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10 Attorneys for Defendants
SANDOZ INC., SANDOZ INTERNATIONAL
11 GMBH, SANDOZ GMBH, AND LEK
PHARMACEUTICALS D.D.
12

13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA
15 SAN FRANCISCO DIVISION
16

17 AMGEN INC. and
AMGEN MANUFACTURING LIMITED,
18
19 Plaintiffs,

20 v.

21 SANDOZ INC., SANDOZ INTERNATIONAL
GMBH, SANDOZ GMBH, and LEK
PHARMACEUTICALS D.D.,
22
23 Defendants.

Case No. 3:16-cv-02581-RS

**DEFENDANTS' MOTION TO STAY
DISCOVERY ORDER**

Date: September 7, 2017
Time: 10:00 am
Ctrm: Courtroom B

The Honorable Maria-Elena James

1 discovery on these issues and avoid the risk of substantial competitive harm to Sandoz. If the
2 Court denies the motion or this request for a stay, Sandoz will work with Amgen to ensure timely
3 completion of the discovery before the March 2018 trial and Amgen will suffer no prejudice.

4 II. BACKGROUND

5 The July 17, 2017 Discovery Order addressed two discovery disputes that the parties
6 presented in joint letters to the Court. (Case 4741 ECF No. 262.) The second dispute concerned
7 Amgen's requested discovery on expected approval, marketing, and sales of Sandoz's proposed
8 pegfilgrastim product. (*Id.* at 7-8.) Sandoz explained that the information sought was highly
9 competitively sensitive and had limited distribution even within Sandoz. (*See* Case 4741 ECF
10 No. 263-6 at 2-3.) Sandoz's pegfilgrastim product has not been launched or even approved by the
11 FDA. (*See id.*) In a recent earnings call, Sandoz publicly announced that the refiling of its
12 pegfilgrastim application with the FDA would not occur until early 2019. (Case 2581 ECF No.
13 92-2, at 11-12.) As such, Sandoz will not be able to launch its product for a year or more after the
14 March 2018 trial in this case.

15 The Discovery Order found that Amgen is entitled to the discovery unless and until the
16 Court separates Amgen's claim for injunctive relief from the jury trial set for March 2018:

17 Unless and until Sandoz seeks bifurcation, and the Presiding Judge
18 limits the issues to be heard at trial, Amgen's claims for injunctive
19 relief are set to be tried before a jury in March 2018. As such, the
20 undersigned finds Amgen is, at this point, entitled to discovery
21 about Sandoz's expected pegfilgrastim approval, marketing, and
22 sales. If Amgen's injunctive relief claim is later bifurcated, the
23 parties may raise this issue anew with the undersigned.

24 (Case 4741 ECF No. 262 at 8.) Promptly after issuance of the Order, Sandoz informed Amgen on
25 July 19, 2017 that it intended to file a motion to separate the issue of equitable relief from the jury
26 trial. (Pai Decl. Ex. A.) Sandoz asked whether Amgen would oppose such a motion. (*Id.*) The
27 parties conferred on July 19 and July 24; during these discussions, Amgen stated that it was still
28 considering Sandoz's proposal. (Pai Decl. ¶ 2.) Amgen sent a letter on July 26 confirming that it
would oppose the motion (Pai Decl. Ex. B at 3), which Sandoz then filed on July 28. (Case 2581

1 ECF No. 92.) The parties conferred regarding the motion to stay on July 31 and August 1, at
2 which time Amgen confirmed it will oppose. (Pai Decl. ¶ 3.)

3 III. ARGUMENT

4 The Court has broad discretion to stay discovery upon a showing of good cause. *Lopez v.*
5 *Suhr*, No. 15-cv-01846-HSG, 2016 U.S. Dist. LEXIS 55694, at *12 (N.D. Cal. Apr. 26, 2016)
6 (citation omitted); *see also Thomas v. Evans*, No. C 06-3581 MMC (PR), 2008 U.S. Dist. LEXIS
7 6439, at *7-8 (N.D. Cal. Jan. 14, 2008) (staying discovery for good cause pending resolution of
8 defendants' motions). The Ninth Circuit has held that implicit in the power of courts to separate
9 issues for trial under Rule 42(b) is the "power to limit discovery to the segregated issues" because
10 "[o]ne of the purposes of Rule 42(b) is to permit deferral of costly and possibly unnecessary
11 discovery proceedings pending resolution of potentially dispositive preliminary issues."
12 *Ellingson Timber Co. v. Great N. Ry. Co.*, 424 F.2d 497, 499 (9th Cir. 1970) (per curiam); *accord*
13 *Craigslist Inc. v. 3Taps Inc.*, 942 F. Supp. 2d 962, 982 (N.D. Cal. 2013) (granting motion to stay
14 discovery on bifurcated counterclaims based on "the likelihood of streamlining discovery . . .
15 even if those counterclaims must ultimately proceed"). This rationale applies strongly here given
16 Sandoz's pending motion to separate the injunctive relief claim for which Amgen seeks the
17 discovery at issue.

18 There is good cause to stay this discovery pending the resolution of Sandoz's motion.
19 **First**, a stay will allow the parties to defer costly and potentially unnecessary discovery on
20 Amgen's injunctive relief claim. Amgen cannot seek injunctive relief unless it prevails on both
21 validity and infringement of the '878 patent. *See* 35 U.S.C. § 271(e)(4)(B) ("[I]njunctive relief
22 may be granted against an *infringer* to prevent the commercial manufacture, use, offer to sell, or
23 sale . . . of an approved drug") (emphasis added). If Sandoz's motion to separate equitable relief
24 is granted and Sandoz prevails on either validity or infringement, then the parties and the Court
25 will never need to reach the issue of injunctive relief. Completing time-consuming and costly
26 discovery and depositions on that issue now would be wasted effort. The fact discovery cutoff
27 passed over a month ago on June 23, so there is no pending fact discovery to be conducted in
28 parallel. The parties have already exchanged opening expert reports and are busy preparing

1 rebuttal expert reports due on September 1. Briefly staying the discovery at issue will allow the
2 Court to rule on Sandoz's motion and potentially save the parties from expending considerable
3 time and resources.

4 *Second*, a stay will avoid or reduce the risk of substantial competitive harm and prejudice
5 to Sandoz. The discovery sought by Amgen about (1) how much product will Sandoz sell,
6 (2) what price will Sandoz set, (3) what markets will Sandoz target, (4) what market share does
7 Sandoz expect to capture from Amgen, and (5) what costs will Sandoz incur, are among the most
8 competitively sensitive information available to each party at this stage. Unnecessarily revealing
9 this information to Amgen and, in turn, Amgen in-house counsel, will put Sandoz at a competitive
10 disadvantage. Staying this discovery pending resolution of Sandoz's motion will lessen the
11 burden and may alleviate it altogether. If the motion to separate is granted, then this discovery
12 will be required only if and when the jury finds infringement of a valid patent.

13 *Third*, a stay will not cause any prejudice to Amgen. The parties have agreed that both
14 parties may supplement any relevant expert reports on remedies when and if new discovery is
15 produced regarding the financial forecasts for pegfilgrastim. (Pai Decl. Ex. B at 3; Ex. C at 1.)
16 Since the parties have already exchanged opening expert reports and soon will be exchanging
17 rebuttal expert reports, it is not possible to incorporate this discovery into the current expert
18 reports. There is no benefit to rushing through this discovery now. If the Court grants Sandoz's
19 motion to separate, and if Amgen wins on liability at trial, it will have at least nine months to
20 complete discovery and seek injunctive relief before pegfilgrastim is approved by the FDA and
21 launched in or after 2019. If the Court denies Sandoz's motion to separate or this motion to stay,
22 Sandoz will work with Amgen to ensure the discovery is completed in a timely manner. The
23 March 2018 trial is over seven months away. Amgen will have ample time to complete discovery
24 and will suffer no prejudice.

25 **IV. CONCLUSION**

26 For the foregoing reasons, Sandoz respectfully requests that the Court stay its July 17,
27 2017 Discovery Order regarding discovery on the expected approval, marketing, and sales of
28 Sandoz's proposed pegfilgrastim product.

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Dated: August 2, 2017

MORRISON & FOERSTER LLP

By: /s/ Eric C. Pai
Eric C. Pai

Attorneys for Defendants
Sandoz Inc., Sandoz International GmbH,
Sandoz GmbH, and Lek Pharmaceuticals d.d.

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13 UNITED STATES DISTRICT COURT
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16 AMGEN INC. and
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19 SANDOZ INC., SANDOZ INTERNATIONAL
20 GMBH, SANDOZ GMBH, and LEK
PHARMACEUTICALS D.D.,

21 Defendants.
22

Case No. 3:16-cv-02581

**DECLARATION OF ERIC C. PAI IN
SUPPORT OF DEFENDANTS' MOTION
TO STAY DISCOVERY ORDER**

Date: September 7, 2017
Time: 10:00 am
Ctrm: Courtroom B

The Honorable Maria-Elena James

1 I, Eric C. Pai, hereby declare as follows:

2 1. I am a member of the bar of the State of California and am of counsel with
3 Morrison & Foerster LLP, counsel of record for Defendants Sandoz Inc., Sandoz International
4 GmbH, Sandoz GmbH, and Lek Pharmaceuticals D.D. (“Sandoz”) in the above-captioned action.
5 I am admitted to practice before this Court. I have personal knowledge of the facts stated herein
6 and, if called as a witness, I could and would testify competently to these facts.

7 2. On July 19 and July 24, 2017, the parties negotiated the separation of injunctive
8 relief from the rest of the March 2018 trial. The parties tried, but did not reach agreement,
9 regarding what additional concessions Sandoz could offer in exchange for Amgen’s agreement on
10 the motion now pending before Judge Seeborg. Amgen formally declared an impasse on this
11 issue in a letter dated July 26. Sandoz thereafter prepared its motion to separate injunctive relief
12 from the trial and filed it on July 28.

13 3. On July 28, 2017, Sandoz also informed Amgen of its intent to file a separate
14 motion to stay the Court’s discovery order pending resolution of the motion to separate injunctive
15 relief. On July 31 and August 1, the parties conferred regarding the motion to stay. On August 1,
16 Amgen confirmed it will oppose the motion.

17 4. Attached as **Exhibit A** is a letter from Brian Kramer, counsel for Sandoz, to Peter
18 Sandel, counsel for Amgen, dated July 19, 2017.

19 5. Attached as **Exhibit B** is a redacted letter from Eric Stone, counsel for Amgen, to
20 Brian Kramer, counsel for Sandoz, dated July 26, 2017.

21 6. Attached as **Exhibit C** is a redacted letter from Brian Kramer, counsel for Sandoz,
22 to Eric Stone, counsel for Amgen, dated July 28, 2017.

23 7. I have redacted portions of Exhibits B and C concerning discussions about
24 infringement expert reports. The infringement expert reports were not related to the financial
25 topics at issue in Sandoz’s motion for a protective order. They likewise are not relevant to the
26 injunctive relief issues that Sandoz is seeking to separate from the March 2018 trial. The
27 redactions make it possible to avoid filing this motion under seal. To the extent that the Court
28 wishes to see unredacted versions of Exhibits B and C, Sandoz is willing to file them under seal.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on August 2, 2017, in Palo Alto, California.

/s/ Eric C. Pai
Eric C. Pai

EXHIBIT A

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July 19, 2017

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By email

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Re: *Amgen Inc., Amgen Manufacturing, Limited v. Sandoz Inc. et al.*, Case Nos. 14-cv-04741, 16-cv-02581

Dear Peter:

I write in response to your letter dated yesterday in which you request that Sandoz provide dates for the deposition(s) of Sandoz's 30(b)(6) witnesses who will testify about each of Amgen's 30(b)(6) topic numbers 13-17, and produce documents regarding the same.

Following Judge James' commentary on the issue of bifurcation and its relation to a renewed motion for a protective order, Sandoz intends to file a motion to bifurcate the issue of injunctive relief from the jury trial set for March 2018. We discussed that possibility at the meet and confer on Wednesday. Can we represent that the parties have met and conferred in person and that Amgen will oppose such a motion? If not, let me know when you can discuss the issue. Sandoz will file the motion soon. We are considering the right procedural steps, but we likely also will request that Judge James stay her order pending resolution of the motion to bifurcate.

In light of the forthcoming motion practice, Sandoz will not at this time provide Amgen with dates on which a witness will testify about each of Amgen's 30(b)(6) topic numbers 13-17, nor will Sandoz produce documents regarding the same. We disagree that this discovery is relevant to Amgen's opening expert reports.

Sincerely,



Brian M. Kramer

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July 26, 2017

By Email

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Re: *Amgen Inc. v. Sandoz Inc.*, Case Nos. 14-04741, 16-02581

Dear Brian:

With opening expert reports due to be exchanged this Friday, July 28, and with Sandoz having failed timely to produce documents regarding [REDACTED] and, contrary to Magistrate Judge James's Order of July 16, refused to provide discovery regarding Sandoz's expected pegfilgrastim approval, marketing and sales, Amgen will need to supplement its expert reports on infringement and remedies after this Friday's deadline.

I. Infringement Reports

[REDACTED]

Brian M. Kramer, Esq.

2

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

II. Remedies Report

On July 17, Magistrate Judge James ordered Sandoz to provide discovery about “Sandoz’s expected pegfilgrastim approval, marketing, and sales.” [Dtk. 262]. As Sandoz is aware, and as we explained to the Court’s staff during our July 12 meet and confer in Magistrate Judge James’s courtroom, the requested—and now ordered—discovery is relevant to Amgen’s remedies and request for an injunction and to the opinion of Amgen’s damages expert. It has been over a week since the Court ordered production, yet Sandoz has not complied with the Court’s order.

Brian M. Kramer, Esq.

3

And while you have stated that Sandoz intends to move to bifurcate the issue of injunctive relief and request a stay of the Magistrate's order, Sandoz has not done so. (To be clear, as I suggested would be the case, Amgen will oppose any such motion.)

Sandoz's failure to provide the ordered discovery has deprived Amgen and its experts of the information needed to address irreparable harm or balance of the hardships with respect to pegfilgrastim. Amgen will supplement its expert reports on these issues following Sandoz's production of the requested discovery. For this report, unlike the infringement report, we cannot propose a schedule. If Sandoz does not intend to seek a stay of the Court's order, however, please begin production of the pegfilgrastim documents by Monday, July 31 or Amgen will move to compel and for other relief before Magistrate Judge James. Sandoz is not entitled to award itself a stay.

Very truly yours,

/s/ Eric Alan Stone

Eric Alan Stone

EAS:ps

EXHIBIT C

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July 28, 2017

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CONTAINS HIGHLY CONFIDENTIAL – BLA MATERIAL

By Email

Eric A. Stone
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Dear Eric:

I write in response to your July 26 letter regarding the opening expert reports due Friday, July 28, and certain discovery related to them.

Reports Regarding Pegfilgrastim Injunctive Relief – “Remedies” Report

Amgen's fundamental request is that Sandoz agree to permit supplementation regarding a report from Amgen's "remedies" expert regarding irreparable harm and the balance of the harms. Sandoz has consistently taken the position that discovery on these issues should be deferred. Thus, we agree that, when and if new discovery is produced regarding the financial forecasts for peg-filgrastim, Amgen and Sandoz should supplement any relevant expert reports on remedies and proceed accordingly. Given the discussion below, there is no need to set a schedule for these steps until further Court orders.

With respect to the discovery, I informed you in my July 19 letter, promptly after Judge James's discovery order, that Sandoz intended to file a motion to separate the issue of equitable relief from the jury trial set for March 2018. I asked you to let me know whether Amgen would agree to or oppose such a motion. When we spoke this Monday, July 24, Amgen still did not have a definitive answer to Sandoz's request to separate injunctive relief from the other factual issues for the jury. Your July 26 letter was the first definitive statement that Amgen will oppose our motion. That is the reason for the delay in our filing the motion.

In light of Amgen's opposition, Sandoz is filing the motion today. We will also promptly seek a stay of Judge James's order following the filing of the motion to separate. Until a

MORRISON | FOERSTER

Eric A. Stone
July 28, 2017
Page Two

ruling on the motion to separate or request to stay, the issue has now been fully explored by the parties.

Infringement Reports

[REDACTED]

[REDACTED]

[REDACTED]

MORRISON | FOERSTER

Eric A. Stone
July 28, 2017
Page Three

[REDACTED]

[REDACTED]

Sincerely,

/s/ Brian M. Kramer

Brian M. Kramer

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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, SANDOZ GMBH, and LEK
PHARMACEUTICALS D.D.,

Defendants.

Case No. 3:16-cv-02581

**[PROPOSED] ORDER GRANTING
DEFENDANTS' MOTION TO STAY
DISCOVERY ORDER**

Date: September 7, 2017
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The Honorable Maria-Elena James

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[Proposed] ORDER

On August 2, 2017, Defendants SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D. (“Sandoz”), by and through its counsel, moved to stay the Court’s Discovery Order of July 17, 2017 (Case No. 3:14-cv-04741-RS, ECF No. 262) regarding discovery on the expected approval, marketing, and sales of Sandoz’s proposed pegfilgrastim product pending resolution of Sandoz’s motion to separate equitable relief (Case No. 3:16-cv-02581-RS, ECF No. 92).

Having fully considered the moving and opposing papers, the arguments of counsel, and the files and records in this case, it is HEREBY ORDERED:

Sandoz’s motion to stay the Court’s Discovery Order of July 17, 2017 is GRANTED in its entirety. Discovery on the issues that relate to the expected approval, marketing, and sales of Sandoz’s proposed pegfilgrastim product is hereby stayed pending resolution of Sandoz’s motion to separate equitable relief.

IT IS SO ORDERED.

Dated: _____

Honorable Maria-Elena James
United States Magistrate Judge