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8
9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA

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12 SANDOZ INC.,
13 Plaintiff,
14 v.
15 AMGEN INC. and AMGEN
16 MANUFACTURING, LIMITED,
17 Defendants.

Case No.

**COMPLAINT FOR
DECLARATORY JUDGMENT OF
PATENT NONINFRINGEMENT
AND INVALIDITY**

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1 Sandoz Inc. (“Sandoz”) hereby alleges for its Complaint against defendants Amgen Inc.
2 and Amgen Manufacturing, Limited (collectively, “Amgen”), as follows:

3 **NATURE OF THE ACTION**

4 1. This is an action for declaratory judgment of noninfringement and invalidity of
5 U.S. Patent No. 9,643,997 (“the ’997 patent”) arising under the Declaratory Judgment Act,
6 28 U.S.C. §§ 2201-2202, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

7 2. This case is a continuation of an already resolved patent dispute venued in this
8 Court involving the same products and the same purification procedures. The same parties
9 litigated patent infringement claims in this District regarding the same patent family, the same
10 products, and the same accused purification processes in Case Nos. 3:14-cv-04741-RS & 3:16-cv-
11 02581-RS. While those cases were pending, Sandoz invited Amgen to include the ’997 patent as
12 a part of those cases and resolve all proceedings in the prior action. However, Amgen did not
13 amend to add those claims in the then-pending litigation; indeed, it did not even respond to
14 Sandoz’s correspondence regarding the patent. Amgen’s claims regarding the related patent with
15 respect to the same products and the same purification procedures were resolved by an order
16 granting judgment under Rule 56 on December 19, 2017. Sandoz believes that elements of that
17 ruling resolve the present dispute as well.

18 3. An actual and justiciable controversy exists under 28 U.S.C. §§ 2201-2202
19 between Sandoz and Amgen as to whether Sandoz infringes any valid claim of the ’997 patent.

20 **PARTIES**

21 4. Sandoz is a corporation organized and existing under the laws of the state of
22 Colorado, with its principal place of business at 100 College Road West, Princeton, New Jersey
23 08540.

24 5. On information and belief, Amgen Inc. is a corporation existing under the laws of
25 the state of Delaware, with its principal place of business at One Amgen Center Drive, Thousand
26 Oaks, California 91320.

1 enforcement. AML previously filed suit against Sandoz in the Northern District of California in
2 Case No. 3:14-cv-04741-RS and again in Case No. 3:16-cv-02581-RS.

3 12. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and 1391(c).
4 Defendant Amgen Inc. is subject to personal jurisdiction in this District and resides in this
5 District. Defendant AML may be sued in any district, pursuant to 28 U.S.C. § 1391(c)(3), as a
6 non-resident. Venue is also proper because a substantial part of the events giving rise to the
7 claims in this action occurred in this District.

8 13. This dispute should be resolved in this District, where venue is proper and where
9 the parties have already litigated similar claims involving the same products, the same patent
10 family, and the same purification processes.

11 **INTRADISTRICT ASSIGNMENT**

12 14. Pursuant to Civil L.R. 3-2(c) and 3-5(b), this is an Intellectual Property Rights
13 Action subject to assignment on a district-wide basis.

14 15. Pursuant to Civil L.R. 3-12, this case is related to Case Nos. 3:14-cv-04741-RS
15 and 3:16-cv-02581-RS and should be assigned to the same District Judge as those cases.

16 **PATENT-IN-SUIT**

17 16. The '997 patent, entitled "Capture purification processes for proteins expressed in
18 a non-mammalian system," states on its face that it issued on May 9, 2017. A true and correct
19 copy of the '997 patent is attached as Exhibit A.

20 17. The '997 patent arises from the same set of patent applications that were the
21 source of United States Patent No. 8,940,878 ("the '878 patent"), which was the subject of Case
22 Nos. 3:14-cv-04741-RS and 3:16-cv-02581-RS. The '997 patent stems from U.S. Patent
23 Application No. 12/822,990, which was the application from which the '878 patent issued. Both
24 patents have the same name, have identical abstracts, and share the same specification.

25 **FACTUAL BACKGROUND**

26 18. Sandoz is a global leader in generic and biosimilar medicines, committed to
27 playing a leading role in driving access to medicine worldwide. As set forth in its Mission and
28 Purpose Statement, Sandoz discovers new ways to improve and extend people's lives. Sandoz

1 contributes to society’s ability to support growing healthcare needs by pioneering novel
2 approaches to help people around the world access high-quality medicine.²

3 19. This case concerns filgrastim and pegfilgrastim, biological products approved by
4 the FDA to address certain side effects of cancer treatment. Amgen began selling filgrastim
5 under the brand name Neupogen® in 1991. Amgen’s “material U.S. patents for filgrastim
6 (NEUPOGEN®) expired in December 2013.”³ Sandoz obtained approval for its biosimilar
7 filgrastim product, Zarxio, in March 2015 and launched the product in September 2015.

8 20. A chemical compound known as polyethylene glycol (“PEG”) can be attached to
9 filgrastim to create pegfilgrastim. This modification causes the protein to remain in the
10 circulatory system for a substantially longer time, and thus pegfilgrastim is often referred to as
11 “long acting” filgrastim. Amgen began selling pegfilgrastim under the brand name Neulasta® in
12 2002. Amgen’s “final material U.S. patent for Neulasta® expired in October 2015.”⁴ Sandoz’s
13 application to market a biosimilar pegfilgrastim product is currently pending before the FDA.

14 21. The parties have already litigated patent infringement claims regarding Sandoz’s
15 biosimilar filgrastim and pegfilgrastim products in this District. (*See Amgen Inc. v. Sandoz Inc.*,
16 Case Nos. 3:14-cv-04741-RS and 3:16-cv-02581-RS.) Amgen accused a purification step in
17 Sandoz’s manufacturing process for filgrastim and pegfilgrastim of infringing U.S. Patent No.
18 8,940,878 (“the ’878 patent”). On December 19, 2017, this Court granted summary judgment of
19 noninfringement of the ’878 patent. The Court entered final judgment in favor of Sandoz on
20 January 8, 2018.

21 22. The ’997 patent at issue here and the previously litigated ’878 patent are in the
22 same patent family and are similar or identical in several key respects. The alleged inventors are
23 the same. The patent names are the same. The abstracts are the same. Aside from formatting
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26 ² See Sandoz, Our Mission and Purpose, (last visited February 21, 2019),
27 <https://www.sandoz.com/about-us/who-we-are/our-mission-and-purpose>.

28 ³ Amgen Form 10-K for the fiscal year ended December 31, 2013, at 3.

⁴ Amgen Form 10-K for the fiscal year ended December 31, 2018, at 47.

1 and related application data, the specifications of both patents are identical. The '997 patent
2 issued from a division of the application that issued as the '878 patent.

3 23. The claims of both patents are also similar. Claim 9 of the '997 patent, one of just
4 two independent claims in the '997 patent, states:

5 9. A method of purifying a protein expressed in a non-native limited solubility
6 form in a non-mammalian expression system comprising:

7 (a) solubilizing the expressed protein in a solubilization solution comprising
8 one or more of the following:

- 9 (i) a denaturant;
- 10 (ii) a reductant; and
- 11 (iii) a surfactant;

12 (b) forming a refold solution comprising the solubilization solution and a refold
13 buffer, the refold buffer comprising one or more of the following:

- 14 (i) a denaturant;
- 15 (ii) an aggregation suppressor;
- 16 (iii) a protein stabilizer; and
- 17 (iv) a redox component;

18 (c) applying the refold solution to a separation matrix under conditions suitable
19 for the protein to associate with the matrix;

20 (d) washing the separation matrix; and

21 (e) eluting the protein from the separation matrix.

22 By comparison, claim 7 of the '878 patent, the only independent claim that Amgen asserted in the
23 prior litigation, states:

24 7. A method of purifying a protein expressed in a non-native limited solubility
25 form in a non-mammalian expression system comprising:

26 (a) expressing a protein in a non-native limited solubility form in a non-
27 mammalian cell;

28 (b) lysing a non-mammalian cell;

(c) solubilizing the expressed protein in a solubilization solution comprising
one or more of the following:

- (i) a denaturant;
- (ii) a reductant; and
- (iii) a surfactant;

(d) forming a refold solution comprising the solubilization solution and a refold
buffer, the refold buffer comprising one or more of the following:

- (i) a denaturant;
- (ii) an aggregation suppressor;
- (iii) a protein stabilizer; and
- (iv) a redox component;

(e) directly applying the refold solution to a separation matrix under conditions
suitable for the protein to associate with the matrix;

(f) washing the separation matrix; and

(g) eluting the protein from the separation matrix, wherein the separation
matrix is a non-affinity resin selected from the group consisting of ion
exchange, mixed mode, and a hydrophobic interaction resin.

1 24. The only differences between claim 9 of the '997 patent and claim 7 of the '878
2 patent are shown above in underlined red text. None of those differences are implicated by the
3 grounds on which Sandoz sought summary judgment of noninfringement of the '878 patent in the
4 prior litigation, which focused on the absence in the accused process of the claimed steps of
5 “washing the separation matrix” and “eluting the protein from the separation matrix.” Those
6 same steps are required by the claims of the '997 patent, and therefore the same grounds for
7 noninfringement apply with respect to the '997 patent.

8 25. The '997 patent issued on May 9, 2017, while the litigation over the '878 patent
9 was still pending before this Court. On June 7, 2017, Amgen’s counsel sent a letter to Sandoz’s
10 counsel stating Amgen’s belief that it could reasonably assert a claim for infringement of the '997
11 patent with respect to Sandoz’s making, using, offering to sell, selling, or importing into the
12 United States Sandoz’s filgrastim and pegfilgrastim products.

13 26. In response on July 7, 2017, Sandoz identified the overlap between the pending
14 litigation on the '878 patent and any potential issues with respect to the '997 patent. To provide
15 for a prompt and efficient resolution of these issues, Sandoz invited Amgen to bring its purported
16 claims regarding the '997 patent immediately and resolve them as part of the existing litigation.

17 27. Despite Sandoz’s invitation, Amgen did not amend its claim in the then-pending
18 litigation to assert the '997 patent and did not otherwise pursue the assertions made in its June 7,
19 2017 letter in any way.

20 28. More than 20 months have passed since Amgen first asserted its potential claims
21 with respect to the '997 patent, and Amgen still has not filed suit on those claims. Sandoz has
22 been marketing and selling its biosimilar filgrastim product, Zarxio, throughout this time. And as
23 Sandoz notified Amgen on February 21, 2019 pursuant to 42 U.S.C. § 262(*I*)(8)(A), Sandoz
24 intends to begin commercially marketing its biosimilar pegfilgrastim product at the earliest
25 possible opportunity on or after 180 days from the date of its notice.

26 29. Amgen’s delay alone undercuts any claim that Amgen is entitled to any injunctive
27 relief based on the '997 patent. Nonetheless, Amgen has not disavowed the intention to seek a
28 preliminary injunction pursuant to 42 U.S.C. § 262(*I*)(8)(B). With the filing of this Complaint,

1 Sandoz seeks to ensure that any issues with respect to the '997 patent, including any preliminary
2 injunction motion, are resolved promptly, efficiently, and well in advance of the launch of
3 Sandoz's pegfilgrastim product.

4 **COUNT I**

5 **(Declaratory Judgment of Noninfringement of U.S. Patent No. 9,643,997)**

6 30. Sandoz incorporates by reference each allegation set forth in paragraphs 1 through
7 29 above as if fully set forth herein.

8 31. Amgen has asserted that Amgen Inc. is the owner of the '997 patent.

9 32. Amgen has asserted that the making, use, offer for sale, sale, or importation into
10 the United States of Sandoz's biosimilar filgrastim and pegfilgrastim products infringes or will
11 infringe the '997 patent.

12 33. Sandoz asserts that the making, use, offer for sale, sale, or importation into the
13 United States of Sandoz's biosimilar filgrastim and pegfilgrastim products does not and will not
14 infringe any valid claim of the '997 patent, whether directly or indirectly, either literally or under
15 the doctrine of equivalents.

16 34. As a result of Amgen's allegations against Sandoz, an actual and justiciable case
17 or controversy exists between Sandoz and Amgen as to the infringement of the claims of the '997
18 patent.

19 35. Sandoz is entitled to a declaration that the making, use, offer for sale, sale, or
20 importation into the United States of Sandoz's biosimilar filgrastim and pegfilgrastim products
21 does not and will not infringe any valid claim of the '997 patent. Such a declaration is necessary
22 and appropriate at this time to determine the rights and obligations of the parties.

23 **COUNT II**

24 **(Declaratory Judgment of Invalidity of U.S. Patent No. 9,643,997)**

25 36. Sandoz incorporates by reference each allegation set forth in paragraphs 1 through
26 35 above as if fully set forth herein.

27 37. Amgen has asserted that Amgen Inc. is the owner of the '997 patent.

