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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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1 TO ALL PARTIES AND THEIR COUNSEL: PLEASE TAKE NOTICE that on March
2 24, 2015, Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (together, “Amgen”)
3 pursuant to Federal Rule of Civil Procedure 62(c) and Federal Rule of Appellate Procedure 8(a),
4 move this Court for a motion for an injunction pending appeal of this Court’s Order dated March
5 19, 2015 (the “Order”), based on the Federal Rules, the Local Rules of this District, this
6 memorandum, the record of this proceeding, and any matters of which the Court takes judicial
7 notice.¹ Per Local Rule 7-2(a) the noticed hearing date is April 30, 2015, but the parties have
8 agreed to an expedited briefing schedule under which briefing will be complete by April 2, 2015.
9 Amgen respectfully requests that, should the Court deem a hearing necessary, the Court set the
10 date for such hearing as soon after April 2nd as the Court’s schedule will allow.

11 **ISSUE TO BE DECIDED AND RELIEF SOUGHT**

12 On March 19th, the Court denied Amgen’s motion for a preliminary injunction, and
13 granted judgment on the pleadings as to two of Amgen’s claims and five of Sandoz’s
14 counterclaims. In a separate motion, the parties today jointly requested that the Court enter a
15 final judgment as to those claims and counterclaims pursuant to Fed. R. Civ. P. 54(b). (Dkt. No.
16 106.) Pursuant to the parties’ joint motion, Amgen will notice an appeal to the Federal Circuit
17 from the Court’s denial of its motion for a preliminary injunction and, if the Court enters a Rule
18 54(b) final judgment, from that judgment as well. The parties have agreed to expedite appellate
19 briefing and to request an early date for oral argument, ideally in the Federal Circuit’s June
20 calendar. And Sandoz has agreed to refrain from launching its Zarxio product until the earlier of
21 May 11, 2015 or a decision by the Federal Circuit on Amgen’s application for an injunction
22 pending appeal, in order to give both this Court and, if need be, the Federal Circuit time to
23 consider Amgen’s application for an injunction pending appeal. Even with expedited treatment,
24

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

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

4 The questions presented on this application for an injunction pending appeal are:

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

13 **PRELIMINARY STATEMENT**

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

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

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

11 STATEMENT OF FACTS

12 Procedural Posture

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

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

24 As the Court recognized in its Order, the disputes presented in the now-decided motions
25 "exclusively concern[] questions of law." (Order at 3.) Rather than burdening the Court with a
26 repetition of the underlying facts regarding the BPCIA, Sandoz's and Amgen's discussions of
27 Sandoz's non-provision of its BLA and manufacturing information, and the other facts addressed
28

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

6 **The Pending Motions and Proposed Appeal**

7 Today, Amgen and Sandoz filed a joint motion requesting that the Court enter final
8 judgment under Fed. R. Civ. P. 54(b) with regard to Amgen's First and Second Causes of Action
9 and Sandoz's First through Fifth Causes of Action. (Dkt. No. 106.) If the Court enters a Rule
10 54(b) judgment as to those claims and counterclaims, Amgen will appeal from that judgment
11 along with appealing from the Court's denial of Amgen's motion for a preliminary injunction. If
12 the Court declines to enter a Rule 54(b) judgment, Amgen will appeal from only the denial of the
13 preliminary injunction.

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

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

23 **ARGUMENT**

24 Federal Rule of Civil Procedure 62(c) allows this Court to issue an injunction pending
25 appeal from an interlocutory order or final judgment "that grants, dissolves, or denies an
26 injunction." Fed. R. Civ. P. 62(c). The filing of a notice of appeal is no bar to such relief: "The
27 district court retains jurisdiction during the pendency of an appeal to act to preserve the status
28

1 quo.” *Natural Res. Def. Council, Inc. v. Sw. Marine Inc.*, 242 F.3d 1163, 1166 (9th Cir. 2001).
2 To determine whether to deny or grant an injunction pending appeal, district courts within the
3 Ninth Circuit consider: (1) whether “the movants established a strong likelihood of success on
4 the merits;” (2) whether “the balance of irreparable harm favor[s] the movants;” and (3) whether
5 “the public interest favor[s] granting the injunction.” *Warm Springs Dam Task Force v. Gribble*,
6 565 F.2d 549, 551 (9th Cir. 1977). As this Court recognized, however (Order at 16-17), the
7 Ninth Circuit—the law of which applies and will be applied by the Federal Circuit to issues not
8 unique to patent law—also recognizes that the first requirement can be satisfied by showing the
9 existence of difficult legal questions and that an injunction is warranted if there is also a balance
10 of hardships tipping sharply toward the movant, irreparable harm, and public interest in an
11 injunction. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). In
12 particular, courts have found serious legal questions may be raised when those legal issues
13 explore new ground. See *Am. Trucking Ass’ns, Inc. v. City of Los Angeles*, Civ. No. 08-4920
14 CAS, 2010 WL 4313973, at *2 (C.D. Cal. Oct. 25, 2010); *Protect Our Water v. Flowers*, 377
15 F. Supp. 2d 882, 884 (E.D. Cal. 2004) (“An injunction is ‘frequently issued where the trial court
16 is charting a new and unexplored ground and the court determines that a novel interpretation of
17 the law may succumb to appellate review.’” (citations omitted)).

18 **I. Amgen’s Appeal Raises Serious Questions**

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

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

2 The Federal Circuit has not yet addressed whether the provisions within 42 U.S.C.
3 § 262(l) are mandatory or optional. The parties' dispute turns around interpretation of provisions
4 of § 262(l) that use the term "shall" to describe the obligations of the biosimilar applicant and the
5 reference product sponsor. While ultimately ruling for Sandoz, the Court recognized that the
6 statute's use of "shall" and the statute's characterization of noncompliance as a "fail[ure]"
7 "lend[] support to Amgen's reading" that the actions described are mandatory. (Order at 9.)
8 Nevertheless, the Court determined that "[i]t is fair to read subsection (l) to demand that, if both
9 parties wish to take advantage of its disclosure procedures, then they 'shall' follow the
10 prescribed procedures; in other words, these procedures are 'required' where the parties elect to
11 take advantage of their benefits, and may be taken away when parties 'fail.'" (*Id.*)

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

19 The Court relied on *County of Ramsey v. MERSCORP Holdings, Inc.*, 962 F. Supp. 2d
20 1082 (D. Minn. 2013), for the proposition that "shall" is not always mandatory, because "failure
21 to comply with a provision containing 'shall' [is] not unlawful, where the statute contemplate[s]
22 and provides[s] for such a scenario." (Order at 10.) Amgen respectfully submits that *County of*
23 *Ramsey* is not so broad. The statute at issue in that case imposed no duty to record mortgages; it
24 simply informed a mortgagee how to record a mortgage to protect it against subsequent
25 purchasers. (*See* Dkt. No. 83-4 at 8 n.2 (Amgen's Reply).) Sandoz concedes that a biosimilar
26 applicant must follow the procedures of the BPCIA. It simply argues that the BPCIA
27 contemplates two optional, parallel procedures.

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

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

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

9 **A. Amgen’s Neupogen[®] Market Will Be Irreversibly Changed by the Launch of
10 Sandoz’s Biosimilar Product**

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

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

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 [REDACTED]

27 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]

6 Thus, the price erosion that Mr. Azelby (and Dr. Philipson, Amgen’s economist) said
7 might occur—the conditional nature of their testimony being that Sandoz’s pricing plans were
8 not known to them at the time—is now certain to happen. The market for filgrastim is price-
9 sensitive and, because there is no unmet clinical need (that is, there is no evidence that a
10 significant number of patients needing filgrastim currently do not receive it, either through
11 Amgen’s Neupogen® or Teva’s Granix® product), sales of Zarxio will come at the expense of
12 Neupogen® to which it is biosimilar. (See Dkt. No. 56-2 ¶¶ 15, 16 (Azelby Decl.)) [REDACTED]

13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 [REDACTED] As Dr. Philipson
17 explained, in the subjunctive because he did not yet know the true facts, “Amgen’s primary
18 response to Sandoz’s unlawfully premature sales would be to reduce prices . . . which again leads
19 to a downward price and reimbursement spiral” (Dkt. No. 56-5 ¶ 78 (Philipson Report));
20 *see also* [REDACTED]

21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]

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

1 lower price and will be irreparable. If Zarxio’s launch is not enjoined but the Federal Circuit
 2 ultimately reverses this Court’s Order and Sandoz exits the market until it has followed the terms
 3 of the BPCIA’s patent-exchange and 180-day notice provisions, Amgen will not be able to
 4 restore its prices to the level they were at before Sandoz entered. As Amgen’s Robert Azelby
 5 testified, if Amgen were forced to lower Neupogen[®] prices to compete with Zarxio “it would be
 6 very difficult if not impossible for Amgen to simply raise its prices back to what they were
 7 before Zarxio competition.” (Dkt. No. 56-2 ¶ 23 (Azelby Decl.)) Courts have long recognized
 8 such examples of price erosion as irreparable harm. *See Abbott Labs. v. Sandoz Inc.*, 544 F.3d
 9 1341, 1361-62 (Fed. Cir. 2008); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed.
 10 Cir. 2006); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir.
 11 2001).

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

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

26 **C. Sandoz’s Launch Would Force Amgen to Divert Its Sales Force**

27 The division of Amgen’s Oncology Salesforce responsible for Neupogen[®] is also

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

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

20 Sandoz has agreed to remain off the market until as late as May 11, 2015 to allow this
 21 Court and, if need be, the Federal Circuit to rule on Amgen's motion (or motions) for an
 22 injunction pending appeal. [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25 [REDACTED]

26 If Sandoz is enjoined from launching its
 27 Zarxio product until the Federal Circuit decides Amgen's appeal, Sandoz faces at most a brief
 28 period of delayed sales. Such harm can be ameliorated by a bond, and would not be an

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.

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1 Date: March 24, 2015

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*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

**DECLARATION OF ALEXANDER D.
BAXTER IN SUPPORT OF
AMGEN'S 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 A** is a true and correct copy of: excerpts from a
8 document produced by Sandoz in this litigation and bearing Bates numbers beginning at
9 SDZ(56)0201396.

10 3. Attached hereto as **Exhibit B** is a true and correct copy of: excerpts from a
11 presentation entitled "OBU Q4 14' QBR Review," produced by Amgen in this litigation and
12 bearing Bates numbers beginning at AMG-NEUP-00002616.

13 4. Attached hereto as **Exhibit C** is a true and correct copy of: excerpts from a
14 presentation entitled "U.S. G-CSF 2014 LR," produced by Amgen in this litigation and bearing
15 Bates numbers beginning at AMG-NEUP-00002697.

16 5. Attached hereto as **Exhibit D** is a true and correct copy of: excerpts from the
17 deposition of Robert Azelby, taken in this litigation on February 15, 2015.

18 6. Attached hereto as **Exhibit E** is a true and correct copy of: a worksheet from an
19 Excel document produced in its native format by Sandoz in this litigation and bearing the Bates
20 number SDZ(56)0201422.

21 I declare under penalty of perjury under the laws of the United States that the foregoing
22 is true and correct and that the foregoing was executed on March 24, 2015, in San Francisco,
23 California.

24 /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: March 24, 2015

By: /s/ Vernon M. Winters

EXHIBIT A

DOCUMENT FILED UNDER SEAL

EXHIBIT B

DOCUMENT FILED UNDER SEAL

EXHIBIT C

DOCUMENT FILED UNDER SEAL

EXHIBIT D

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

Robert Azelby
February 15, 2015

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN)
MANUFACTURING, LIMITED,)

)
Plaintiffs,)

)
v.)

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

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

)
Defendants.)
_____)

VIDEOTAPED DEPOSITION OF ROBERT AZELBY

February 15, 2015

9:02 a.m.

880 South Westlake Boulevard

Westlake Village, California

REPORTED BY:

Kristi Caruthers, CLR, CSR No. 10560

Robert Azelby

February 15, 2015

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WESTLAKE VILLAGE, CALIFORNIA

SUNDAY, FEBRUARY 15, 2015

9:02 A.M.

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THE VIDEOGRAPHER: Good morning.
We're on the record. This is the recorded video deposition of Robert Azelby in the matter of "Amgen Inc., et al., versus Sandoz Inc., et al." taken on behalf of the defendant.

This deposition is taking place at 880 South Westlake Boulevard, Westlake Village, California on February 15th, 2015, at approximately 9:02 a.m.

My name is Stan Beverly. I'm the videographer with U.S. Legal Support located at 11845 West Olympic Boulevard, Los Angeles, California.

Video and audio recording will be taking place unless all counsel have agreed to go off the record.

Would all present please identify themselves, beginning with the witness.

THE DEPONENT: Robert Azelby.

MR. OLSON: Erik Olson of

Robert Azelby

February 15, 2015

1 Morrison & Foerster on behalf of Sandoz.

2 MR. STONE: I'm Eric Stone from
3 Paul Weiss on behalf of the Amgen plaintiffs and
4 the witness. With me is in-house counsel at
5 Amgen, Lois Kawsigroch.

6 THE VIDEOGRAPHER: The certified
7 court reporter is Kristi Caruthers.

8 Would you please swear in the
9 witness.

10
11 ROBERT AZELBY,
12 called as a deponent and sworn in by
13 the deposition reporter, was examined
14 and testified as follows:

15
16 DEPOSITION REPORTER: Right hand,
17 please.

18 Do you solemnly swear that the
19 testimony you are about to give in this matter
20 shall be the truth, the whole truth, and nothing
21 but the truth, so help you God?

22 THE DEPONENT: I do.

23 DEPOSITION REPORTER: Please
24 commence.

25 ///

Robert Azelby

February 15, 2015

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WESTLAKE VILLAGE, CALIFORNIA

SUNDAY, FEBRUARY 15, 2015

1:48 P.M.

---o0o---

THE VIDEOGRAPHER: This marks the beginning of Media number 3 in the video deposition of Robert Azelby. The time is approximately 1:48 p.m. and we're back on the record.

EXAMINATION (Resumed)

BY MR. OLSON:

Q. Mr. Azelby, you understand you're still under oath?

A. Yes.

Q. Yeah. And at some point earlier in the day we were talking about a POA as a document that identifies the amount of time salespeople spend on specific subjects?

A. Correct.

Q. And, again, just remind me what does a POA mean?

A. Basically, it's a plan of action.

Q. Plan of action. Thank you.

Robert Azelby

February 15, 2015

1 it will rise or fall?

2 A. Again, it will all depend on what's
3 happening in the -- in the May, June time frame,
4 which will -- which will mandate how we -- how we
5 set ourselves up for the second half of the year.

6 Q. All right. Based on whatever the
7 latest update is as to the plan or expectations
8 regarding competition, do you have an expectation
9 whether it would rise or fall, based on your
10 current best assumptions?

11 MR. STONE: Object to the form.

12 THE DEPONENT: I don't. I think
13 you're asking me to give you an assumption which
14 will be based on the data in the May and June time
15 frame, and I think there's too many unknowns right
16 now to have a good understanding of what we'd like
17 to do in S2 with the blue team.

18 BY MR. OLSON:

19 Q. Okay. S2 is Semester 2?

20 A. Semester 2. Sorry.

21 Q. That's quite all right.

■

■

■

■

Robert Azelby
February 15, 2015

[REDACTED]

16 Q. Uh-huh. And do you have any
17 recollection as to how it compares to the first
18 semester of 2014?

19 A. I don't have the -- I don't have
20 the data to dig through that.

21 Q. In the planning that Amgen was
22 doing in October of 2014, is the amount that's
23 presently allocated to Neupogen higher or lower
24 than what you were planning for in October of this
25 year --

Robert Azelby

February 15, 2015

1 Q. And so your concern here as to Tvec
2 is solely limited to management and the other
3 support organization?

4 MR. STONE: Objection.

5 THE DEPONENT: On the sales side?

6 (Counsel nodded.)

7 THE DEPONENT: Yes, but I think
8 it's very important.

9 BY MR. OLSON:

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

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Robert Azenby
February 15, 2015

[REDACTED]

22 Q. In terms of just the pure mechanism
23 of the harm to which you're speaking as it relates
24 to salespeople, is it essentially the issue of the
25 amount of time in any call or the POA or set of

Robert Azenby
February 15, 2015

█
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█
4 Q. Right. And that's really the
5 mechanism behind the concern that you're stating
6 about the salespeople's participation?

7 A. Yes, but I -- just being in the
8 business for a very long time, 25 years, and the
9 last five years in oncology, if biosimilars launch
10 and they're aggressive on price, that will take up
11 an enormous amount of time in -- in our customers'
12 heads and talking with our representatives, and it
13 will definitely take time, a significant portion
14 of time away from selling of the on-body injector
15 and Vectibix.

16 MR. OLSON: May I make a
17 suggestion? Why don't we give me 15 minutes to
18 take a look at my notes and see -- I know I have a
19 couple more subjects, but rather than spend ten
20 minutes on the record, let you guys walk for a
21 second, let me grab a couple of subjects and then
22 we are closing in.

23 MR. STONE: Good.

24 THE VIDEOGRAPHER: This marks the
25 end of Media number 3 in the video deposition of

EXHIBIT E

DOCUMENT FILED UNDER SEAL

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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

**[PROPOSED]
ORDER GRANTING AMGEN'S
MOTION FOR AN INJUNCTION
PENDING APPEAL**

1 Having considered the Motion for Injunction Pending Appeal filed on March 24, 2015,
2 by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, “Amgen”), and the
3 opposition thereto filed by Defendant Sandoz Inc. (“Sandoz”), and the materials submitted in
4 support of and opposition to that motion, as well as all other arguments and the record of this
5 case, and good cause having been shown, the Court orders as follows:

6 IT IS HEREBY ORDERED THAT Plaintiffs’ Motion for Injunction Pending Appeal
7 shall be and hereby is GRANTED; and

8 IT IS FURTHER ORDERED THAT Sandoz and all those acting in concert with it or on
9 its behalf, are enjoined from engaging in the commercial manufacture, use, offer to sell, sale
10 within the United States, or importation into the United States of any biosimilar filgrastim
11 product until such time that the Court of Appeals for the Federal Circuit decides Amgen’s appeal
12 from this Court’s Order on Cross Motions for Judgment on the Pleadings and Denying Motion
13 for Preliminary Injunction, issued on March 19, 2015 (Dkt. No. 105), and subsequent Final
14 Judgment entered under Rule 54(b) of the Federal Rules of Civil Procedure, if any.

15
16 *[In the alternative]*

17 IT IS HEREBY ORDERED THAT Plaintiffs’ Motion for Injunction Pending Appeal
18 shall be and hereby is GRANTED; and

19 IT IS FURTHER ORDERED THAT Sandoz and all those acting in concert with it or on
20 its behalf, are enjoined from engaging in the commercial manufacture, use, offer to sell, sale
21 within the United States, or importation into the United States of any biosimilar filgrastim
22 product until such time that the Court of Appeals for the Federal Circuit decides Amgen’s
23 Motion for an Injunction Pending Appeal under Fed. R. App. P. 8(a), which Amgen shall file
24 with the Federal Circuit within two business days of this Order.

IT IS SO ORDERED.

Dated: _____, 2015

The Honorable Richard Seeborg
United States District Judge

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