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Attorneys for Plaintiffs Amgen Inc. and Amgen Manufacturing Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiff, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Civil Action No. _____ **COMPLAINT**

COMPLAINT

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, and Sandoz GmbH (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. 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 Inc. 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 Inc.

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 Defendants Sandoz International GmbH and Sandoz GmbH, Sandoz Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States. Upon information and belief, Sandoz Inc. is also the United States agent for Sandoz International GmbH and Sandoz GmbH 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 New Jersey 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 New Jersey 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, 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 New Jersey and throughout the United States.

NATURE OF THE ACTION

8. This is an action to enforce the patent-dispute-resolution provisions of the BPCIA that Defendants have demonstrated they do not intend to follow. Rather than comply with the required provisions of the BPCIA, Defendants have insisted that Plaintiffs file an immediate patent infringement action under 42 U.S.C. § 262(*l*)(6) before the conclusion of the BPCIA

dispute resolution process and have threatened to seek penalties under the BPCIA if Plaintiffs do not do so. Specifically, Defendants have asserted that Plaintiffs must file its patent infringement lawsuit under 42 U.S.C. § 262(*l*)(6) by March 4, 2016, or such lawsuit is untimely and Plaintiffs' patent infringement damages are limited to a reasonable royalty under 35 U.S.C. § 271(e)(6)(B).

9. Plaintiffs file this action to protect their rights and to obtain an order compelling Defendants to comply with the provisions of the BPCIA. Plaintiffs disagree with Defendants' assertion that Plaintiffs must file a patent infringement lawsuit under 42 U.S.C. § 262(*l*)(6) by March 4, 2016 prior to the conclusion of the BPCIA dispute resolution process. Plaintiffs also disagree with Defendants' assertion that filing such a lawsuit after March 4, 2016 deprives Plaintiffs of their entitlement to other relief for patent infringement that is provided in 35 U.S.C. § 271(e)(4), such as a permanent injunction.

10. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Sandoz Inc.) to rely on the prior licensure and approval status of the innovative biological product (here, NEULASTA®) that the biosimilar purports to copy. Amgen Inc. is the sponsor of the reference product, 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 Inc. was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

11. 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 procedures are set out in 42 U.S.C. § 262(*l*).

12. Seeking the benefits of the subsection (k) pathway, Sandoz Inc. 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 Inc.'s demonstration that NEULASTA® (pegfilgrastim) is "safe, pure, and potent." Defendants received FDA acceptance of the Sandoz aBLA for filing on October 26, 2015.

13. Defendants, however, have indicated that after beginning the statutory exchange process, they are unwilling to complete the procedures of the BPCIA. Defendants have sought to circumvent the BPCIA process by refusing to participate in required procedures and threatening to seek penalties that limit Plaintiffs' relief for infringement to a reasonable royalty—rather than the full complement of remedies available under 35 U.S.C. § 271(e)(4), such as lost profits and injunctive relief—if Plaintiffs did not file a patent infringement action by March 4, 2016.

14. Despite the brief history of litigation under the BPCIA, this is the third time that this particular statutory interpretation dispute—as to the requirements of 42 U.S.C. § 262(*l*)(4) and (5)—has arisen between subsection (k) applicants seeking FDA licensure of a biosimilar product, and their corresponding reference product sponsors. Because Defendants themselves have already caused such a dispute to arise in a prior case, Plaintiffs reasonably believe that the issue will continue to arise, absent adjudication by this Court. In each of the two prior disputes that are pending in district courts, the subsection (k) applicant has attempted to accelerate the

process and timeline specified in the statute for identifying and resolving patent issues by "waiving" the 42 U.S.C. § 262(*l*)(4) and (5) steps preceding the "immediate patent infringement action" of 42 U.S.C. § 262(*l*)(6). Such conduct extinguishes the reference product sponsor's ability to consider and respond to the subsection (k) applicant's contentions regarding patents that the reference product sponsor identified, and entirely evade the negotiations specified in 42 U.S.C. § 262(*l*)(4) and (5).

JURISDICTION AND VENUE

15. This is an action for the violation of the federal BPCIA statute, 42 U.S.C. § 262(*l*).

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

17. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products for sale and use throughout the United States, including in this federal judicial District.

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

A. Sandoz Inc.

19. This Court has personal jurisdiction over Sandoz Inc. by virtue of, *inter alia*, the fact that, on information and belief, Sandoz's principal place of business is in the District of New Jersey.

20. Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH 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.

21. 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 this District. Upon information and belief, Sandoz Inc. purposefully has conducted and continues to conduct business, directly or indirectly, in this District, and this District is a likely destination of Defendants' biopharmaceuticals. Upon information and belief, Sandoz Inc. is registered as a Manufacturer and Wholesaler in the State of New Jersey (No. 5003732). *See* New Jersey Drug Registration and Verification, at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx. Upon information and belief, Sandoz Inc. is registered to do business in New Jersey under Entity Id No. 0100097265. *See* http://www.njportal.com/DOR/BusinessNameSearch.

22. This Court has personal general jurisdiction over Sandoz Inc. by virtue of, *inter alia*, Sandoz Inc. having its principal place of business in this District, having conducted business in this District, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with New Jersey. Upon information and belief, Sandoz Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in New Jersey. 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's jurisdiction in numerous legal proceedings. *See, e.g.*, Sandoz Inc.'s Answer, Defenses, and Counterclaims, *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc., et al.*, Civil Action No. 15-1716 (JBS)(KMW) (D.N.J. April 13, 2015), Dkt. No. 54; Sandoz Inc.'s Answer, Defenses, and Counterclaims, *United Therapeutics Corp. v. Sandoz Inc.*, Civil Action No. 14-5499 (PGS)(LHG) (D.N.J. November 12, 2014), Dkt. No. 13; Sandoz

Inc.'s Answer, Defenses, and Counterclaims, *Astrazeneca Pharm. LP, et al. v. Sandoz Inc., et al.*, Civil Action No. 14-3547 (RMB)(KMW) (D.N.J. July 29, 2014), Dkt. No. 21.

23. Upon information and belief, Sandoz Inc., in collaboration with Sandoz International GmbH and Sandoz GmbH, prepared the Sandoz aBLA in this federal judicial District. This Court thus has personal specific jurisdiction which exists where the Sandoz aBLA was prepared.

B. Sandoz International GmbH (Germany)

24. 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 New Jersey and in the United States.

25. 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 filing 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.

26. 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."

27. 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, filing 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.

28. 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."

29. Upon information and belief, Sandoz International GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to communicate with Amgen Inc. to begin following the information exchange procedures under the BPCIA only to refuse to engage in subsequent required steps.

30. 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 in New Jersey and throughout the United States.

31. 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 violating the mandatory procedures of the BPCIA that has led to foreseeable harm and injury to Plaintiffs in Sandoz Inc.'s principal place of business.

32. 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 New Jersey, 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)

33. 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 New Jersey and in the United States.

34. 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."

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

36. 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 Sandoz GmbH facilities. In addition, on the EU Clinical Trials Register, Sandoz GmbH is listed as the sponsor for 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.

37. Upon information and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to file an aBLA seeking approval from FDA to market and sell the

Sandoz Pegfilgrastim Product in the State of New Jersey and throughout the United States, which gives rise to Plaintiffs' claim that Defendants violated the mandatory provisions of the BPCIA.

38. Upon information and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to communicate with Amgen Inc. to begin following the information exchange procedures under the BPCIA only to refuse to engage in subsequent required steps.

39. 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 in New Jersey and throughout the United States.

40. 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 violating the mandatory procedures of the BPCIA that has led to foreseeable harm and injury to Plaintiffs in Sandoz Inc.'s principal place of business.

41. 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 New Jersey, 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. Venue

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

BACKGROUND

A. The BPCIA Reflects Congress's Balancing Innovation and Price Competition

43. The Federal Circuit explained in *Amgen v. Sandoz*:

> In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA, which established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product ("reference product"). Pub. L. No. 111–148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 et seq.). Congress established such "a biosimilar pathway balancing innovation and consumer interests." BPCIA, Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804.

794 F.3d 1347, 1351 (Fed. Cir. 2015).

44. The Federal Circuit also explained, "The BPCIA has certain similarities in its goals and procedures to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984)," but it also differs in other respects. *Id.*

45. Like the Hatch-Waxman Act, the BPCIA contains provisions that balance innovation and price competition. On one side of the balance, the BPCIA created an abbreviated approval pathway, 42 U.S.C. § 262(k), for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." The BPCIA defines a "biosimilar" to be a biological product that: (1) is "highly similar to the reference product notwithstanding minor differences in clinically inactive

components," and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2)(A), (B). The BPCIA defines a "reference product" to be "a single biological product licensed under subsection (a) against which the biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

46. As opposed to applicants following the subsection 262(a) pathway, biosimilar applicants following the subsection 262(k) pathway have the advantage of referencing the innovator's license—FDA evaluates the safety and efficacy of the applicant's biological product by relying on the innovator's prior demonstration of safety, purity, and potency of the reference product. Specifically, the subsection 262(k) pathway may only be used where the prior applicant for the reference product has submitted an application under 42 U.S.C. § 262(a) for approval of a reference product, and FDA has determined that the RPS has demonstrated that "the biological product that is the subject of the application is safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I).

47. Before the BPCIA, reference to another's biological license could be made only with the permission of the RPS. A RPS enjoyed permanent and exclusive rights to its clinical trial data and FDA license. The BPCIA advanced the public's interest in price competition in part by diminishing these rights, allowing a biosimilar applicant to "reference" the RPS's license rather than incurring the delay and costs of generating its own clinical data.

48. Consequently, the subsection 262(k) pathway allows the biosimilar applicant to avoid the time and expense incurred by the RPS for development and clinical testing, and to gain licensure to commercialize its biological product in the market sooner as a biosimilar than it could have done through an independent demonstration of safety, purity, and potency under the §

262(a) pathway. The subsection 262(k) pathway is thus referred to as an "abbreviated" approval pathway.

49. In addition to providing these benefits, approval under the subsection 262(k) pathway offers another benefit to the biosimilar applicant: a product that is approved as a biosimilar can take advantage of the existing market for the reference product created by the RPS.

50. On the other side of the balance, Congress implemented a detailed procedure to protect the interests of the RPS, tying this procedure to the biosimilar applicant's choice to submit an aBLA under, and gain the benefit of, the abbreviated subsection 262(k) pathway. 42 U.S.C. § 262(*l*)(1)(B)(i). As the Federal Circuit explained in *Amgen v. Sandoz*:

> Moreover, the BPCIA established a patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code. The BPCIA amended the Patent Act to create an artificial "act of infringement" and to allow infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. *See* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6). The BPCIA also established a unique and elaborate process for information exchange between the biosimilar applicant and the RPS to resolve patent disputes. *See* 42 U.S.C. § 262(*l*).
>
> Under that process, codified at 42 U.S.C. § 262(*l*), the biosimilar applicant grants the RPS confidential access to its aBLA and the manufacturing information regarding the biosimilar product no later than 20 days after FDA accepts its application for review. *Id.* § 262(*l*)(1)–(2). The parties then exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted by the RPS, as well as their respective positions on infringement, validity, and enforceability of those patents. *Id.* § 262(*l*)(3). Following that exchange, which could take up to six months, the parties negotiate to formulate a list of patents ("listed patents") that would be the subject of an immediate infringement action, *id.* § 262(*l*)(4)–(5), and the RPS then sues the biosimilar applicant within 30 days, *id.* § 262(*l*)(6). That information exchange and negotiation thus contemplates an immediate infringement action brought by the RPS based only on listed patents.

794 F.3d 1347, 1352 (Fed. Cir. 2015).

51. Of particular relevance here, in 42 U.S.C. § 262(*l*), the BPCIA sets forth requirements that the biosimilar applicant must follow to obtain the benefits of filing its aBLA

under the subsection 262(k) pathway after the biosimilar applicant has provided its abbreviated application and manufacturing information under 42 U.S.C. § 262(*l*)(2) and the parties have exchanged patent lists and contentions under 42 U.S.C. § 262(l)(3)(A) and 42 U.S.C. § 262(*l*)(3)(B). Specifically:

- 42 U.S.C. § 262(*l*)(3)(C) provides that the RPS shall respond to the biosimilar applicant's contentions under 42 U.S.C. § 262(*l*)(3)(B) no later than 60 days after receipt of the 42 U.S.C. § 262(*l*)(3)(B) response:

  > (C) Description by reference product sponsor
  >
  > Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

- 42 U.S.C. § 262(*l*)(4) provides that the parties shall engage in good faith negotiations following the biosimilar applicant's receipt of the 42 U.S.C. § 262(*l*)(3)(C) response:

  > (4) Patent resolution negotiations
  >
  > (A) In general. After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).
  >
  > (B) Failure to reach agreement. If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the

subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

- 42 U.S.C. § 262(*l*)(5) provides for a patent resolution procedure if there is no agreement following the good faith negotiations of 42 U.S.C. § 262(*l*)(4):

> (5) Patent resolution if no agreement
>
> (A) Number of patents. The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).
>
> (B) Exchange of patent lists
>
> (i) In general. On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—
>
> (I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and
>
> (II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).
>
> (ii) Number of patents listed by reference product sponsor
>
> (I) In general. Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).
>
> (II) Exception. If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

- 42 U.S.C. § 262(*l*)(6) provides for an immediate patent infringement action following an agreement under 42 U.S.C. § 262(*l*)(4) or no later than 30 days after the exchange of lists under 42 U.S.C. § 262(*l*)(5)(B):

> (6) Immediate patent infringement action
>
> > (A) Action if agreement on patent list. If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.
> >
> > (B) Action if no agreement on patent list. If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

52. If the RPS does not bring suit within thirty days of the selection of patents for immediate litigation under 42 U.S.C. § 262(*l*)(4) or 42 U.S.C. § 262(*l*)(5) if necessary, its "sole and exclusive remedy" will be "a reasonable royalty." 35 U.S.C. § 271(e)(6)(B). Specifically 35 U.S.C. § 271(e)(6) provides:

> (A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—
>
> > (i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and
> >
> > (ii) for which an action for infringement of the patent with respect to the biological product—
> >
> > > (I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or
> > >
> > > (II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

> (B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.
>
> (C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

53. If the subsection (k) applicant fails to complete an action required by it under paragraphs (*l*)(3)(B)(ii), (*l*)(5), (*l*)(6)(C)(i), (*l*)(7), or (*l*)(8)(A), the RPS, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7). 42 U.S.C. § 262(*l*)(9)(B).

B. Plaintiffs' NEULASTA® Product

54. 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.

55. 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.

56. 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 regimes.

C. Defendants' Biosimilar Product and aBLA

57. Upon information and belief, Sandoz Inc. filed its 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.

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

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

60. 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 Inc. 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 Inc.'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).

61. Defendants are piggybacking on the fruits of Plaintiffs' trailblazing efforts. Defendants have publicly announced that they filed their 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.

D. Defendants' Refusal to Comply with the BPCIA

62. Defendants have once again tried to reap the commercial benefits provided to biosimilar manufacturers under the BPCIA while seeking to avoid the obligations in the same Act that Congress established to protect innovators such as Plaintiffs.

63. On November 12 and 13, 2015, Plaintiffs received emails from in-house counsel for Sandoz Inc. saying that Defendants received FDA acceptance of the Sandoz aBLA for filing on October 26, 2015, and Sandoz Inc. planned to make a disclosure under 42 U.S.C. § 262(*l*)(2) by November 15, 2015.

64. On November 13, 2015, which was, on information and belief, within 20 days after FDA notified Defendants that the Sandoz aBLA had been accepted for review, Sandoz Inc. provided Plaintiffs with a file transfer link to electronic files in eCTD format that Sandoz Inc. represented to constitute its aBLA and information relating to the manufacturing process for the Sandoz Pegfilgrastim Product.

65. On January 12, 2016 and pursuant to 42 U.S.C. § 262(*l*)(3)(A), Plaintiffs provided Sandoz Inc. with a list of patents for which it believed a claim of patent infringement could reasonably be asserted against the Sandoz Pegfilgrastim Product ("Plaintiffs' (*l*)(3)(A) list"). The list identified two patents: U.S. Patent Nos. 8,940,878 ("the '878 patent") and 5,824,784 ("the '784 patent"). Plaintiffs further noted that they were not prepared to license these patents to Sandoz Inc. at that time.

66. On February 2, 2016, Sandoz Inc. responded to Plaintiffs' (*l*)(3)(A) list by providing contentions that the '878 and '784 patents are invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Sandoz aBLA.

67. Sandoz Inc. also stated that it no longer wished to follow the strictures of the BPCIA because it effectively had Plaintiffs' positions pursuant to 42 U.S.C. § 262(*l*)(3)(C). Sandoz Inc. also stated that it was "waiving" its right to receive Plaintiffs' statement pursuant to 42 U.S.C. § 262(*l*)(3)(C), and declared that negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5) were unnecessary. Sandoz Inc. then insisted that Plaintiffs file an action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(6) within 30 days, *i.e.*, by March 4, 2016. Sandoz Inc. asserted that, "Otherwise, the penalty for an untimely suit—that the 'sole and exclusive remedy' for any infringement be limited to a 'reasonable royalty'—applies. *See* 35 U.S.C. § 271(e)(6)(B)."

68. Defendants have failed to participate, and thus, have not complied with the process defined in the statute that must precede an "immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6). Each of these steps is required under the BPCIA, and the BPCIA does not permit parties to skip them or "waive" them for any reason. Specifically:

- Paragraph (*l*)(4) negotiations begin "[a]fter receipt by the subsection (k) applicant of the statement under paragraph (3)(C)." Thus such negotiations have not already happened.

- Likewise, the time to file a paragraph (*l*)(6) lawsuit begins either with an agreement between the RPS and the subsection (k) applicant "as described in paragraph [(*l*)](4)," or with "the exchange of lists under paragraph [(*l*)](5)(B)," neither of which has happened yet.

- And the provisions of 35 U.S.C. § 271(e)(6) apply only where suit is not timely filed with respect to a patent "identified, as applicable in the list of patents described in" paragraph 262(*l*)(4) or 262(*l*)(5)(B), and neither such list exists yet.

69. By refusing to participate in a timely and complete manner under the BPCIA, including by seeking to extinguish Plaintiffs' ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Plaintiffs had properly identified, and entirely evading the negotiations specified in 42 U.S.C. § 262(*l*)(4) and (5), Defendants have repudiated their obligations under the BPCIA. Pursuant to 42 U.S.C. § 262 (*l*)(9)(B), Defendants' repudiation of the BPCIA bars Defendants from bringing a declaratory judgment action on any patent included in Plaintiffs' paragraph (*l*)(3)(A) list (including any additions thereto under paragraph (*l*)(7)).

COUNT 1: DECLARATORY JUDGMENT THAT DEFENDANTS VIOLATED THE MANDATORY PROCEDURES OF THE BPCIA

70. Plaintiffs incorporate by reference paragraphs 1-69 as if fully set forth herein. This claim arises under the BPCIA, 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

71. Defendants have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4), and § 262(*l*)(5) if necessary, by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and § 262(*l*)(5) if necessary. No list of patents for the Sandoz Pegfilgrastim Product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

72. Defendants have also alleged that Plaintiffs cannot timely file a patent infringement lawsuit under 42 U.S.C. § 262(*l*)(6) after March 4, 2016. If Plaintiffs do not file such a lawsuit by March 4, 2016, Defendants have alleged that Plaintiffs are not entitled to infringement damages other than a reasonable royalty.

73. An actual controversy has arisen and now exists between the parties concerning whether Defendants may "waive" or refuse to participate in BPCIA's mandatory information-exchange provisions, including 42 U.S.C. § 262(*l*)(4); and whether Defendants' unilateral actions compel Plaintiffs to file its patent infringement lawsuit under 42 U.S.C. § 262(*l*)(6) on March 4, 2016, prior to the negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and § 262(*l*)(5) if necessary.

74. Defendants' violations of the BPCIA have injured Plaintiffs by allegedly depriving Plaintiffs of relief for infringement other than reasonable royalty damages, *e.g.*, lost profits damages and injunctive relief available under 35 U.S.C. § 271(e)(4). Defendants' violations of the BPCIA have also deprived Plaintiffs of the procedural protections of the statute, created uncertainty in the BPCIA information exchange process, and subjected Plaintiffs to the burden of unnecessary litigation.

75. Defendants' violations of the BPCIA's information exchange procedures, individually and collectively, have caused and will cause Plaintiffs injury, including irreparable harm for which Plaintiffs have no adequate remedy at law, and will continue unless the statutory requirements are declared and enforced by this Court.

PRAYER FOR RELIEF

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

A. a declaration that Defendants have failed to comply with the requirements of the BPCIA mandatory information-exchange provisions, including 42 U.S.C. § 262(*l*)(4) and § 262(*l*)(5) if necessary;

B. a declaration that Defendants' failure to comply with the requirements of the BPCIA mandatory information-exchange provisions, including 42 U.S.C. § 262(*l*)(4) and § 262(*l*)(5) if necessary, means that there can be no "immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6);

C. a declaration that Plaintiffs' not filing a patent infringement action by March 4, 2016—before the parties have complied with 42 U.S.C. § 262(l)(4), and § 262(l)(5) if necessary—does not deprive Plaintiffs of the remedies for infringement available under 35 U.S.C. § 271(e)(4), including lost profits damages and injunctive relief;

D. an order compelling Defendants to comply with the BPCIA mandatory information-exchange provisions set forth in 42 U.S.C. § 262(*l*)(4) and § 262(*l*)(5) if necessary;

E. an order compelling Defendants to compensate Plaintiffs for and awarding damages incurred as a result of Defendants' actions or inactions;

F. an award to Plaintiffs of their attorneys' fees, costs, and expenses; and

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

Dated: March 4, 2016

Respectfully submitted,

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