

Vernon M. Winters (SBN 130128)
SIDLEY AUSTIN LLP
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
Email: vwinters@sidley.com

Rachel Krevans (SBN 116421)
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105-2482
Telephone: (415) 268-7000
Facsimile: (415) 268-7522
Email: rkrevans@mof.com
Additional counsel listed on signature page

Nicholas Groombridge (*pro hac vice*)
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
Email: ngroombridge@paulweiss.com
Additional counsel listed on signature page

*Attorneys for Defendants Sandoz Inc., Sandoz
GmbH, and Sandoz International GmbH
(Case No. 3:14-cv-4741 only)*

*Attorneys for Plaintiffs Amgen Inc.
and Amgen Manufacturing Limited*

James W. Beard (S.B.N. 267242)
KIRKLAND & ELLIS LLP
555 California Street
San Francisco, California 94104
Telephone: (415) 439-1400
Facsimile: (415) 439-1500
Email: james.beard@kirkland.com
Additional counsel listed on signature page

Attorneys for Defendant Sandoz Inc.

**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.
AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC. SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS, D.D., Defendants.

Case No. 3:14-cv-04741-RS
Case No. 3:16-cv-02581-RS

**JOINT CASE MANAGEMENT
STATEMENT**

Date: October 28, 2016
Time: 10:00 AM
Dept: Courtroom 3
Judge: Hon. Richard Seeborg

1 Pursuant to the Stipulation and Order to Continue Case Management Conference as
2 Modified by the Court (-04741 Dkt. No. 211; -02581 Dkt. No. 47), the Standing Order for all
3 Judges of the Northern District of California / Contents of Joint Case Management Statement
4 (“Standing Order”), Civil Local Rule 16-9, and Federal Rule of Civil Procedure 26(f), Plaintiffs
5 Amgen Inc. and Amgen Manufacturing, Limited (together, “Amgen”) and Defendants Sandoz
6 Inc. (“Sandoz”), hereby submit the following Joint Case Management Statement for both cases.
7 Sandoz GmbH and Sandoz International GmbH join this statement solely for Case No. -04741
8 and adopt the positions of Sandoz set forth herein for purposes of that case only. Reference
9 herein to “the Parties” shall mean Amgen, Sandoz, and, for purposes of Case No. -04741 only,
10 Sandoz GmbH and Sandoz International GmbH.

11 **1. Jurisdiction and Service**

12 In Case No. 3:14-cv-04741-RS (“the -04741 case”), this Court has subject matter
13 jurisdiction over Amgen’s patent infringement claims and Sandoz Inc.’s sixth, seventh, eighth,
14 and ninth counterclaims under 28 U.S.C. §§ 1331 and 1338(a). There are no issues currently to
15 be resolved regarding personal jurisdiction or venue with regard to Sandoz Inc. or Amgen. No
16 parties remain to be served. In Case No. 3:14-cv-02581-RS (“the -02581 case”), this Court has
17 subject matter jurisdiction over Amgen’s patent infringement claims and Sandoz Inc.’s
18 counterclaims under 28 U.S.C. §§ 1331 and 1338(a). There are no issues currently to be
19 resolved regarding personal jurisdiction or venue with regard to Sandoz Inc. or Amgen. Amgen
20 asserts that Sandoz GmbH, Sandoz International GmbH, Lek Pharmaceuticals, d.d. are proper
21 parties in this action. Prior to the CMC, Amgen will file a motion requesting issuance of letters
22 rogatory and an order appointing an international process server, so that it may effect service on
23 Sandoz GmbH, Sandoz International GmbH, and Lek Pharmaceuticals, d.d.

24 **2. Facts**

25 In 1991, Amgen obtained a license from FDA under 42 U.S.C. § 262(a) for
26 NEUPOGEN® (filgrastim) for treating side effects of certain forms of cancer therapy. Amgen
27 discovered, developed, and markets NEUPOGEN® (filgrastim), a recombinant biologic protein
28

1 that stimulates the production of neutrophils, a type of white blood cells and is used to
 2 counteract a chemotherapy-induced neutrophil deficiency. Sandoz filed an application under 42
 3 U.S.C. § 262(k) (“aBLA”) seeking FDA approval of a biosimilar filgrastim product,
 4 ZARXIO®, designating Amgen’s NEUPOGEN® as the reference product. In July 2014,
 5 Sandoz informed Amgen that FDA had accepted its aBLA and that it intended to sell upon FDA
 6 approval, which was expected in the first half of 2015, which Sandoz contends was a legally
 7 effective notice of commercial marketing.

- 8 • On October 24, 2014, Amgen sued Sandoz Inc., Sandoz International GmbH, and Sandoz
 9 GmbH in this Court, asserting unlawful competition under California Business &
 10 Professions Code § 17200 et seq., conversion, and infringement of U.S. Patent 6,162,427
 11 (“the ’427 patent”). Amgen alleged that Sandoz violated the BPCIA by seeking licensure
 12 by reference to Amgen’s license and failing to disclose to Amgen the information
 13 required by 42 U.S.C. § 262(l)(2)(A) and by failing to comply with the notice of
 14 commercial marketing under 42 U.S.C. § 262(l)(8)(A). On November 20, 2014, Sandoz
 15 answered the Complaint and counterclaimed for declaratory judgments that its reading of
 16 the BPCIA was correct, noninfringement of the ’427 patent, and invalidity of the ’427
 17 patent. (-04741 case Dkt. No. 22.) On December 15, 2014 Amgen answered Sandoz’s
 18 counterclaims. (-04741 case Dkt. No. 28.) Following this Court’s grant of partial
 19 judgment to Sandoz, entry of judgment against Amgen on its state law claims, and denial
 20 of Amgen’s motion for a preliminary injunction (Dkt. No. 105), the Court granted Rule
 21 54(b) judgment on the dismissed claims and stayed all remaining claims in this action,
 22 pending the Federal Circuit’s resolution of Amgen’s appeal. (Dkt. No. 111.) The Federal
 23 Circuit decided the appeal on July 21, 2015, *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347
 24 (Fed. Cir. 2015), and denied both parties’ petitions. Order Denying Petitions, *Amgen Inc.*
 25 *v. Sandoz Inc.*, No. 15-1499 (Fed. Cir. Oct. 16, 2015), Dkt. No. 162. Sandoz then filed a
 26 petition for a writ of certiorari to the Supreme Court of the United States on February 16,
 27 2016, seeking review of the Federal Circuit’s decision regarding 42 U.S.C. § 262(l)(8),
 28 which Amgen opposed. On March 21, 2016, Amgen filed a conditional cross-petition for
 a writ of certiorari, seeking review of the Federal Circuit’s decision regarding 42 U.S.C.
 § 262(l)(2)(A), if the Court grants Sandoz’s petition, which Sandoz opposed. The
 Supreme Court called for the views of the Solicitor General regarding both petitions.
Sandoz Inc. v. Amgen Inc., No. 15-1039; *Amgen Inc. v. Sandoz Inc.*, No. 15-1195.
- Sandoz launched ZARXIO® on September 3, 2015. On September 8, 2015 the Court
 issued an order granting the Parties’ joint motion to lift the stay in this case as to
 Amgen’s claims of patent infringement and Sandoz’s related counterclaims, and entered a
 schedule through the completion of claim construction. (-04741 Dkt. No. 133.) Pursuant
 to that schedule, Amgen amended its complaint on October 15, 2015. Amgen’s First
 Amended and Supplemental Complaint asserts infringement of the ’427 patent under 35
 U.S.C. § 271(e)(2)(C)(ii) and/or 35 U.S.C. § 271(b), and U.S. Patent No. 8,940,878 (“the
 ’878 patent”) under 35 U.S.C. § 271(e)(2)(C)(ii) and/or 35 U.S.C. § 271(g). Amgen has
 requested relief including: a permanent injunction, damages adequate to compensate

1 Amgen for Sandoz's infringement in accordance with 35 U.S.C. § 284; declaring
 2 Sandoz's infringement is willful and deliberate, and justifies an increase in damages of up
 3 to three times in accordance with 35 U.S.C. § 284; declaring that this is an exceptional
 case and an award to Amgen of its attorneys' fees and costs pursuant to 35 U.S.C. § 285;
 and awarding Amgen such other and further relief as the court deems just and proper.

- 4 • On November 2, 2015, Sandoz Inc., Sandoz GmbH, and Sandoz International GmbH
 5 each answered Amgen's First Amended and Supplemental Complaint. Sandoz Inc.
 6 denied Amgen's claims and counterclaimed for a declaratory judgment of
 noninfringement and invalidity of the '427 and '878 patents. Sandoz GmbH and Sandoz
 7 International GmbH denied Amgen's claims and denied that they were subject to the
 District Court's jurisdiction. Sandoz requested relief including: denying Amgen all relief
 8 requested under the First Amended Complaint; declaring Sandoz has not and will not
 infringe the '427 and '878 patents; declaring the '427 and '878 patents are invalid;
 9 awarding Sandoz its costs and reasonable attorneys' fees; and awarding any other such
 relief as is just and proper.
- 10 • On May 12, 2016, Amgen Inc. and Amgen Manufacturing Limited (collectively,
 11 "Amgen") filed a patent infringement action against Sandoz Inc., Sandoz International
 GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d. (collectively, "Sandoz") arising out
 12 of Sandoz's submission of an application to FDA for a license to market a biosimilar
 version of Amgen's NEULASTA® (pegfilgrastim) product. Amgen asserts that Sandoz
 13 infringed the '878 patent and 5,824,784 (the "'784 patent") under 35 U.S.C.
 14 § 271(e)(2)(C) by submitting its aBLA to FDA. Amgen further seeks a declaratory
 judgment of infringement of the '878 patent under 35 U.S.C. § 271(g). Amgen seeks a
 15 judgment that Sandoz has infringed one or more claims of the '878 patent under 35
 U.S.C. § 271(e)(2)(C); a judgment that Sandoz has infringed or will infringe one or more
 16 claims of the '878 patent by engaging in the manufacture, import, offer for sale, sale, or
 use within the United States of Sandoz's biosimilar pegfilgrastim product before the
 17 expiration of the '878 patent; a judgment that Sandoz has infringed one or more claims of
 the '784 patent under 35 U.S.C. § 271(e)(2)(C); a judgment compelling Sandoz to pay to
 18 Amgen damages or other monetary relief adequate to compensate for Sandoz's
 infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284; an
 19 injunction that enjoins Sandoz, as well as all officers, employees, agents, representatives,
 affiliates, assignees, successors, and affiliates of Sandoz, and all persons acting on behalf
 20 of or at the direction of, or in concert with Sandoz, from infringing the '878 patent, or
 contributing to or inducing anyone to do the same, by acts including the manufacture,
 21 use, offer to sell, sale, distribution, or importation of any current or future versions of a
 product that infringes, or the use or manufacturing of which infringes the '878 patent, in
 22 accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283; a declaration that this is
 an exceptional case and awarding to Amgen their attorneys' fees and costs pursuant to 35
 23 U.S.C. § 285, and expenses; and such other relief that the court may deem just and
 24 proper.
- 25 • On June 23, 2016, Sandoz Inc. filed an answer to Amgen's complaint, denying Amgen's
 26 claims, and asserted counterclaims against Amgen. Sandoz Inc.'s counterclaims seek
 27 (1) a declaratory judgment of noninfringement of the '878 patent, (2) a declaratory
 judgment of invalidity of the '878 patent, (3) a declaratory judgment of noninfringement
 28

1 of the '784 patent, and (4) a declaratory judgment of invalidity of the '784 patent.
2 Amgen answered the counterclaims on July 18, 2016.

- 3 • On May 27, 2016, the Court so-ordered the Parties' stipulated request to relate the -04741
4 and -02581 cases. After claim-construction proceedings for the '427 and '878 patents,
5 this Court issued a claim construction decision on August 4, 2016. The Parties
6 understand that claim construction is binding in both cases. The Parties disagree on the
7 conditions under which additional '878 terms may be raised for construction. Amgen
8 proposes that the Parties may raise additional claim terms if disputes arise requiring
9 resolution in the pegfilgrastim case, consistent with *O2 Micro Int'l Ltd. v. Beyond
10 Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an
11 actual dispute regarding the proper scope of these claims, the court, not the jury, must
12 resolve that dispute."). Sandoz proposes that the parties may raise additional terms only
13 if good cause is shown based on newly produced documents in the pegfilgrastim case.

9 **3. Legal Issues in Dispute**

10 In the -04741 case, the Parties dispute infringement and invalidity of the '427 and '878
11 patents, as well as whether Amgen is entitled to remedies for patent infringement. In the -02581
12 case, the Parties dispute the issues as to the '878 and '784 patents.

13 **4. Motions**

14 In the -02581 case, Amgen anticipates filing a motion for issuance of letters rogatory
15 and an order appointing an international process server to effect service on Sandoz GmbH,
16 Sandoz International GmbH, and Lek Pharmaceuticals, d.d. Amgen does not anticipate filing
17 any other motions at this time. Sandoz anticipates filing early summary judgment motions of
18 non-infringement and/or invalidity, based on the Court's claim construction ruling for the '427
19 and '878 patents.

20 **5. Amendment of Pleadings**

21 In the -04741 case, the deadline to amend the pleadings to add parties, claims, patents,
22 products or counterclaims was October 15, 2015. In the -02581 case, the Parties propose
23 November 4, 2016 as the deadline to amend the pleadings to add parties, claims, patents,
24 products or counterclaims. The Parties reserve all their rights under Federal Rule of Civil
25 Procedure 15 and this Court's local rules.

26 **6. Evidence Preservation**

27 Amgen and Sandoz have reviewed the Guidelines for the Discovery of Electronically
28

1 Stored Information (“ESI Guidelines”), and have met and conferred about reasonable and
2 proportionate steps to take regarding evidence preservation. Amgen and Sandoz confirm that
3 they have taken appropriate and reasonable measures to preserve relevant evidence.

4 **7. Disclosures**

5 In the -04741 case, Amgen and Sandoz Inc. exchanged initial disclosures pursuant to
6 Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure on January 15, 2015. Amgen
7 provided supplemental initial disclosures on January 21, 2015, February 5, 2015, November 5,
8 2015, and August 11, 2016. Sandoz provided supplemental initial disclosures on December 18,
9 2015. In the -02581 case, Amgen and Sandoz Inc. exchanged initial disclosures pursuant to
10 Rule 26(a)(1)(A) of the Federal Rules of Civil Procedure on August 11, 2016.

11 **8. Discovery**

- 12 • Discovery Taken to Date: In the -04741 case, Amgen and Sandoz exchanged disclosures
13 as described above. The Parties have served written discovery (requests for production
14 interrogatories, and requests for admission) to which the other Party has responded,
15 except that Amgen’s response to Sandoz’s fifth set of requests for production and third
16 set of interrogatories is due on September 29, 2016. Sandoz also produced its aBLA for
17 filgrastim to Amgen in February 2015. Amgen deposed Alexander Thole on February
18 26, 2015 and expert Gordon Rausser, Ph.D. on March 2, 2015. Sandoz deposed expert
19 Tomas Philipson, Ph.D on February 13, 2015 and Robert Azelby on February 15, 2015.
20 Amgen disclosed asserted claims and infringement contentions on February 5, 2015 and
21 amended them on October 15, 2015. Sandoz disclosed invalidity contentions on
22 December 11, 2015. Sandoz has moved for issuance of letters rogatory to pursue
23 discovery from Roche Diagnostics GmbH and from Mr. Peter-Paul Ochlich. Amgen did
24 not oppose Sandoz’s motions. The Parties’ document production is ongoing. In the -
25 02581 case, Amgen served two sets of requests for production, a set of interrogatories,
26 and a request for admission on August 24, 2016. Sandoz’s responses are due September
27 26, 2016, and Sandoz has agreed to complete early written discovery for the ‘784 patent
28 by September 23, 2016.
- Scope of Anticipated Discovery: Amgen intends to pursue discovery relating to all the
factual and legal contentions identified above that involve factual disputes rather than
pure issues of law. For the -04741 case, Amgen continues to pursue the topics described
in the September 23, 2015 Joint Case Management Statement (-04741 Dkt. No. 137).
For the -02581 case, Amgen intends to pursue discovery regarding at least the following
subject matter: Sandoz’s activities alleged to constitute infringement of the ‘784 patent
and the ‘878 patent; the amount and disposition of lots of pegfilgrastim manufactured
by, manufactured for, or delivered to Sandoz and the location of any pegfilgrastim
product on October 19, 2015; methods used in the manufacture of Sandoz’s biosimilar

1 pegfilgrastim product; knowledge and consideration of the '878 patent and the '784
2 patent; communications with the FDA; marketing and business strategy for biosimilar
3 pegfilgrastim product; documents on competition and the relevant market; the
4 development, manufacture, importation and use of Sandoz's biosimilar pegfilgrastim
5 product; the activities and involvement of the various Sandoz entities with respect to the
6 development, manufacture, importation, sale, offer for sale, and use of the Sandoz
7 biosimilar pegfilgrastim product; Sandoz's aBLA and manufacturing information;
8 Sandoz's contentions regarding the invalidity of the '878 patent [and the '784 patent];
9 and Sandoz's contentions regarding the noninfringement of Sandoz's biosimilar
10 pegfilgrastim product.

11 Sandoz intends to pursue discovery relating to all the factual and legal contentions
12 identified above as well as issues related to Sandoz's defenses. For the -04741 case,
13 Sandoz continues to pursue the topics described in the September 23, 2015 Joint Case
14 Management Statement (-04741 Dkt. No. 137). For the -02581 case, Sandoz intends to
15 pursue discovery relating to all the factual and legal contentions identified above as well
16 as issues related to Sandoz's defenses and counterclaims in this action. Among other
17 things, Sandoz intends to pursue discovery regarding, *inter alia*: Amgen's BLA for
18 NEULASTA®, including communications with the FDA; documents reflecting the
19 development, manufacture, and use of NEULASTA® for the use in mobilization of stem
20 cells, including clinical trial documents; documents reflecting the conception and
21 reduction to practice of the claimed inventions; documents reflecting prior sales, offer
22 for sales, and/or public use of the claimed inventions; documents reflecting patent
23 ownership and licensing; documents reflecting the sales, marketing, and business
24 strategy for NEULASTA®; information relevant to Sandoz's invalidity contentions,
25 once served, and Amgen's contentions, once served, regarding the alleged infringement
26 and validity of the '878 patent [and the '784 patent].

- 27 • Conduct of Discovery: The Parties do not believe that discovery should be conducted in
28 phases. In the -02581 case, the Parties are working together to conduct discovery on the
'784 patent expeditiously to evaluate how to move forward. The Parties believe
discovery should be limited to the claims and defenses set forth in this action in
accordance with Rule 26, as amended in light of new information learned in discovery.
- Written Discovery Requests: The Parties expect to continue to issue written discovery
requests on a rolling basis as appropriate, including requests for admission, document
requests, and interrogatories, directed to each of the above subjects and others as the
need arises.
- Anticipated Deponents: The Parties expect to depose employees and representatives of
each Party entity, including those pursuant to Rule 30(b)(6), as well as any technical and
damages expert witnesses who may provide opinions on behalf of each Party, and
relevant third party witnesses.
- Expert Witnesses: The Parties each anticipate needing one or more experts in the fields
of technology to which the '427 patent, '784 patent, and '878 patent are directed and in
the field of damages. The Parties agree that expert communications and drafts will be
protected as provided in Fed. R. Civ. P. 26(b)(4).

- 1 • Electronically Stored Information (ESI): The Parties have met and conferred regarding
2 the scope of electronic discovery, including determining the form of any production, the
3 identities of the custodians, potential search terms, the scope of metadata provided, and
4 the relevant time period. In the -04741 case, the Parties have entered into a stipulated e-
5 discovery order as informed by the Northern District of California’s ESI Guidelines. (-
6 04741 Dkt. No. 155.) The Parties intend to enter into a similar order in the -02581 case.
- 7 • Privilege Log: In both cases, the Parties agree that there will be no requirement to
8 identify on a privilege log any attorney-client communications and/or attorney work-
9 product that was created on or after October 24, 2014, the date of the filing of the
10 Complaint for the -04741 case in the Northern District of California. The Parties agree
11 that neither Party shall be obligated to log e-mail communication in which an attorney
12 appears in the “from” line and the only recipients are employees or other attorneys for
13 the Party or communications in which an employee of a Party appears in the “from” line,
14 only attorneys appear in the “to” line and all other recipients are employees or attorneys
15 for the party. The Parties agree that a party shall not have to log each e-mail in any
16 applicable chain but shall log only the highest level communication. The Parties
17 otherwise agree that the production of privilege logs will be governed by Fed. R. Civ. P.
18 26(b)(5). The Parties further agree to provide their privilege logs twenty-one (21) days
19 after the deadline for close of document production (which is the deadline for
20 completing all non-expert discovery), except that privileged documents that may be
21 relevant to depositions, and that are identified by the producing party as privileged
22 before such depositions, shall be included on a privilege log that is served at least seven
23 (7) days before the scheduled deposition. Failure to provide a pre-deposition privilege
24 log will not be deemed a waiver of any privilege, and no Party will argue to the contrary.
- 25 • Protective Order: In the -04741 case, the Parties entered a Stipulated Protective Order
26 that was entered by the Court on February 9, 2015. (-04741 Dkt. No. 60.) The Parties
27 have been conferring regarding a Stipulated Protective Order for the -02581 case.
- 28 • Any Proposed Limitations or Modifications of the Discovery Rules: In the -04741 case,
the Court ordered that discovery be limited as follows: “(a) fifteen (15) non-expert
depositions per party; twenty-five (25) interrogatories per party, including all discrete
subparts; (c) a reasonable number of requests for production of documents or for
inspection per party; and (d) forty (40) requests for admission per party, not including
any requests for admission relating to authenticity.” (-04741 Dkt. No. 144.) The Parties
propose that the same limitations apply to the -02581 case. For both fact and expert
depositions, the Parties will work in good faith to agree to the date, location, deponent,
and burden of expenses for the deposition of the Parties’ employees so that no party
suffers excessive burden caused by another party’s request to depose such employees.
No fact witness shall be deposed for more than seven (7) hours total absent an
agreement between the Parties or leave of the Court. Each 7 hours of a Rule 30(b)(6)
deposition (from a single notice) constitutes 1 deposition, regardless of the number of
witnesses. No single witness may be deposed longer than 14 hours total even if deposed
in his personal capacity and as a Rule 30(b)(6) witness, and the Parties will work in
good faith to limit the total deposition time of any such witness. No Party will use a Rule
30(b)(6) notice to seek the infringement, validity, enforceability or other legal
contentions of the opposing party. Each side may serve up to 25 written interrogatories

1 and up to 40 requests for admission upon the opposing side, not including any requests
2 for admission relating to authenticity. Discrete subparts in any interrogatory will each
3 count as a separate interrogatory. In addition, the Parties agree that each deposition of a
4 foreign witness conducted in a foreign language through an interpreter shall be permitted
5 1.5 times the amount of time set forth above if the entirety of the testimony is in a
6 foreign language and this expansion of time shall apply to the total amount of time
7 available for depositions.

- 8 • Identification of Any Discovery Disputes: There are currently no discovery disputes
9 between the Parties.
- 10 • Additional Matters Required by Local Patent Rule 2-1: The Parties have included any
11 proposed modifications to the obligations and deadlines established by the Patent Local
12 Rules in the proposed schedule in Exhibit A below. The timing of the -02581 case's
13 claim construction discovery schedule is set forth in Exhibit A below. At this point in
14 the case, the Parties are not in a position to determine whether they will rely on experts
15 for claim construction purposes for the -02581 case, but should the Parties desire to use
16 an expert and are permitted to do so by the Court, the Parties will work in good faith to
17 set a schedule at that time. As to the -02581 case's claim construction hearing, the
18 Parties are not currently in a position to determine whether live testimony will be
19 presented or the estimated length of the hearing. Amgen as Plaintiff will present its
20 claim construction arguments first. Both parties may offer a short summary, explanation
21 of the technology at issue and/or tutorial presentation to educate the court about the
22 technology at issue.

23 **9. Class Actions**

24 The -04741 and -02581 cases are not class actions.

25 **10. Related Cases**

26 The -04741 and -02581 cases are related. There are no other related cases.

27 **11. Relief**

28 In the -04741 case, the relief sought by Amgen is set forth on pages 42-43 of its October
15, 2015 First Amended and Supplemental Complaint (-04741 Dkt. No. 145). The relief sought
by Sandoz is set forth on pages 34-35 of Sandoz Inc.'s November 2, 2015 Answer and
Counterclaims (-04741 Dkt. No. 149), pages 20-21 of Sandoz GmbH's November 2, 2015
Answer (-04741 Dkt. No. 150), and pages 21-22 of Sandoz International GmbH's Answer (-
04741 Dkt. No. 151). In the -02581 case, the relief sought by Amgen is set forth on page 20 of
its May 12, 2015 Complaint (-02581 Dkt. No. 1). The relief sought by Sandoz Inc. is set forth
on pages 19-20 of its Answer and Counterclaims (-02581 Dkt. No. 22).

1 **12. Settlement and ADR**

2 In the -04741 case, the Parties met and conferred pursuant to ADR L.R. 3-5(a), and did
3 not reach agreement on an ADR process. The Parties attended an ADR Phone Conference held
4 on January 21, 2015 with Daniel Bowling. In the -02581 case, the Parties met and conferred
5 pursuant to ADR L.R. 3-5(a), and did not reach agreement on an ADR process. The Parties are
6 scheduled to attend an ADR Phone Conference on October 24, 2016.

7 **13. Consent to Magistrate Judge For All Purposes**

8 The Parties have not consented to proceed before a magistrate judge for all purposes.

9 **14. Other References**

10 The Parties agree that this case is not suitable for reference to binding arbitration, a
11 special master, or the Judicial Panel on Multidistrict Litigation.

12 **15. Narrowing of Issues**

13 The Parties are not presently aware of any issues that can be narrowed by agreement.
14 The Parties reserve the right to seek further narrowing of issues and will do so in conjunction
15 with the mandatory Pretrial Conference.

16 **16. Expedited Trial Procedure**

17 The Parties do not believe that this case is the type of case that can be handled under the
18 Expedited Trial Procedure of General Order No. 64, Attachment A.

19 **17. Scheduling**

20 The cases will be governed by the Patent Local Rules. Together with the deadlines
21 specified by the Rules, the Parties propose the schedule in Exhibit A. Although the Parties have
22 proposed specific dates for each pre-trial deadline, the Parties understand that such dates may
23 change to the extent the Court cannot accommodate the Parties' proposed dates for the Pretrial
24 Conference and Trial. The Parties dispute whether to permit early summary judgment motions:

- 25 • Sandoz proposes that the schedule include specified dates for early summary judgment
26 motions, including dates for responsive and reply briefs, and for the associated hearing.
27 Based on the Court's claim construction ruling on the '427 and '878 patents, Sandoz
28 anticipates filing early summary judgment motions on non-infringement and/or invalidity
 of the asserted claims. Sandoz proposes to do so before opening expert reports are due

1 and before significant expense has been devoted to the expert discovery phase of the
2 case. Resolution of non-infringement and/or invalidity issues at that stage of the
3 litigation will potentially eliminate the need for costly expert discovery and subsequent
4 trial on these issues. In addition, Sandoz proposes a briefing schedule that permits more
5 time for the responsive and reply briefs than is contemplated by the Court's local rules.
6 For these reasons, Sandoz proposes that specific dates be included in the case schedule
7 for early summary judgment motions.

- 8 • Amgen disagrees that two rounds of summary judgment motions are necessary, once
9 before expert discovery and once after expert discovery. Under the proposed Sandoz
10 schedule for early motions, the Court hearing will take place 15 days prior to the deadline
11 for opening expert reports, and thus Amgen expects that it will need to prepare its
12 opening reports despite the pendency of the motions. In addition, oppositions to the early
13 summary judgment motions will likely involve the submission of expert declarations.
14 Thus, early motions will not save significant expenses.

15 **18. Trial**

16 In both cases, the Parties have both requested trial by jury for all issues so triable. The
17 Parties anticipate the length of trial to be approximately 7-9 days.

18 **19. Disclosure of Non-Party Interested Entities or Persons**

19 In both cases, the Parties have filed Certifications of Interested Entities or Persons
20 required by Civil L.R. 3-15, and restate here the content of the certifications.

- 21 • Plaintiff Amgen Inc. states that it is a publicly-held corporation. It has no parent
22 corporation and no publicly-held corporation owns 10% or more of its stock. Plaintiff
23 Amgen Manufacturing, Ltd. states that it is a wholly owned subsidiary of Amgen Inc.
24 Apart from Amgen Inc., there is no publicly-held corporation with a 10% or greater
25 ownership in AML.
- 26 • Defendants Sandoz Inc., Sandoz GmbH, and Sandoz International GmbH each state that
27 they are an indirect subsidiary of Novartis AG. Novartis AG's shares are listed and
28 traded on the SIX Swiss Exchange as well as on the NYSE in the form of American
29 Depository Receipts representing Novartis American Depository Shares.

30 **20. Professional Conduct**

31 All attorneys of record for the Parties have reviewed the Guidelines for Professional
32 Conduct for the Northern District of California.

33 **21. Other Matters**

34 The Parties have not identified any other matters that may facilitate the just, speedy and
35 inexpensive disposition of this matter.

1 Respectfully submitted,

2 Dated: September 19, 2016

3 By: /s/ Nicholas Groombridge
4 Nicholas Groombridge
5 PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
6 1285 Avenue of the Americas
7 New York, NY 10019-6064
8 Telephone: (212) 373-3000
9 Facsimile: (212) 757-3990
10 Email: ngroombridge@paulweiss.com

11 Vernon M. Winters (SBN 130128)
12 SIDLEY AUSTIN LLP
13 555 California Street, Suite 2000
14 San Francisco, CA 94104-1503
15 Telephone: (415) 772-1200
16 Facsimile: (415) 772-7400
17 vwinters@sidley.com

18 *Attorneys for Amgen Inc. and Amgen Manufacturing, Ltd.*

19 Dated: September 19, 2016

20 By: /s/ Rachel Krevans
21 Rachel Krevans (SBN 116421)
22 MORRISON & FOERSTER
23 425 Market Street
24 San Francisco, CA 94105-2482
25 Telephone: (415) 268-7000
26 Facsimile: (415) 268-7522
27 Email: rkrevans@mof.com

28 *Attorneys for Sandoz Inc., Sandoz GmbH, and Sandoz
International GmbH
(Case No. 3:14-cv-04741 only)*

1 Dated: September 19, 2016

2 By: /s/ James W. Beard
3 James W. Beard (S.B.N. 267242)
4 KIRKLAND & ELLIS LLP
5 555 California Street
6 San Francisco, California 94104
7 Telephone: (415) 439-1400
8 Facsimile: (415) 439-1500
9 Email: james.beard@kirkland.com

10 *Attorneys for Sandoz Inc.*

SIGNATURE ATTESTATION

Pursuant to Civil Local Rule 5-1(i)(3), I hereby certify that concurrence in the filing of this document has been obtained from each of the other Signatories shown above.

Dated: September 19, 2016

By: /s/ Nicholas Groombridge
Nicholas Groombridge

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ADDITIONAL COUNSEL

SIDLEY AUSTIN LLP

Alexander D. Baxter (SBN 281569)
555 California Street, Suite 2000
San Francisco, CA 94104-1503
Telephone: (415) 772-1200
Facsimile: (415) 772-7400
Email: abaxter@sidley.com

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

Eric Alan Stone (*pro hac vice*)
Jennifer H. Wu (*pro hac vice*)
Jennifer Gordon
Peter Sandel (*pro hac vice*)
Ana J. Friedman (*pro hac vice*)
Arielle K. Linsey (*pro hac vice*)
Stephen A. Maniscalco (*pro hac vice*)
1285 Avenue of the Americas
New York, NY 10019-6064
Telephone: (212) 373-3000
Facsimile: (212) 757-3990
Email: estone@paulweiss.com
jwu@paulweiss.com
psandel@paulweiss.com
jgordon@paulweiss.com
afriedman@paulweiss.com
alinsky@paulweiss.com
smaniscalco@paulweiss.com

AMGEN INC.

Wendy A. Whiteford (SBN 150283)
Lois M. Kwasigroch (SBN 130159)
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
Telephone: (805) 447-1000
Facsimile: (805) 447-1010
Email: wendy@amgen.com

*Attorneys for Plaintiffs Amgen Inc.
and Amgen Manufacturing Limited*

MORRISON & FOERSTER LLP

Erik J. Olson (SBN 175815)
Eric C. Pai (SBN 247604)
755 Page Mill Road
Palo Alto, California 94304
Telephone: 650.813.5600
Facsimile: 650.494.0792
Email: ejolson@mofocom
epai@mofocom

Stephen David Keane (S.B.N. 247588)
12531 High Bluff Drive, Ste. 100
San Diego, California 92130
Telephone: (858) 720-5100
Facsimile: (858) 720-5125
Email: skeane@mofocom

Grant J. Esposito (*pro hac vice*)
250 West 55th Street
New York, NY 10019-9601
Telephone: (212) 468-8000
Facsimile: (212) 468-7900
Email: gesposito@mofocom

*Attorneys for Defendants Sandoz Inc., Sandoz
GmbH, and Sandoz International GmbH
(Case No. 3:14-cv-4741 only)*

KIRKLAND & ELLIS LLP

James F. Hurst (*pro hac vice*)
Cristina Q. Almendarez (*pro hac vice*)
300 North LaSalle
Chicago, Illinois 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
Email: james.hurst@kirkland.com
cristina.almendarez@kirkland.com

Jeanna M. Wacker (*pro hac vice*)
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
Facsimile: (212) 446-4900
Email: jeanna.wacker@kirkland.com

Attorneys for Defendant Sandoz Inc.

Exhibit A: Proposed Schedule**Amgen v. Sandoz, Case No. 3:14-cv-04741-RS (N.D. Cal.)****Amgen v. Sandoz, Case No. 3:16-cv-02581RS (N.D. Cal.)**

Description	Amgen's Proposed Date	Sandoz's Proposed Date
[Pegfilgrastim only] Completion of early written discovery for '784 patent	9/23/2016	
[Pegfilgrastim only] Amgen provides decision whether to go forward on '784 patent	10/21/2016	
[Pegfilgrastim only] Last day to: <ul style="list-style-type: none"> • meet and confer re: initial disclosures, early settlement, ADR process selection, and discovery plan • file ADR Certification signed by Parties and Counsel (form available at http://www.cand.uscourts.gov) • file either Stipulation to ADR Process or Notice of Need for ADR Phone Conference http://www.adr.cand.uscourts.gov (form available at http://www.cand.uscourts.gov) 	10/6/2016 [21 days prior to CMC]	
[Pegfilgrastim only] Infringement Contentions	11/4/2016	Not later than 14 days after CMC. Patent L.R. 3-1.
[Pegfilgrastim only] Last day to complete initial disclosures.	10/20/2016 [7 days prior to CMC]	

Description	Amgen's Proposed Date	Sandoz's Proposed Date
Joint Case Management Conference	10/28/2016, 10:00 a.m.	
[Pegfilgrastim only] Invalidity Contentions	12/19/2016 Not later than 45 days after infringement contentions. Patent L.R. 3-3.	
[Pegfilgrastim only] Exchange of Claim Terms (for '784 and additional terms for '878 under certain conditions ¹)	12/30/2016 Not later than 14 days after invalidity contentions. Patent L.R. 4-1.	
[Pegfilgrastim only] Exchange of Proposed Claim Constructions and Evidence (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)	1/13/2016 Constructions and extrinsic evidence exchanged not later than 21 days after exchanging terms. Patent L.R. 4-2.	
[Pegfilgrastim only] Joint Claim Construction and Prehearing Statement (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)	1/27/2017 Not later than 60 days after service of invalidity contentions. Patent L.R. 4-3.	
[Pegfilgrastim only] End of Claim Construction Discovery (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)	2/27/2017 Not later than 30 days after Joint Claim Construction and Prehearing Statement. Patent L.R. 4-4.	

¹ The Parties disagree on the conditions under which additional '878 terms may be raised for construction. Amgen proposes that the Parties may raise additional claim terms if disputes arise requiring resolution in the pegfilgrastim case, consistent with *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute."). Sandoz proposes that the parties may raise additional terms only if good cause is shown based on newly produced documents in the pegfilgrastim case.

Description	Amgen's Proposed Date	Sandoz's Proposed Date
<p>[Pegfilgrastim only] Opening Claim Construction Brief (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)</p>	<p>3/13/2017 Not later than 45 days after Joint Claim Construction and Prehearing Statement. Patent L.R. 4-5(a).</p>	
<p>[Pegfilgrastim only] Responsive Claim Construction Brief (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)</p>	<p>3/27/2017 Not later than 14 days after opening briefs. Patent L.R. 4-5(b).</p>	
<p>[Pegfilgrastim only] Reply Claim Construction Brief (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)</p>	<p>4/3/2017 Not later than 7 days after opposition briefs. Patent L.R. 4-5(c).</p>	
<p>[Pegfilgrastim only] Claim Construction Hearing (for '784 and additional terms for '878 under certain conditions, <i>see supra</i> n.1)</p>	<p>4/17/2017 or subject to the convenience of the Court Subject to the convenience of the Court's calendar, 2 weeks after submission of reply brief. Patent L.R. 4-6.</p>	
<p>Early Dispositive Motions</p>	<p>Amgen disagrees that early dispositive motions are appropriate</p>	<p>3/31/2017</p>
<p>Early Dispositive Motion Responsive Briefs</p>	<p>Amgen disagrees that early dispositive motions are appropriate</p>	<p>4/21/2017</p>
<p>Early Dispositive Motion Reply Briefs</p>	<p>Amgen disagrees that early dispositive motions are appropriate</p>	<p>5/5/2017</p>
<p>Completion of Non-Expert Discovery</p>	<p>5/10/2017</p>	
<p>Final Privilege Logs</p>	<p>5/24/2017</p>	
<p>Early Dispositive Motion Hearing</p>	<p>Amgen disagrees that early dispositive motions are appropriate</p>	<p>6/1/2017 or at the Court's earliest convenience</p>

Description	Amgen's Proposed Date	Sandoz's Proposed Date
Opening Expert Reports (on issues where the party bears the burden of proof)	6/16/2017	
Rebuttal Expert Reports	7/21/2017	
Reply Expert Report (to rebut any alleged secondary considerations of non-obviousness, which shall be addressed first by Amgen in its Rebuttal Expert Reports)	8/4/2017	
Completion of Expert Discovery	9/13/2017	
Deadline for Dispositive Motions	10/4/2017	
Dispositive Motion Responsive Briefs	10/18/2017	
Dispositive Motion Reply Briefs	10/27/2017	
Dispositive Motion Hearing	11/8/2017 or at the Court's convenience	
Pretrial Meet and Confer [21 Days prior to the final Pretrial Conference; Judge Seeborg Guidelines, ¶ A]	11/9/2017	
Joint Pretrial Statement and Order, Pretrial Exchanges, and Motions in Limine [10 days prior to the final Pretrial Conference; Judge Seeborg Guidelines, ¶¶ B, D]	11/20/2017	
Jury Voir Dire Questions, Proposed Jury Instructions, and Proposed Jury Verdict Forms [5 days prior to the final Pretrial Conference; Judge Seeborg Guidelines, ¶ D]	11/24/2017	
Oppositions to Motions in Limine [3 days prior to final Pretrial Conference; Judge Seeborg Guidelines, ¶¶ B, D]	11/27/2017	
Pretrial Conference	11/30/2017	

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Description	Amgen's Proposed Date	Sandoz's Proposed Date
Optional Trial Briefs, Deposition and Discovery Designations [5 days prior to Trial; Judge Seeborg Guidelines, ¶ D]	12/4/2017	
Trial	Week of 12/11/2017 or at the Court's convenience	