, use, offer to sale, sale within the United States, or importation into the United
17 States of any biosimilar filgrastim product. (*See* Dkt. No. 108-7.) It is true that Amgen
18 identified "launch" of Zarxio as a cause of irreparable harm, but in using that word it did not
19 limit the relief sought or the nature of appropriate relief. Promotional activities, taking orders,
20 collecting revenue, detailing physicians, and a host of other activities are encompassed by the
21 term "launch." In fact, when Sandoz's own expert, Dr. Rausser, catalogued the harms that
22 Sandoz would face if it could not, in his term, "launch" Zarxio, he included the [REDACTED]
23 [REDACTED]
24 [REDACTED] are part of "launch." (*See, e.g.*, Dkt. No. 71-9 ¶¶ 95-98.) Nor can Sandoz credibly
25 argue that irreparable harm to Amgen would occur only upon Sandoz "shipping its product to
26 customers in commercial quantities." Amgen is harmed as well by Sandoz's representatives
27 detailing doctors, by Sandoz's marketing materials in publications and doctors' offices, and by
28

1 any effort to launch Zarxio.

2 **CONCLUSION**

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

1 Date: April 2, 2015

2 /s/ Vernon M. Winters

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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

**DECLARATION OF ALEXANDER D.
BAXTER IN SUPPORT OF
AMGEN'S REPLY SUPPORTING ITS
MOTION FOR AN INJUNCTION
PENDING APPEAL**

1 I, Alexander D. Baxter, declare and state as follows:

2 1. I am an attorney licensed to practice before this Court and an associate of the law
3 firm Sidley Austin LLP, attorneys of record for plaintiffs Amgen Inc. and Amgen
4 Manufacturing, Limited (together, "Amgen") in the above-captioned matter. I have personal
5 knowledge of the facts set forth in this Declaration, and if called upon as a witness, I could and
6 would testify competently as to these facts.

7 2. Attached hereto as **Exhibit F** is a true and correct copy of the order granting
8 Amgen's unopposed motion to expedite briefing schedule, issued by the United States Court of
9 Appeals for the Federal Circuit, No. 15-1499, Dkt. 19 (Mar. 27, 2015).

10
11 I declare under penalty of perjury under the laws of the United States that the foregoing
12 is true and correct and that the foregoing was executed on April 2, 2015, in San Francisco,
13 California.

14 */s/ Alexander D. Baxter*

Alexander D. Baxter

ATTESTATION

I, Vernon M. Winters, am the ECF user whose user ID and password are being used to file the foregoing document. Pursuant to Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of this document has been obtained from Alexander D. Baxter.

Dated: April 2, 2015

By: /s/ Vernon M. Winters

EXHIBIT F

NOTE: This order is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**AMGEN INC., AMGEN MANUFACTURING,
LIMITED,**
Plaintiffs-Appellants

v.

**SANDOZ INC., SANDOZ INTERNATIONAL GMBH,
SANDOZ GMBH,**
Defendant-Appellee

2015-1499

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

ON MOTION

O R D E R

Appellants move without opposition to expedite the
briefing schedule.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is granted. Appellants' opening brief is due no later than April 3, 2015. Appellee's brief is due no later than April 21, 2015. Appellants' reply brief is due no later than April 28, 2015. The joint appendix is due no later than April 30, 2015. Oral argument will be scheduled by subsequent order.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court