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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, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D. Defendants.	Case No. _____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d. (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Amgen Manufacturing Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML manufactures and sells biologic medicines for treating particular diseases in humans. AML is a wholly-owned subsidiary of Amgen.

3. Upon information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business in New Jersey at 100 College Road West, Princeton, NJ 08540. Upon information and belief, acting in concert with Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d., Sandoz Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of California and throughout the United States. Upon information and belief, Sandoz Inc. is also the United States agent for Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d. for purposes including, but not limited to, filing regulatory submissions to and corresponding with the Food and Drug Administration ("FDA").

4. Upon information and belief, Sandoz International GmbH is a corporation existing under the laws of the Federal Republic of Germany with its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany. Upon information and belief, acting in

concert with each of the other Defendants, Sandoz International GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of California and throughout the United States.

5. Upon information and belief, Sandoz GmbH is a corporation existing under the laws of the Republic of Austria with its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. Upon information and belief, acting in concert with each of the other Defendants, Sandoz GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of California and throughout the United States.

6. Upon information and belief, Sandoz GmbH operates as a subsidiary of Sandoz International GmbH.

7. Upon information and belief, Lek Pharmaceuticals d.d. is a corporation existing under the laws of Slovenia, having its principal place of business at Verovškova 57, 1526 Ljubljana, Slovenia. Upon information and belief, acting in concert with each of the other Defendants, Lek Pharmaceuticals d.d. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of California and throughout the United States.

8. Upon information and belief, Lek Pharmaceuticals d.d. operates as a subsidiary of Sandoz International GmbH.

9. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the State of California and throughout the United States.

NATURE OF THE ACTION

10. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the

BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, *inter alia*, 35 U.S.C. § 271 and 42 U.S.C. § 262).

11. The asserted patents are U.S. Patent Nos. 8,940,878 ("the '878 Patent") and 5,824,784 ("the '784 Patent"). Amgen is the owner of all rights, title, and interest in the '878 and '784 Patents. The '878 Patent claims a method of purifying proteins that is used in the manufacture of a biological product; and the '784 Patent claims a biological product, the use of a biological product, and the manufacture thereof.

12. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Sandoz Inc., acting in concert with the other Defendants) to rely on the prior licensure and approval status of the innovative biological product (here, NEULASTA®) that the biosimilar purports to copy. Amgen is the sponsor of the reference product ("reference product sponsor" or "RPS"), NEULASTA®, which is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that a biological product is safe, pure, and potent, as Amgen was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

13. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the reference product sponsor ("RPS") to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. §§ 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

14. Seeking the benefits of the subsection (k) pathway, Sandoz Inc., acting in concert with the other Defendants, submitted Defendants' abbreviated Biologics License Application No. 761045 (the "Sandoz aBLA") to FDA pursuant to the BPCIA, specifically 42 U.S.C.

§ 262(k) (also known as § 351(k) of the Public Health Service Act ("PHSA")), requesting that its biological product ("the Sandoz Pegfilgrastim Product") be licensed by relying on Amgen's demonstration that NEULASTA® (pegfilgrastim) is "safe, pure, and potent."

15. Upon information and belief Sandoz Inc., acting in concert with the other Defendants, submitted the Sandoz aBLA to FDA prior to October 2015, and thus before the expirations of the '878 Patent and the '784 Patent on October 8, 2031 and October 20, 2015, respectively.

16. Upon information and belief, Defendants received FDA acceptance of the Sandoz aBLA for review on October 26, 2015.

17. In November 2015, the parties began exchanging information as required by the BPCIA. This information exchange culminated in the parties' agreement on April 12, 2016 that the '878 Patent and the '784 Patent were properly included in any immediate infringement action that Plaintiffs were to file under 42 U.S.C. § 262(*l*)(6)(A). Both patents were identified in the lists of patents under 42 U.S.C. § 262(*l*)(3).

18. Under 35 U.S.C. § 271(e)(2)(C), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3), or could have been, if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 n.3 (Fed. Cir. 2015).

19. Here, Defendants committed an act of infringement with respect to each of the '878 and '784 Patents under 35 U.S.C. § 271(e)(2)(C) when they caused Sandoz Inc. to submit the Sandoz aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Sandoz Pegfilgrastim Product.

20. If FDA approves the Sandoz aBLA and Defendants import the Sandoz Pegfilgrastim Product into the United States, or offer to sell, sell, or use the Sandoz

Pegfilgrastim Product within the United States, Defendants will also infringe one or more claims of the '878 Patent under 35 U.S.C. § 271(g).

JURISDICTION AND VENUE

21. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

22. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b). Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, market, distribute, and sell pharmaceutical products, for use throughout the United States, including in this federal judicial District.

24. For purposes of intradistrict assignment pursuant to Civil Local Rules 3-2(c) and 3-5(b), this Intellectual Property Action is to be assigned on a district-wide basis.

25. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

A. Sandoz Inc.

26. Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals d.d. hold themselves out as a unitary entity and have represented to the public that their activities are directed, controlled, and carried out as a single entity.

27. Upon information and belief, Sandoz Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for sale and use throughout the United States, including in California and this federal judicial District.

28. This Court has personal specific jurisdiction over Sandoz Inc. because Sandoz Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California. In particular, Sandoz, Inc.

collaborates to develop, manufacture, seek approval for, and sell the Sandoz Pegfilgrastim Product, which will cause tortious injury to Plaintiffs. For example, on November 12 and 13, 2015, Amgen received emails from Sandoz Inc. saying that the Sandoz aBLA had been accepted by FDA for review. Moreover, upon information and belief, following any FDA approval of the Sandoz Pegfilgrastim Product, Sandoz Inc. will sell the Sandoz Pegfilgrastim Product that is the subject of the patent infringement claims in this action in California and throughout the United States.

29. This Court has personal general jurisdiction over Sandoz Inc. by virtue of, *inter alia*, its having conducted business in this District, having availed itself of the rights and benefits of California law, and having engaged in substantial and continuing contacts with California. Upon information and belief, Sandoz Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in California and this District. In addition, Sandoz Inc. has availed itself of this Court by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court as a patent infringement plaintiff, *see, e.g.*, *Sandoz Inc. v. Amgen Inc.,* 3:13-cv-02904-MMC, 2013 WL 6000069 (N.D. Cal. Nov. 12, 2013), *aff'd*, 773 F.3d 1274 (Fed. Cir. 2014), and consented to the personal jurisdiction of this Court in numerous other legal proceedings. *See, e.g.*, *Genentech, Inc. v. Sandoz Inc.,* 3:11-cv-01925-JSW (N.D. Cal.); *Takeda Pharmaceutical, Co., Ltd. v. Sandoz Inc.,* 5:13-cv-02418-LHK (N.D. Cal.); *Takeda Pharmaceutical, Co., Ltd. v. Sandoz Inc.,* 3:12-cv-00446-JCS (N.D. Cal.).

B. Sandoz International GmbH (Germany)

30. Upon information and belief, Sandoz International GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in California and in the United States.

31. Upon information and belief, Sandoz International GmbH exercises considerable control over Sandoz Inc. with respect to biosimilar products, and approves significant decisions

of Sandoz Inc. such as allowing Sandoz Inc. to act as the agent for Sandoz International GmbH in connection with preparing and submitting the Sandoz aBLA, and acting as Sandoz International GmbH's agent in the United States. For example, the Sandoz Management Team includes "Richard Francis, the Global Head of Sandoz," and "Peter Goldschmidt, President of Sandoz US and Head of North America." Upon information and belief, Mr. Francis is the head of Sandoz International GmbH, Mr. Goldschmidt is the President of Sandoz Inc. as well as the Head of North American Operations at Sandoz International GmbH, and Mr. Goldschmidt directly or indirectly reports to Mr. Francis.

32. In addition, Sandoz International GmbH and Sandoz Inc. hold themselves out as a unitary entity and have represented to the public that the activities of Sandoz International GmbH and Sandoz Inc. are directed, controlled, and carried out by a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com, attached hereto as Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

33. Upon information and belief, Sandoz International GmbH is actively involved with planning Sandoz Inc.'s new products, communicating with FDA regarding the Sandoz Pegfilgrastim Product, submitting the Sandoz aBLA for the Sandoz Pegfilgrastim Product, and deciding how to engage in the BPCIA information exchange process. For example, Sandoz Inc.'s President, Mr. Goldschmidt, is also the Head of North American Operations at Sandoz International GmbH. Upon information and belief, Sandoz International GmbH's executives are actively involved in Defendants' strategy for obtaining FDA approval of the Sandoz Pegfilgrastim Product. For example, Mark McCamish, the Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz International GmbH, has made statements regarding FDA's acceptance of the Sandoz aBLA for the Sandoz Pegfilgrastim Product. *See* Press Release, Sandoz, "Sandoz Continues to Advance its Biosimilars Program: Regulatory Submission for Sandoz' Proposed Biosimilar Pegfilgrastim Accepted by the FDA" (Nov. 18,

2015), http://www.sandoz.com/media_center/ press_releases_news/global_news/2015-11-18-regulatory-submission-for-biosimilar-pegfilgrastim-accepted-by-the-fda.shtml, attached hereto as Exhibit B. Upon information and belief, Mr. McCamish is based out of Munich Area, Germany.

34. Defendants have issued press releases and media presentations regarding the development of the Sandoz Pegfilgrastim Product from Holzkirchen, Germany, the location of Sandoz International GmbH. Defendants issued a press release on November 18, 2015 from Holzkirchen, Germany, announcing that FDA had accepted an application by "Sandoz" for pegfilgrastim. *See* Press Release, Sandoz, "Sandoz Continues to Advance its Biosimilars Program: Regulatory Submission for Sandoz' Proposed Biosimilar Pegfilgrastim Accepted by the FDA" (Nov. 18, 2015), http://www.sandoz.com/media_center/ press_releases_news/global_news/2015-11-18-regulatory-submission-for-biosimilar-pegfilgrastim-accepted-by-the-fda.shtml, attached hereto as Exhibit B. Defendants issued a press release on December 7, 2015 from Holzkirchen, Germany, announcing results from a study comparing the safety and efficacy of the Sandoz Pegfilgrastim Product with NEULASTA®. *See* Press Release, Sandoz, "Phase III Data Shows Sandoz' Proposed Biosimilar Pegfilgrastim Has Similar Safety and Efficacy as the Reference Product" (Dec. 7, 2015), http://www.sandoz.com/ media_center/press_releases_news/global_news/2015-12-07-pegfilgrastim-has-similar-safety-and-efficacy-as-the-reference-product.shtml, attached hereto as Exhibit C. Upon information and belief, these press releases concerning the Sandoz aBLA and Sandoz Pegfilgrastim Product were issued on behalf of Sandoz International GmbH. In addition, Sandoz International GmbH's Facts & Figures 2012, attached hereto as Exhibit D, lists the Holzkirchen address and www.sandoz.com includes the following note: "2012: Sandoz announces Phase III biosimilar trials for filgrastim (Amgen's Neupogen®) for the US market and pegfilgrastim (Amgen's Neulasta®) globally."

35. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz International GmbH. Upon information and belief,

Sandoz International GmbH has or will directly or indirectly manufacture, import into the United States, and/or sell the Sandoz Pegfilgrastim Product that is the subject of the infringement claim in this action in California and throughout the United States.

36. This Court has personal specific jurisdiction over Sandoz International GmbH because Sandoz International GmbH has directly, or through its agent, committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California.

37. Additionally, and in the alternative, Plaintiffs allege that to the extent Sandoz International GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of California, Sandoz International GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

C. Sandoz GmbH (Austria)

38. Upon information and belief, Sandoz GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in California and in the United States.

39. Upon information and belief, Sandoz GmbH operates as a subsidiary of Sandoz International GmbH.

40. Sandoz GmbH and Sandoz Inc. hold themselves out as a unitary entity and have represented to the public that the activities of Sandoz GmbH and Sandoz Inc. are directed, controlled, and carried out by a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com, attached hereto Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

41. Upon information and belief, Sandoz GmbH is actively involved with planning Sandoz Inc.'s new products, communicating with FDA regarding the Sandoz Pegfilgrastim Product, submitting the Sandoz aBLA, and deciding how to engage in the BPCIA information exchange process.

42. Title 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted to FDA under the § 262(k) pathway "shall include" information demonstrating "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." Upon information and belief, the Sandoz Pegfilgrastim Product is manufactured at least in part at Sandoz GmbH facilities. In addition, on the EU Clinical Trials Register, Sandoz GmbH is listed as the sponsor for clinical trials such as "A randomized, double-blind, parallel-group, multi-center Phase 3 comparative study investigating efficacy and safety of LA-EP2006 and NEULASTA® in breast cancer patients treated with myelosuppressive chemotherapy" and "Pivotal study in breast cancer patients investigating efficacy and safety of LA-EP2006 and NEULASTA®." *See* https://www.clinicaltrialsregister.eu/ctr-search/trial/2011-004532-58/BG, attached hereto as Exhibit E and https://www.clinicaltrialsregister.eu/ctr-search/trial/2012-002039-28/ES, attached hereto as Exhibit F.

43. Upon information and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to submit an aBLA seeking approval from FDA to market and sell the Sandoz Pegfilgrastim Product in the State of California and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

44. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz GmbH. Upon information and belief, Sandoz GmbH has or will directly or indirectly manufacture, import into the United States, and/or sell the Sandoz Pegfilgrastim Product that is the subject of the infringement claim in this action in California and throughout the United States.

45. This Court has personal specific jurisdiction over Sandoz GmbH because Sandoz GmbH has directly, or through its agent, committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California.

46. Additionally, and in the alternative, Plaintiffs allege that to the extent Sandoz GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of California, Sandoz GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

D. Lek Pharmaceuticals d.d. (Slovenia)

47. Upon information and belief, Lek Pharmaceuticals d.d. collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in California and in the United States.

48. Upon information and belief, Lek Pharmaceuticals d.d operates as a subsidiary of Sandoz International GmbH.

49. Lek Pharmaceuticals d.d. maintains a public website where it identifies itself as "Lek: a Sandoz company," and also says that "Lek is a part of Sandoz." *See* http://www.lek.si/en/about-us/, attached hereto as Exhibit G. On Sandoz's website, Lek is described as "a Sandoz company" with a "role within Sandoz" that includes "a global development center for products and technologies; a global manufacturing center for active pharmaceutical ingredients and medicines; a competence center for the development of vertically integrated products; [and] a Sandoz competence center in the field of development and manufacturing of biosimilar products." *See* http://www.sandoz.com/media_center/press_releases_news/Sandoz_around_the_world/lek_one_of_the_strongest_development_centers_in_slovenia_.shtml, attached hereto as Exhibit H.

50. Upon information and belief, Lek Pharmaceuticals d.d. is actively involved with planning Sandoz Inc.'s new products, communicating with FDA regarding the Sandoz Pegfilgrastim Product, submitting the Sandoz aBLA, and deciding how to engage in the BPCIA information exchange process.

51. Title 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted to FDA under the § 262(k) pathway "shall include" information demonstrating "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." Upon information and belief, the Sandoz Pegfilgrastim Product is manufactured at least in part at Lek Pharmaceuticals d.d. facilities. For example, scientists at Lek Pharmaceuticals d.d. have published articles describing pegylation, and specifically the N-terminal pegylation of G-CSF to produce pegfilgrastim. *See* Menči Kunstelj et al., Cysteine-Specific PEGylation of rhG-CSF via Selenylsulfide Bond, 24 Bioconjugate Chem. 889 (2013), attached hereto as Exhibit I; Katarina Fidler et al., The Characterization and Potential use of G-CSF Dimers and their Pegylated Conjugates, 58 Acta Chim. Slov. 1 (2011), attached hereto as Exhibit J; Simona Jevševar et al., Review: PEGylation of therapeutic proteins, 5 Biotechnol. J. 113 (2010), attached hereto as Exhibit K; Mateja Kusterle et al., Size of Pegylated Protein Conjugates Studied by Various Methods, 55 Acta Chim. Slov. 594 (2008), attached hereto as Exhibit L. In addition, Lek Pharmaceuticals d.d. issued a press release on November 21, 2014 stating that, "The second generation, pegfilgrastim, the obtaining of which the winning team successfully transferred into production at the [Lek Pharamceuticals d.d.] Mengeš site [in Slovenia], has completed clinical trials." *See* Press Release, Lek: a Sandoz company, "Team of scientists at Mengeš Biopharmaceuticals and the National Institute of Chemistry Ljubljana receive the Puh Award for outstanding achievements in the field of scientific research and development activities and their transfer in production" (Nov. 21, 2014), http://www.lek.si/en/media-room/press-releases/810/, attached hereto as Exhibit M.

52. Upon information and belief, Lek Pharmaceuticals d.d. acted in concert with, directed, and/or authorized Sandoz Inc. to submit an aBLA seeking approval from FDA to market and sell the Sandoz Pegfilgrastim Product in the State of California and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

53. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Lek Pharmaceuticals d.d. Upon information and belief, Lek Pharmaceuticals d.d. has or will directly or indirectly manufacture, import into the United States, and/or sell the Sandoz Pegfilgrastim Product that is the subject of the infringement claim in this action in California and throughout the United States.

54. This Court has personal specific jurisdiction over Lek Pharmaceuticals d.d. because Lek Pharmaceuticals d.d. has directly, or through its agent, committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California.

55. Additionally, and in the alternative, Plaintiffs allege that to the extent Lek Pharmaceuticals d.d. is not subject to the jurisdiction of the courts of general jurisdiction of the State of California, Lek Pharmaceuticals d.d. likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

THE PATENTS-IN-SUIT: U.S. PATENT NOS. 8,940,878 AND 5,824,784

56. Amgen is the owner of all right, title, and interest in the '878 Patent.

57. The '878 Patent is titled "Capture Purification Processes for Proteins Expressed in a Non-Mammalian System" and was duly and legally issued by the USPTO on January 27, 2015. The inventors of the '878 Patent are Joseph Edward Shultz and Roger Hart. A true and correct copy of the '878 Patent is attached hereto as Exhibit N.

58. The '878 Patent covers a method of purifying proteins.

59. The ’878 Patent is assigned to Amgen, and expires on October 8, 2031 with the patent term adjustment of 471 days.

60. Amgen is the owner of all rights, title, and interest in the ’784 Patent.

61. The ’784 Patent is titled “N-Terminally Chemically Modified Protein Compositions and Methods.” The ’784 Patent was duly and legally issued on October 20, 1998 by the USPTO. The inventors of the ’784 Patent are Olaf B. Kinstler, Nancy E. Gabriel, Christrine E. Farrer, and Randolf B. DePrince. A true and correct copy of the ’784 Patent is attached to this Complaint as Exhibit O.

62. The ’784 Patent relates, in part, to novel compositions of N-terminally chemically modified G-CSF, to methods of treatment using the same compositions, and to preparations of the same compositions, *e.g.*, a substantially homogenous preparation of N-terminally PEGylated G-CSF, and methods of N-terminally modifying G-CSF and analogs thereof.

63. The ’784 Patent claims a biological product, the use of a biological product, and the manufacture thereof.

64. The ’784 Patent is assigned to Amgen, and expired on October 20, 2015.

PLAINTIFFS’ NEULASTA® PRODUCT

65. The active ingredient in Plaintiffs’ innovative NEULASTA® product is pegfilgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor (“G-CSF”) conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of the G-CSF.

66. NEULASTA® is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on the surface of certain types of cells, NEULASTA® stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result

from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEULASTA® counteracts neutropenia.

67. The availability of NEULASTA® represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by thus facilitating more effective chemotherapy regimens.

THE SANDOZ PEGFILGRASTIM PRODUCT AND aBLA

68. Upon information and belief, Sandoz Inc., acting in concert with the other Defendants, submitted the Sandoz aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Sandoz Pegfilgrastim Product, a biosimilar version of Plaintiffs' NEULASTA® (pegfilgrastim) product.

69. Upon information and belief, the Sandoz aBLA references and relies on the approval and licensure of Plaintiffs' NEULASTA® (pegfilgrastim) product in support of Defendants' request for FDA approval.

70. Upon information and belief, the Sandoz Pegfilgrastim Product is designed to copy and compete with Plaintiffs' NEULASTA® (pegfilgrastim).

71. Upon information and belief, Defendants did not seek to independently demonstrate to FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen did in its BLA for its innovative biological product NEULASTA® (pegfilgrastim). Rather, upon information and belief, Defendants requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen's FDA license for NEULASTA® (pegfilgrastim). Accordingly, Defendants submitted to FDA publicly-available information regarding FDA's previous licensure determination that NEULASTA® (pegfilgrastim) is "safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

72. Defendants are piggybacking on the fruits of Plaintiffs' trailblazing efforts. Defendants have publicly announced that they submitted the Sandoz aBLA under the subsection

(k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Sandoz Pegfilgrastim Product that they assert is a biosimilar version of Plaintiffs' NEULASTA®. *See* Press Release, Sandoz, "Sandoz Continues to Advance its Biosimilars Program: Regulatory Submission for Sandoz' Proposed Biosimilar Pegfilgrastim Accepted by the FDA" (Nov. 18, 2015), http://www.sandoz.com/media_center/press_releases_news/global_news/2015-11-18-regulatory-submission-for-biosimilar-pegfilgrastim-accepted-by-the-fda.shtml, attached hereto as Exhibit B.

INFORMATION EXCHANGE UNDER 42 U.S.C. § 262(*l*)

73. On November 13, 2015, which was, upon information and belief, within 20 days after FDA notified Defendants that the Sandoz aBLA had been accepted for review, the parties began exchanging information as required by the BPCIA. This information exchange culminated in the parties' agreement on April 12, 2016 that the '878 Patent and the '784 Patent were properly included in any immediate infringement action that Plaintiffs were to file under 42 U.S.C. § 262(*l*)(6)(A). Both of the '878 and '784 Patents were identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3).

74. Plaintiffs now file this immediate patent infringement action against Defendants pursuant to 42 U.S.C. § 262(*l*)(6)(A). This action follows "not later than 30 days after" the parties' agreement as to the patents described in under 42 U.S.C. § 262(*l*)(4).

FIRST CAUSE OF ACTION:
INFRINGEMENT OF THE '878 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

75. Plaintiffs incorporate by reference paragraphs 1-74 as if fully set forth herein.

76. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Sandoz Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

77. Under 35 U.S.C. § 271(e)(2)(C), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3), or could have been, if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a

biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 n.3 (Fed. Cir. 2015).

78. Here, Defendants committed an act of infringement with respect to each of the '878 and '784 Patents under 35 U.S.C. § 271(e)(2)(C) when they caused Sandoz Inc. to submit the Sandoz aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Sandoz Pegfilgrastim Product.

79. Upon information and belief, Defendants intend to manufacture, use, sell, offer for sale, and/or import the Sandoz Pegfilgrastim Product before the expiration of the '878 Patent.

80. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of the Sandoz Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '878 Patent.

81. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '878 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

82. Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States before the expiration of the '878 Patent has or will cause injury to Plaintiffs, entitling them to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND CAUSE OF ACTION:
DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '878 PATENT UNDER 35 U.S.C. § 271(g)

83. Plaintiffs incorporate by reference paragraphs 1-82 as if fully set forth herein.

84. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Sandoz Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

85. FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. Upon information and belief, Defendants believe that FDA may act upon the Sandoz aBLA as soon as July 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

86. Upon information and belief, Defendants intend to, and will upon FDA licensure of the Sandoz aBLA, import into the United States or offer to sell, sell, or use within the United States the Sandoz Pegfilgrastim Product, which will infringe one or more claims of the '878 Patent under 35 U.S.C. § 271(g).

87. An actual controversy has arisen and now exists between the parties concerning whether the Sandoz Pegfilgrastim Product has or will infringe one or more claims of the '878 Patent.

88. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '878 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States the Sandoz Pegfilgrastim Product before the expiration of the '878 Patent.

89. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States the Sandoz Pegfilgrastim Product before the expiration of the '878 Patent.

90. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz Pegfilgrastim Product before the expiration of the '878 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284.

THIRD CAUSE OF ACTION:
INFRINGEMENT OF THE '784 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

91. Plaintiffs incorporate by reference paragraphs 1-90 as if fully set forth herein.

92. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Sandoz Pegfilgrastim Product, a biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

93. Under 35 U.S.C. § 271(e)(2)(C), it is an act of infringement to submit an application seeking approval of a biological product with respect to patents identified in the lists of patents described in 42 U.S.C. § 262(*l*)(3), or could have been, if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. *See Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1356 n.3 (Fed. Cir. 2015).

94. Here, Defendants committed an act of infringement with respect to the '784 Patent under 35 U.S.C. § 271(e)(2)(C) when they caused Sandoz Inc. to submit the Sandoz aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Sandoz Pegfilgrastim Product.

95. Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz Pegfilgrastim Product before the expiration of the '784 Patent has or will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 271(e)(4)(C).

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against Defendants and grant the following relief:

A. a judgment that Defendants have infringed one or more claims of the '878 Patent under 35 U.S.C. § 271(e)(2)(C);

B. a judgment that Defendants have infringed or will infringe one or more claims of the '878 Patent by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Sandoz Pegfilgrastim Product before the expiration of the '878 Patent;

C. a judgment that Defendants have infringed one or more claims of the '784 Patent under 35 U.S.C. § 271(e)(2)(C);

D. a judgment compelling Defendants to pay to Plaintiffs damages or other monetary relief adequate to compensate for Defendants' infringement, in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;

E. an injunction that enjoins Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, from infringing the '878 Patent, or contributing to or inducing anyone to do the same, by acts including the manufacture, 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 accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

F. a declaration that this is an exceptional case and awarding to Plaintiffs their attorneys' fees and costs pursuant to 35 U.S.C. § 285, and expenses;

H. and such other relief as this Court may deem just and proper.

Date: May 12, 2016

/s/ Vernon M. Winters

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