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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, and SANDOZ GMBH, Defendants.	Case No. _____ **COMPLAINT FOR PATENT INFRINGEMENT, CONVERSION, AND UNFAIR COMPETITION (CAL. BUS. & PROF. CODE § 17200)** **JURY TRIAL DEMANDED**

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:

NATURE OF THE ACTION

1. This lawsuit is necessary because Defendants refuse to follow the rules. Defendants' unlawful efforts are part of a scheme to sell a copy of one of Plaintiffs' most successful therapeutic products. Defendants are seeking approval from the United States Food and Drug Administration ("FDA") to sell their biosimilar product under a new abbreviated approval pathway, but they have not followed all the statutory requirements that must be met before Defendants' product can legally be sold. Specifically, Defendants' failure to follow the rules Congress put in place to resolve patent disputes with innovators such as Plaintiffs has caused harm to Plaintiffs and necessitates this action.

2. Defendants' unlawful activities arise in connection with their effort to gain approval to market and sell a version of NEUPOGEN® (filgrastim), a highly successful product invented by Plaintiff Amgen Inc. ("Amgen") for treating the side effects of certain forms of cancer therapy. NEUPOGEN® (filgrastim) was major advance in the field of oncology and has benefited millions of cancer patients since it was introduced in 1991. NEUPOGEN® (filgrastim) is a biotechnology product—it is made using recombinant DNA technology and was the result of substantial original research and development by Amgen.

3. Since NEUPOGEN® (filgrastim) is regulated by the FDA as a biologic product, Amgen had to conduct extensive clinical trials and then submit the results of those trials to the FDA in order to prove that NEUPOGEN® (filgrastim) is safe, pure, and potent. Over the years, Amgen has accumulated and submitted to FDA a large amount of clinical trial results showing NEUPOGEN® (filgrastim) to be safe and effective in treating various conditions.

4. Prior to 2010, any other company wishing to sell its own version of NEUPOGEN® (filgrastim) would have had to undertake the same extensive effort to prove to the FDA that their proposed version was also safe, pure and potent. In 2010, Congress created a new the statutory framework, known as the Biosimilars Price Competition and Innovation Act ("BPCIA"), that governs the regulatory approval, marketing, and sale of biological products known as "biosimilars." The BPCIA reflects Congress's efforts to balance the rights of innovators, such as Amgen, and the rights of applicants, such as Defendants, who seek to develop biosimilar versions of innovators' drugs.

5. Developing new therapeutic products from scratch is extremely expensive: current studies estimate the cost of obtaining FDA approval of a new drug as more than $1 billion. The BPCIA allows a biosimilar applicant to avoid this expense by taking advantage of the extensive and costly clinical trials previously conducted by the original creator of the biologic product to show that it is safe, pure, and potent. But there is also another side to this procedure: the BPCIA requires a biosimilar applicant to disclose its FDA application (known as a Biologics Licensing Application or "BLA") and manufacturing information to the innovator within 20 days of filing that application. That disclosure allows the innovator to assess which patents the biosimilar applicant's activities could infringe and, critically, to start a process that will allow the innovator to bring its patent claims before the applicant can begin selling an infringing product and thereby irreparably damage the market.

6. Based on a letter that Defendants sent to Amgen and on other public information, Defendants have submitted a BLA that seeks approval under the provisions of the BPCIA to market a biosimilar copy of NEUPOGEN® (filgrastim). But they have refused to provide Amgen with the BLA and manufacturing information in a timely manner, except under conditions nowhere imposed by the BPCIA, and to otherwise comply with what the statute requires them to do.

7. Defendants' scheme to follow only those parts of the BPCIA they consider helpful and to flaunt the part they consider unhelpful to them is unlawful. In particular, these acts constitute unfair competition under California Business & Professions Code § 17200, et

seq. and conversion under California common law. Defendants have also committed a statutory act of patent infringement under the United States patent law, 35 U.S.C. § 271(e)(2)(C)(ii), by submitting an application for approval of a biological product and failing to provide the BLA and manufacturing information as required by the BPCIA. Despite Amgen's requests, Defendants refuse to honor their obligations under the BPCIA. Accordingly, Plaintiffs turn to this Court for protection of their legal rights. Plaintiffs seek injunctive relief, restitution, attorneys' fees, costs, and expenses.

THE PARTIES

8. 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.

9. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. AML manufactures and sells biologic medicines for treating particular diseases in humans.

10. Upon information and belief, Sandoz Inc. is a corporation existing under the laws of the state of New Jersey, with its principal place of business at 506 Carnegie Drive, Suite 400, Princeton, New Jersey 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 California 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 FDA.

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

Defendants Sandoz Inc. and Sandoz GmbH, 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.

12. Upon information and belief, Sandoz GmbH is a corporation existing under the laws of Austria with its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. Upon information and belief, acting in concert with Defendants Sandoz Inc. and Sandoz International GmbH, 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.

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

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

15. 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 in the United States.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over Plaintiffs' patent infringement claim under 28 U.S.C. § 1331 and 1338(a).

17. The Court also has subject matter jurisdiction over Plaintiffs' unfair competition and conversion claims under 28 U.S.C. §§ 1367 and 1338(b).

18. In the alternative, this Court has subject matter over the case under 28 U.S.C. § 1332 because there is diversity among the parties and the amount in controversy, without interest and costs, exceeds $75,000.

19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c), and 28 U.S.C. § 1400(b). Upon information and belief, the 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.

20. 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.

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

A. Sandoz Inc.

22. 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.

23. 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 and the tortious acts of unfair competition and conversion that have 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 disputed biosimilar product, which will cause tortious injury to Plaintiffs. For example, Amgen received a letter from in-house counsel for Sandoz Inc. dated July 25, 2014, that informed Amgen that Defendants' application for the Sandoz biosimilar product had been accepted by the FDA for review. Moreover, upon information and belief, Sandoz Inc., following any FDA approval of the biosimilar product, will sell the Sandoz biosimilar product that is the subject of the patent infringement, unfair competition, and conversion claims in this action in California and throughout the United States.

24. 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 has regular and continuous commercial

business dealings with representatives, agents, distributors, and customers located in California and this district. In addition, Sandoz has availed itself of this Court as a patent infringement plaintiff, *see, e.g.*, *Sandoz Inc. v. Amgen Inc.,* 3:13-cv-02904-MMC (N.D. Cal.) (appeal pending, Fed. Cir. Appeal No. 2014-1693), 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)

25. 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.

26. 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 BLA, 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.

27. 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, namely, Sandoz. For example, Sandoz maintains an Internet website at the URL www.sandoz.com attached hereto as Ex. 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."

28. Upon information and belief, Sandoz International GmbH is actively involved with planning Sandoz Inc.'s new products and filing the Sandoz BLA for the biosimilar product in dispute. For example, Sandoz Inc.'s President, Mr. Goldschmidt, is also the Head of North American Operations at Sandoz International GmbH.

29. Upon information and belief, Sandoz International GmbH acted in concert with Sandoz Inc. to develop a biosimilar version of Plaintiffs' NEUPOGEN® (filgrastim). Upon information and belief, Sandoz International GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to file a BLA seeking approval from the FDA to market and sell the Sandoz biosimilar product in the State of California and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement. For example, Novartis AG, the ultimate corporate parent of both Sandoz International GmbH and Sandoz Inc., issued a press release on July 24, 2014 from Holzkirchen, Germany announcing that the FDA had accepted Sandoz's application for biosimilar filgrastim. *See* Press Release, Novartis, FDA Accepts Sandoz Application For Biosimilar Filgrastim (July 24, 2014), http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml, attached hereto as Ex. B. Upon information and belief, the press release announcing the FDA's acceptance of the Sandoz's BLA, which is the subject of Plaintiffs' claims, was issued on behalf of Sandoz International GmbH.

30. Upon information and belief, Sandoz International GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to communicate with Amgen after receiving FDA notification of the FDA's acceptance and to unlawfully withhold the BLA for the Sandoz biosimilar product from Amgen while at the same time obtaining the benefits of the

§ 262(k) pathway (such as making use of the FDA's prior determinations as to the safety, purity, and potency of Plaintiffs' NEUPOGEN® (filgrastim)), which directly gives rise to Plaintiffs' claims of unfair competition and conversion. For example, Amgen received correspondence from Sandoz International GmbH dated September 4, 2014 that refers to "**our** decision not to disclose our application to Amgen." (emphasis added). Similarly, Amgen received further correspondence from Sandoz International, GmbH dated October 20, 2014 that refers to an earlier communication from Sandoz, Inc. as "our July 8, 2014 letter" and to an appeal filed by Sandoz, Inc. in co-pending litigation with Amgen as "our appeal." Letter from Julia Pike, Head, Global IP Litigation, Sandoz Int'l GmbH, to Wendy A. Whiteford, Vice President Law, Amgen Inc. (Oct. 20, 2014). These communications evidence that Sandoz International, GmbH and Sandoz, Inc. are working in concert in their scheme to unlawfully withhold from Amgen the information concerning the Sandoz biosimilar product that is required to be provided under 42 U.S.C. § 262(l)(2)(A).

31. 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, following any FDA approval, will directly or indirectly manufacture and/or sell the Sandoz biosimilar product that is the subject of the infringement, unfair competition, and conversion claims in this action in California and throughout the United States.

32. 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 and the tortious acts of unfair competition and conversion that have led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California.

33. 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.

B. Sandoz GmbH (Austria)

34. 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.

35. 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, namely, Sandoz. For example, Sandoz maintains an Internet website at the URL www.sandoz.com, attached hereto Ex. 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."

36. Upon information and belief, Sandoz GmbH is actively involved with planning Sandoz Inc.'s new biosimilar filgrastim products and filing Defendants' BLA for the biosimilar product in dispute. 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted to the 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 biosimilar product that is the subject of Defendants' BLA is manufactured at Sandoz GmbH facilities. Therefore, upon information and belief, Sandoz GmbH actively participated in the preparation of Defendants' BLA, for example by providing information regarding the facilities in which the Sandoz biosimilar product is manufactured, processed, packed, or held. Upon information and belief, Sandoz GmbH has provided similar information for biosimilar filgrastim products in Europe and manufactures those European products. For example, Sandoz GmbH applied for approval to market biosimilar filgrastim in

Europe, which it manufactures and sells as ZARZIO®. Sandoz GmbH has also stated that its Kundl facility is the "API manufacturing facility" of ZARZIO®. *See* Sandoz Company Presentation (May 15, 2012), attached hereto as Ex. C.

37. Upon information and belief, Sandoz GmbH acted in concert with Sandoz Inc. to develop a biosimilar version of Plaintiffs' NEUPOGEN® (filgrastim). Upon information and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to file a BLA seeking approval from the FDA to market and sell the Sandoz biosimilar product in the State of California and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement. For example, Sandoz GmbH provided ZARZIO® to the then-Global Medical Director at Sandoz International GmbH, Michael Muenzberg, to assess ZARZIO®'s biosimilarity to Plaintiffs' NEUPOGEN® (filgrastim) product. *See* M. Muenzberg et al., *Development of a New G-CSF Product Based on Biosimilarity Assessment*, 21 ANNALS OF ONCOLOGY 1419 (2010), attached hereto as Ex. D.

38. Upon information and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to communicate with Amgen after receiving FDA notification of the FDA's acceptance and to unlawfully withhold the BLA for the Sandoz biosimilar product from Amgen while at the same time obtaining the benefits of the § 262(k) pathway (such as making use of the FDA's prior determinations as to the safety, purity, and potency of Plaintiffs' NEUPOGEN® (filgrastim)), which directly gives rise to Plaintiffs' claims of unfair competition and conversion.

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, following any FDA approval, will directly or indirectly manufacture and/or sell the Sandoz biosimilar product that is the subject of the infringement, unfair competition and conversion claims in this action in California 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 the commission of, the tortious act of patent infringement and the

tortious acts of unfair competition and conversion that have led to foreseeable harm and injury to Amgen, a corporation with its principal place of business in California

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 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.

AMGEN OBTAINS FDA APPROVAL FOR ITS INNOVATIVE G-CSF BIOLOGICAL PRODUCT, NEUPOGEN®, UNDER 42 U.S.C. § 262(a)

42. A company seeking to market a biological product for human therapeutic use in the United States must first file a BLA seeking to obtain a license from the FDA. Prior to seeking FDA approval, developers of innovative biological products typically go through three clinical development phases before their developers seek FDA approval: Phase I, which typically tests safety, tolerability, and pharmacologic properties on healthy human volunteers, and Phases II and III, which typically test safety and efficacy on, respectively, a small and then a larger group of afflicted patients. If testing in each phase succeeds, the developer may be in a position to submit a BLA for FDA approval. The BLA includes, among other things, technical data on the characterization and composition of the biological product, toxicology studies in animals, the means for manufacturing, clinical trial results to establish the safety and efficacy of the biological product, and labeling for use of the biological product for which approval is requested. *See* 21 C.F.R. §§ 601 et seq.

43. After submission of the BLA, innovative developers must pass demanding stages of clearance. For example, innovative developers are required to demonstrate to the FDA 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)); and "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." 42 U.S.C. § 262(a)(2)(C)(i)(II). If

the FDA determines that the biological product or the facility does not meet the requirements, the BLA will be denied.

44. Not surprisingly, the development of innovative pharmaceutical products requires the investment of enormous amounts of time and money. For example, the time to develop a drug is ten to fifteen years, and the average cost to develop a drug (including the cost of failures) was $1.2 billion or higher in the early 2000s. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2013 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY, at 32, attached hereto as Ex. E; Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 HEALTH ECONOMICS 130, 139, 141 (2010), attached hereto at Ex. F (finding that the cost of drug development (or the net revenue needed to make investment in new drugs profitable) is over $1 billion: "a firm would need expected net revenue of over $1 billion to develop one more drug for the market").

45. Amgen went through each of the requirements of 42 U.S.C. § 262(a) (the "§ 262(a) pathway") to obtain a license from the FDA for its innovative biological product NEUPOGEN® (filgrastim). In 1991, the FDA approved NEUPOGEN® (filgrastim), pursuant to BLA No. 103353, for decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA later approved a series of additional indications for the therapeutic use of NEUPOGEN® (filgrastim), including the treatment of patients with severe chronic neutropenia, patients with acute myeloid leukemia receiving induction or consolidation chemotherapy, patients receiving bone marrow transplant, and patients undergoing peripheral blood progenitor cell collection and therapy. Each of these new indications necessitated Amgen's further investment to conduct additional clinical testing, submit a supplemental BLA, and prove to the FDA's satisfaction that NEUPOGEN® (filgrastim) was safe, pure, and potent for each new indication. These approvals are the direct result of very significant investments by Amgen in the development and clinical trials of

NEUPOGEN® (filgrastim). The biological product license to NEUPOGEN® (filgrastim) is owned by Amgen and exclusively licensed to AML.

46. The active ingredient in NEUPOGEN® is filgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor or "G-CSF." NEUPOGEN® (filgrastim) is also known as recombinant methionyl human granulocyte-colony stimulating factor. By binding to specific receptors on the surface of certain types of cells, NEUPOGEN® (filgrastim) 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. NEUPOGEN® (filgrastim) counteracts neutropenia. The availability of NEUPOGEN® (filgrastim) 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.

47. Another major advance provided by NEUPOGEN® (filgrastim) is for patients undergoing peripheral blood progenitor cell collection and transplant. In order to successfully treat certain forms of blood cancer, patients undergo hematopoietic progenitor cell transplants. NEUPOGEN® (filgrastim) is indicated for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. Mobilization with NEUPOGEN® (filgrastim) allows for the collection of increased numbers of hematopoietic progenitor cells capable of engraftment compared with collection without the use of NEUPOGEN® (filgrastim) or from bone marrow harvest. Furthermore, transplantation with an increased number of hematopoietic progenitor cells can lead to faster engraftment, which may result in a faster recovery for the patient after transplant.

THE BPCIA REFLECTS A CONGRESSIONAL BALANCE OF THE INTERESTS OF INNOVATORS AND BIOSIMILAR APPLICANTS UNDER THE 262(k) PATHWAY

48. On March 23, 2010, the BPCIA was enacted, creating an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" to be a biological product that is (1) "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).

49. As opposed to applicants under the § 262(a) pathway, biosimilar applicants are permitted to make use of the FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by the FDA. Specifically, the § 262(k) pathway may only be used where the prior applicant of 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 reference product sponsor 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). A biosimilar applicant may only request FDA evaluation for biosimilarity under the § 262(k) pathway with respect to no more than one reference product § 262(k)(5)(A) and must submit to the FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). Consequently, the § 262(k) pathway allows the biosimilar applicant to cut short the time and expensive cost of clinical testing, and 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 § 262(k) pathway is thus referred to as an "abbreviated" approval pathway.

50. The purpose of the BPCIA is to establish "a biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) (amending 42 U.S.C. § 262). The statutory provisions of the BPCIA reflect Congressional intent to achieve this balance. In addition to saving the time and expense of the traditional approval pathway under § 262(a), approval under the § 262(k) pathway offers other benefits 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 reference product sponsor. Specifically, the the Patient Protection and Affordable Care Act (PPACA) created a higher Medicare payment rate for biosimilars in the physician clinic setting. Pub. L. No. 111-148, § 3139(a), 124 Stat. 119, 439 (2010) (amending 42 U.S.C. § 1395w-3a). In the case of drugs (both biologics and small molecule drugs) other than biosimilars, the Medicare payment rate is the Average Sales Price (ASP)[1] of the drug plus 6 percent of that ASP. 42 U.S.C. § 1395w-3a(b)(1). Under the PPACA amendments, the Medicare payment rate for biosimilars is the ASP of the biosimilar, plus 6 percent of the *reference product's* ASP. 42 U.S.C. § 1395w-3a(b)(8). This results in a higher payment rate for physicians, assuming the ASP of the reference product is higher than that of the biosimilar. *See* Michael McCaughan, *Biosimilar Reimbursement Under The Sequester: The Lower The Price, The Bigger The Spread*, THE PINK SHEET DAILY (Aug. 8, 2014), attached hereto as Ex. G.

51. Further, a biosimilar product can be approved as "interchangeable" if it meets certain criteria, *i.e.*, the biosimilar product "can be expected to produce the same clinical result as the reference product in any given patient" and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference

[1] ASP is calculated by the Centers for Medicare & Medicaid Services based on sales information reported to the agency by manufacturers. 42 U.S.C. § 1395w-3a(c).

product is not greater than the risk of using the reference product without such alternation or switch." 42 U.S.C. §§ 262(k)(4)(A), 262(k)(4)(B). The designation of a biosimilar product as interchangeable provides additional value to the biosimilar applicant by permitting the product to be "substituted for the reference product without the intervention of the health care provider who prescribed the reference product" (42 U.S.C. §§ 262(i)(3)); and providing the biosimilar applicant with market exclusivity compared to other biosimilar products. 42 U.S.C. §§ 262(k)(6) (specifying time periods and conditions for exclusivity).

52. On the other hand, the BPCIA also sets forth a detailed and elaborate procedure adopted by Congress as a way of balancing the interests of reference product sponsors and biosimilar applicants under the § 262(k) pathway. Of particular relevance to this lawsuit, the BPCIA sets forth particular requirements that the biosimilar applicant must follow in order to obtain the benefits of filing its BLA under the § 262(k) pathway. 42 U.S.C. § 262(l). Among other things, these provisions require the biosimilar applicant to provide a copy of its BLA, together with other information necessary to describe the process(es) for manufacturing the biosimilar product to the reference product sponsor. *See* 42 U.S.C. § 262(l)(2). This permits the reference product sponsor to evaluate whether it can assert patent claims against the biosimilar applicant for making, using, offering to sell, selling, or importing into the United States the biosimilar product.

53. Specifically, 42 U.S.C. § 262(l) provides the following carefully crafted series of steps for the identification of patents potentially blocking commercialization of the proposed biosimilar, as well as specific times for completing these steps that are emphasized in bold below:

a. ***Within 20 days*** after the FDA has accepted its abbreviated application, the biosimilar applicant must provide the reference product sponsor: (i) a copy of the biosimilar application and (ii) other information describing the process(es) for manufacturing the biosimilar product. 42 U.S.C. § 262(l)(2). The reference product sponsor must keep the BLA and manufacturing information confidential, and may only use such material to evaluate infringement. 42 U.S.C. § 262(l)(1).

b. ***Within 60 days*** after receiving the BLA and manufacturing information, the reference product sponsor must provide the biosimilar applicant with a list of all patents that the reference product sponsor reasonably believes are infringed, such that they could be

asserted by either the reference product sponsor or a patent owner that has granted exclusive rights to the reference product sponsor. 42 U.S.C. § 262(l)(3)(A). The reference product sponsor must also identify which, if any, of these patents it would be prepared to license to the biosimilar applicant. 42 U.S.C. § 262(l)(3)(A)(ii).

c. ***Within 60 days*** after receiving the foregoing list from the reference product sponsor, the biosimilar applicant may provide to the reference product sponsor a list of patents that the biosimilar applicant believes could be subject to a claim of patent infringement. 42 U.S.C. § 262(l)(3)(B)(i). ***Within the same 60 days***, regarding any patents listed by the reference product sponsor or the biosimilar applicant, the biosimilar applicant must also provide: (I) a statement describing, on a claim by claim basis, a factual and legal basis for an opinion that a patent is invalid, unenforceable, or not infringed; or (II) a statement that the biosimilar applicant does not intend to market until the patent expires. 42 U.S.C. § 262(l)(3)(B))ii). The biosimilar applicant must also provide a response to the reference product sponsor's identification of any patents it would be prepared to license. 42 U.S.C. § 262(l)(3)(B)(iii).

d. ***Within 60 days*** after receiving the information described immediately above, the reference product sponsor must provide, regarding each patent discussed in (I) above, a reciprocal statement describing, on a claim by claim basis, a factual and legal basis for an opinion that a patent will be infringed as well as a response to any statement regarding validity and enforceability. 42 U.S.C. § 262(l)(3)(C).

e. After this exchange of information, both parties must engage in good faith negotiations to identify which patents, if any, should be subject to patent infringement litigation. 42 U.S.C. § 262(l)(4)(A). If the parties reach agreement ***within 15 days*** of starting negotiations, the reference product sponsor must bring an "immediate" patent infringement action against the biosimilar applicant on the negotiated list of patents ***within 30 days*** of such agreement. 42 U.S.C. § 262(l)(6)(A). If the parties do not reach agreement ***within 15 days*** of starting negotiations, the biosimilar applicant must notify the reference product sponsor of the number of patents it will provide in a second list, and the parties then simultaneously exchange within five days of this notice a list of patents that each party believes should be the subject of infringement litigation. 42 U.S.C. § 262(l)(5). ***Within 30 days*** after exchanging these lists, the reference product sponsor must bring an "immediate" patent infringement action against the biosimilar applicant on all patents on these simultaneously exchanged lists. 42 U.S.C. § 262(l)(6)(B).

f. Even after the immediate litigation of 42 U.S.C. § 262(l)(6)(B) has commenced, the reference product sponsor may identify additional patents that are newly issued or licensed after the reference product sponsor provided its patent list under 42 U.S.C. § 262(l)(3)(A). Specifically, the reference product sponsor may, not later than 30 days after the issuance or licensing supplement that list with the newly issued or licensed patent(s). 42 U.S.C. § 262(l)(7).

54. The mandatory time periods set forth in 42 U.S.C. § 262(l) give the reference product sponsor a limited time after receiving the biosimilar applicant's BLA and

manufacturing information, the biosimilar applicant's contentions, and the biosimilar applicant's response to initial licensing opportunities to consider patent infringement before filing a lawsuit against the biosimilar applicant. Specifically, 42 U.S.C. § 262(l) provides the reference product sponsor with 225 days after receiving the BLA and manufacturing information to exchange patent lists, provide detailed statements of infringement, validity, and enforceability, and engage in good faith negotiations regarding such patent lists prior to filing the "immediate" patent infringement action against the biosimilar applicant. *See* ¶¶ 53(b), (c), (d), (e), *supra.* These procedures provide the reference product sponsor with the benefit of certainty, both as to the scope of the patent disputes and also the characteristics of the biosimilar product.

55. 42 U.S.C. § 262(l) also requires the biosimilar applicant provide the reference product sponsor notice at least 180 days before the biosimilar applicant's first commercial marketing of the biosimilar. 42 U.S.C. § 262(l)(8)(A). The biosimilar applicant's obligation to provide this advanced notice of commercial marketing is not conditioned on performance of any act by the reference product sponsor nor exempted in the circumstance of a biosimilar applicant having failed to make the initial disclosures pursuant to 42 USC § 262(l)(2)(A). Rather, 42 U.S.C. § 262(l)(8)(A) simply provides that the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of first commercial marketing of the biological product licensed under subsection (k)."

56. The advanced notice of commercial marketing does, however, enable the reference product sponsor to seek a preliminary injunction before commercial marketing of the biosimilar product has commenced. 42 U.S.C. § 262(l)(8)(B) permits the reference product sponsor to seek a preliminary injunction enjoining the biosimilar applicant from commercially manufacturing or selling the biosimilar product until the court decides the disputed patent issues with respect to any patent that is on the exchanged patent lists, but which were not listed, by negotiation or exchange, for immediate litigation. Accordingly, this provision gives the courts an opportunity to consider the reference product sponsor's motion for preliminary injunction

before the status quo has changed; and gives the reference product sponsor the opportunity to stop the biosimilar applicant from launching its product before the patent issues are resolved.

57. This Court has determined that the notice of commercial marketing must take place on or after FDA approval; that decision is currently on appeal. *See Sandoz Inc. v. Amgen Inc.,* No. C-13-2904, 2013 WL 6000069, at *2 (N.D. Cal. Nov. 12, 2013) (appeal pending, Fed. Cir. Appeal No. 2014-1693) ("Sandoz cannot, as a matter of law, have provided a 'notice of commercial marketing' because, as discussed above, its etanercept product is not 'licensed under subsection (k).'").

58. After receiving the notice of commercial marketing and before such date of first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the biosimilar applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent identified for immediate patent litigation in the lists described above (*see* ¶ 53(e), *supra*). 42 U.S.C. § 262(l)(8)(B). This provision gives the courts an opportunity to consider the reference product sponsor's motion for preliminary injunction before the status quo has changed and gives the reference product sponsor the opportunity to stop the biosimilar applicant from launching its product before the patent issues are resolved.

DEFENDANTS' BIOSIMILAR APPLICATION UNDER 42 U.S.C. 262(k)

59. Upon information and belief, Defendants filed a BLA with the FDA under § 351(k) of the Public Health Service Act, codified as 42 U.S.C. § 262(k), to obtain approval to commercially market, manufacture, import and sell a biosimilar version of NEUPOGEN® (filgrastim) for treating particular diseases in the United States.

60. Upon information and belief, the biosimilar product that is the subject of Defendants' BLA is designed to copy and compete with Plaintiffs' NEUPOGEN® (filgrastim). Upon information and belief, Defendants will instruct or direct others to administer the Sandoz biosimilar product to certain patients for treating particular diseases in

the United States in the same way that Plaintiffs' NEUPOGEN® (filgrastim) is administered. Upon information and belief, Defendants are seeking FDA approval for one or more indications for which NEUPOGEN® (filgrastim) is already approved.

61. Upon information and belief, Defendants' BLA is the first application that the FDA has accepted under the § 262(k) pathway.

62. Upon information and belief, Defendants have not and do not seek to independently demonstrate to the 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 NEUPOGEN® (filgrastim). Rather, upon information and belief, Defendants have requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen's FDA license for NEUPOGEN® (filgrastim). Accordingly, Defendants submitted to the FDA publicly-available information regarding the FDA's previous licensure determination that NEUPOGEN® (filgrastim) is "safe, pure, and potent." 42 U.S.C. 262(k)(2)(A)(iii)(I).

63. Upon information and belief, Defendants "received notification from the FDA on July 7, 2014" that the FDA had accepted their BLA for the Sandoz biosimilar product. Letter from Robin Adelstein, Vice President, Legal, IP & Compliance, Sandoz Inc., to Wendy A. Whiteford, Vice President Law, Amgen Inc. (July 25, 2014). Pursuant to the Biosimilar Biological Product Authorization Performance Goal and Procedures, which sets forth FDA goals for fiscal years 2013-2017, the FDA is committed to reviewing and acting "on 70 percent of original biosimilar biological product application submissions within 10 months of receipt" for biosimilar biological product applications filed in 2014.[1] Therefore, the FDA will complete its final review of Sandoz's biosimilar product at least by May 2015. Upon information and belief, Defendants believe that they may secure FDA approval of the Sandoz biosimilar product before

[1] FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/%20HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf, attached as Ex. I.

May 2015. *See* Letter from Robin Adelstein, Vice President, Legal, IP & Compliance, to David J. Scott, General Counsel and Secretary, Amgen Inc. (July 8, 2014) (Defendants' "reasoned belief" is that their BLA for the Sandoz biosimilar product "will be approved by the FDA in or around Q1/2 of 2015."); Letter (Oct. 20, 2014), *supra* ¶ 30 (confirming that "Sandoz continues to expect FDA approval in or around Q1/2 of 2015").

64. Defendants' receipt of FDA notification that their BLA had been accepted for review triggered the mandatory obligations set forth in 42 U.S.C. § 262(l). Specifically, the following provisions are required of Defendants, and would have been required of Amgen and FDA but for Defendants' failure to timely comply with their initial disclosure pursuant to 42 U.S.C. § 262(l)(2)(A):

Provision	**Date**
FDA notifies Defendants that their application for the Sandoz biosimilar product has been accepted for review.	Thursday, July 7, 2014
Subsection (k) application information. Not later than 20 days after Defendants' receipt of FDA notification: • Defendants "shall provide" to Amgen a copy of the application submitted to the FDA under § 262(k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application. 42 U.S.C. § 262(l)(2).	On or before Monday, July 28, 2014
List and description of patents. Not later than 60 days after Amgen's receipt of Defendants' BLA and manufacturing information: • Amgen "shall provide" to Defendants a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted by Amgen. 42 U.S.C. § 262(l)(3)(A)(i). • Amgen "shall provide" to Defendants an identification of the patents on such list that Amgen would be prepared to license to Defendants. 42 U.S.C. § 262(l)(3)(A)(ii).	On or before Friday, September 26, 2014
List and description by subsection (k) applicant. Not later than 60 days after Defendants' receipt of Amgen's patent list: • Defendants "may provide" to Amgen a list of patents that Defendants believes could reasonably be asserted by	On or before Tuesday, November 25, 2014

Provision	Date
Amgen. 42 U.S.C. § 262(l)(3)(B)(i). • Defendants "shall provide" to Amgen with respect to each patent on Plaintiffs' list a detailed statement describing on a claim by claim basis, the factual and legal basis of Defendants' opinion that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the Sandoz biosimilar product; or a statement that Defendants do not intend to begin commercial marketing of the Sandoz biosimilar product before the date that such patent expires. 42 U.S.C. § 262(l)(3)(B)(ii). • Defendants "shall provide" to Amgen a response regarding each patent identified by Amgen in its patent list. 42 U.S.C. § 262(l)(3)(B)(iii).	
Description by reference product sponsor. Not later than 60 days after Amgen's receipt of Defendants' list and statement: • Amgen "shall provide" to Defendants a detailed statement that describes, with respect to each patent described in Defendants' detailed statement, on a claim by claim basis, the factual and legal basis of Plaintiffs' opinion that such patent will be infringed by the commercial marketing of the Sandoz biosimilar product and a response to Defendants' statement concerning validity and enforceability. 42 U.S.C. § 262(l)(3)(C).	On or before Monday, January 26, 2015
Patent resolution negotiations. After Defendants receive Plaintiffs' detailed statement: • Amgen and Defendants "shall engage" in good faith negotiations to agree on which, if any, patents listed by Amgen and Defendants shall be the subject of an action under 42 U.S.C. § 262(l)(6) for patent infringement. 42 U.S.C. § 262(l)(4).	
Immediate patent infringement action if agreement on patent list. If there is agreement, then not later than 30 days after such agreement: • Amgen "shall bring" an action for patent infringement with respect to each patent. 42 U.S.C. § 262(l)(6)(A).	On or before Wednesday, February 25, 2015, assuming negotiations began on Monday, January 26, 2015.
Patent resolution if no agreement. If there is no agreement, then within 15 days of beginning negotiations:	On or before Monday, February 16, 2015,

Provision	Date
• Defendants "shall notify" Amgen of the number of patents that Defendants will provide to Amgen. 42 U.S.C. §§ 262(l)(4)(B), 262(l)(5)(A). • Within 5 days after Defendants notifies Amgen, the parties "shall" simultaneously exchange the list of patents that each party believes should be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6). 42 U.S.C. § 262(l)(5)(i).	assuming that Defendants notified Amgen on Tuesday, February 10, 2015.
Immediate patent infringement action if no agreement on patent list. Not later than 30 days after the exchange of second patent lists if there is no agreement: • Amgen "shall bring" an action for patent infringement with respect to each patent that is included on such lists. 42 U.S.C. § 262(l)(6)(B).	On or before Wednesday, March 18, 2015
Notification and publication of the Complaint. Not later than 30 days after Amgen serves a complaint to Defendants in an action for patent infringement under 42 U.S.C. § 262(l)(6): • Defendants "shall provide" the FDA with notice and a copy of such complaint. 42 U.S.C. § 262(l)(6)(C)(i). • The FDA "shall publish" in the Federal Register notice of the received complaint. 42 U.S.C. § 262(l)(6)(C)(ii).	On or before Friday, March 27, 2015 if there were agreement On or before Friday, April 17, 2015 if there were no agreement

65. In addition, Defendants are required under 42 U.S.C. § 262(l)(8)(A) to provide notice to Amgen not later than 180 days before the date of first commercial marketing, which this Court has held can only take place on or after FDA approval, as discussed above in ¶ 57.

66. After receiving such notice and before such date of the first commercial marketing, Amgen may seek a preliminary injunction prohibiting Defendants from engaging in the commercial manufacture or sale of the Sandoz biosimilar product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is on the exchanged patent lists, but not on the negotiated or exchanged lists for immediate litigation. 42 U.S.C. § 262(l)(8)(B). This provision is intended to permit Amgen

to seek an injunction in time to prevent irreparable harm to Plaintiffs, *i.e.,* before Defendants first market commercially or launch the Sandoz biosimilar product.

67. Upon information and belief, Defendants are attempting to obtain the benefits of the BPCIA by filing their BLA under the § 262(k) pathway without complying with the requirements that Congress also imposed through the BPCIA on biosimilar applicants. For example, Defendants made a deliberate decision not to provide Amgen with a copy of its BLA, together with other information necessary to describe the process(es) for manufacturing the biosimilar product, within 20 days of receiving notification of FDA acceptance of their application. Under 42 U.S.C. § 262(l)(2), Sandoz was required to provide Amgen with such materials by Monday, July 28, 2014. To date, Amgen still has not received such materials, and Defendants continue to enjoy the benefit of FDA review of their application in reliance on Amgen's prior biological product license for filgrastim.

68. Instead of providing their BLA and manufacturing information, Defendants proposed to Amgen that the parties exchange information without following the mandatory provisions of 42 U.S.C. § 262(l)(2). On July 28, 2014, Amgen received a letter from Defendants stating that they "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance." Letter (July 25, 2014), *supra* ¶ 63. Upon information and belief, Defendants' failure to provide their BLA and manufacturing information was an attempt to prevent Amgen from learning the details of their process(es) for manufacture, to avoid patent infringement litigation on any manufacturing patents, and to avoid the patent exchanges required by the statute; and instead to go directly to litigation. Defendants indicated that they wished to sidestep the entire procedure laid out by the statute in their correspondence. *Id.* ("Amgen is entitled to start a declaratory judgment action"). They confirmed this point in their subsequent letter as well. Letter from Julia Pike, Head of Global IP Litigation, to Wendy A. Whiteford, Vice President Law, Amgen Inc. (Sept. 4, 2014) (Amgen's "next step *under the BPCIA can only be* starting a declaratory judgment action as specified in that statute") (emphasis in original).

69. In addition, Defendants proposed in July 8, 2014 and July 21, 2014 Letters that they provide Amgen with their BLA pursuant to an Offer of Confidential Access. Letter (July 25, 2014), *supra* ¶ 63; *see also* Letter (July 8, 2014), *supra* ¶ 63 (also proposing an Offer of Confidential Access). In both letters, Defendants proposed exchanging their BLA, but not manufacturing information. In the July 8, 2014 Letter, Defendants also proposed that Amgen forfeit its right to use the exchanged BLA information as a basis to allege infringement under 35 § 271(g), which provides that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent." 42 U.S.C. § 262(l)(1)(A) permits the biosimilar applicant and the reference product sponsor to agree to alternative provisions for the exchange of confidential information. But, this provision applies only to the confidentiality terms that will apply to the information exchanged. The sequence and content of the exchanges, and the obligations imposed on the biosimilar applicant and reference product sponsor, by 42 U.S.C. § 262(l)(2) through 42 U.S.C. § 262(l)(8) are mandatory regardless of what confidentiality provisions may be agreed under 42 U.S.C. § 262(l)(1). Further, in the absence of agreement ("unless otherwise agreed to" by the biosimilar applicant and the reference product), the statute requires that the parties proceed with the confidentiality provisions provided in 42 U.S.C. § 262(l)(1)(A). Defendants' Offer of Confidential Access purported to replace the requirements of 42 U.S.C. § 262(l)(2) through 42 U.S.C. § 262(l)(8) with an entirely different procedure under which Amgen would have been obligated to commence any patent infringement litigation within 60 days of its receipt of Defendants' BLA information; attempted to limit the exchange of information to Defendants' BLA and not include any manufacturing information; and in the July 8, 2014 Letter, attempted to limit Amgen's cause of actions for patent infringement to exclude process patents. Defendants' attempts to modify the statutory provisions is not legally permissible.

70. Amgen responded that it was not willing to agree to Sandoz's Offers of Confidential Access that each attempted to narrow the scope of Defendants' disclosures

compared to that set forth in the statute, and reminded Defendants of their statutory obligation to provide its BLA and manufacturing information to Amgen. Letter from Wendy A. Whiteford, Vice President Law, Amgen Inc., to Robin Adelstein, Vice President, Legal IP & Compliance, Sandoz Inc. (Aug. 22, 2014). After Amgen responded, Defendants sent Amgen another letter dated September 4, 2014, asserting that Defendants had decided "not to disclose our application to Amgen" and chosen not to exercise their "right to use the patent information exchange process of the BPCIA." Letter (Sept. 4, 2014), *supra* ¶ 68. Defendants sent another letter on October 20, 2014, purporting to "remind" Amgen of "our July 8, 2014 letter which provided you with Sandoz's notice of commercial marketing pursuant to 42 U.S.C. 262(l)(8)(A)." Letter (Oct. 20, 2014), *supra* ¶ 30.

71. Upon information and belief, Defendants' violation of 42 U.S.C. § 262(l)(2) is part of a carefully orchestrated scheme to deprive Amgen of the substantive and procedural benefits of the BPCIA.

72. In particular, receipt of the BLA and manufacturing information gives the reference product sponsor the opportunity to evaluate the manufacturing processes used by the biosimilar applicant to determine whether those processes would infringe any patents held by the reference product sponsor, including under 35 U.S.C. § 271(g). The purpose of the statutory provisions of 42 U.S.C. § 262(l)(2) is, *inter alia*, to permit such an evaluation, as in the absence of such a disclosure, the reference product sponsor has no access to the BLA and manufacturing information. Had Defendants provided Amgen with a copy of their BLA and manufacturing information, Amgen would have been in a position: (1) to provide to Defendants a list of patents for which Amgen believes a claim of patent infringement could reasonably be asserted as to the Sandoz biosimilar product, and (2) to identify to Defendants whether Amgen would be prepared to grant a license to Defendants under any of the patents included on such a list. *See* 42 U.S.C. § 262(l)(3)(A). Amgen has an extensive portfolio of patents relating to various aspects of the manufacture of biological products. However, because Defendants' manufacturing process for the Sandoz biosimilar product is secret, without the disclosure required under 42 U.S.C. § 262(l)(2) Amgen's ability to

conduct a full and complete evaluation of its patent portfolio with respect to Defendants' specific product, process(es) of manufacture, and uses is undermined and delayed. By unlawfully withholding the information required under 42 U.S.C. § 262(l)(2) Defendants have thereby frustrated the statutory purpose and deprived Plaintiffs of the opportunity to seek redress for potential infringement.

73. One patent which Amgen believes could have been identified on its list pursuant to 42 U.S.C. § 262(l)(3)(A)(i), is U.S. Patent No. 6,162,427 ("the '427 patent"), which covers a method of using NEUPOGEN® (filgrastim) to treat a disease requiring peripheral stem cell transplantation in a patient in need of such treatment. However, Amgen holds numerous other patents directed to processes for manufacturing products such as the Sandoz biosimilar product. As noted above, had Defendants provided Amgen with a copy of their BLA and information necessary to describe the process(es) for manufacturing the Sandoz biosimilar product, Amgen would have complied with its obligations under 42 U.S.C. § 262(l)(3) and identified any patents to which a claim of patent infringement could reasonably be asserted. Amgen therefore reserves the right to seek leave to assert additional patents following eventual receipt of Defendants' BLA and manufacturing information and other relevant information to be produced in discovery in this action under the Federal Rules.

74. Further, had Defendants complied with the statutory requirements, then Amgen could have brought a patent infringement action, if necessary, against Defendants under 42 U.S.C. § 262(l)(6) in February or March 2015. Because Defendants did not comply with the mandatory disclosure requirements of 42 U.S.C. § 262(l)(2), however, Amgen was deprived of any opportunity to review Defendants' BLA and manufacturing information, identify a comprehensive list of infringed patents, and review Defendants' contentions, and, possibly, licensing position, prior to bringing an action. Amgen also lost the benefit of the time provided in 42 U.S.C. § 262(l)(2) for Amgen and Defendants to identify potentially disputed patents, the time to evaluate those patents, the substantive exchange of statements concerning those patents, and the ability to identify more patents after exchanging patent lists prior to Amgen bringing a patent infringement action. Defendants' actions also create the

substantial and continuing risk that Plaintiffs may not be able to obtain manufacturing information regarding Defendants' biosimilar product that would permit Plaintiffs to assert their process patents prior to commercialization of the biosimilar product. Forcing Plaintiffs to assert one or more of their patents (including process patents) after Defendants' commercial entry into the market harms Plaintiffs by diminishing the value of such patents.

75. Additionally, Defendants violated the statute by not providing Amgen with a legally operative notice of commercial marketing. Upon information and belief, Defendants do not intend to provide Amgen with a notice of commercial marketing on or after FDA approval. Therefore, Defendants intend to and/or will violate the BPCIA absent an order of the Court compelling Defendants to comply.

76. Each of Defendants' unlawful acts (violation of 42 U.S.C. § 262(l)(2)(A) and violation of 42 U.S.C. § 262(l)(8)(A)) independently deprive Amgen of the benefits afforded under the statute and which Congress provided to reference product sponsors. Defendants' failure to provide the BLA and manufacturing information to Amgen under 42 U.S.C. § 262(l)(2)(A) deprives Plaintiffs of the opportunity to seek a preliminary injunction enjoining Defendants from engaging in the commercial manufacture or sale of the Sandoz biosimilar product in time to prevent irreparable harm to Plaintiffs, *i.e.,* after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product. In addition, Defendants' failure to provide a legally operative notice of commercial marketing deprives Plaintiffs of the opportunity to seek a court intervention to prevent Plaintiffs from suffering irreparable harm. This too prevents Plaintiffs from enjoining Defendants in time to prevent irreparable harm.

FIRST CAUSE OF ACTION
(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200 et seq.)

77. The allegations of ¶¶ 1-76 are repeated and incorporated herein by reference.

78. Defendants' actions in filing a BLA with the FDA under the § 262(k) pathway for approval to commercially market, manufacture, import and sell a biosimilar version of Plaintiffs' product NEUPOGEN® (filgrastim), and in planning the launch of a biosimilar

version of Plaintiffs' product NEUPOGEN® (filgrastim) is a business practice under California state law of unfair competition.

79. Defendants have violated Cal. Bus. & Prof. Code § 17200 et seq. by seeking FDA approval for Sandoz biosimilar product under the BPCIA's abbreviated approval pathway of § 262(k), while refusing to comply with other statutory requirements of the BPCIA, specifically those that protect the interest of Amgen (the reference product sponsor). As set forth in ¶¶ 50-58 and ¶ 64 above, Defendants' receipt of FDA notification that their BLA was accepted for review triggers a set of deadlines requiring, among other things, Defendants to provide their BLA and manufacturing information to Amgen within twenty days. Defendants have unlawfully withheld from Amgen the BLA and manufacturing information that Defendants were required to disclose under 42 U.S.C. § 262(l)(2)(A).

80. In addition and as a separate and independent unlawful act, Defendants have failed and/or will imminently fail to meet its statutory obligation under 42 U.S.C. § 262(l)(8)(A) to provide notice of commercial marketing to Amgen upon or after FDA approval. Defendants' violations of the BPCIA satisfy the "unlawful" prong of § 17200.

81. By reason of, and as a direct and proximate result of, Defendants' independent acts of unlawful conduct, Plaintiffs have suffered and will continue to suffer injury to its business and property. As set forth in ¶¶ 64-76 above, Defendants' actions deprive Amgen of the BLA and manufacturing information, Defendants' patent list(s), and Defendants' detailed statements, all of which are required under the statute. Accordingly, Plaintiffs do not have sufficient information to identify patents and infringement claims; and Plaintiffs' determination of whether to file a patent infringement action and which patent claims to assert against Defendants is delayed. Further and as an independent ground, Defendants' conduct threatens to deprive Plaintiffs of the opportunity to seek a preliminary injunction in time to prevent irreparable harm, *i.e.,* after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product.

82. By reason of and as a direct and proximate cause of Defendants' unlawful conduct, Plaintiffs have suffered economic injury to their business in the form of lost money

that was spent to monitor and respond to Defendants' acts of unfair competition. Plaintiffs will also suffer lost profits and increased costs if Defendants are permitted to commercially market the Sandoz biosimilar product without satisfying their obligations under 42 U.S.C. § 262(l). In addition, Plaintiffs will suffer loss of value of their patents as a result of Defendants' actions by forcing Plaintiffs to assert one or more of their patents (including process patents) after Defendants' commercial entry into the market as discussed in ¶ 74 above.

83. Plaintiffs are entitled to full restitution for the revenues, earnings, profits, compensation, and benefits that Plaintiffs will lose and Defendants obtain as a result of such unlawful business practices. For example, if Defendants are permitted to commercially market the Sandoz biosimilar product without providing the required 180-day notice to Amgen that would have allowed Plaintiffs to bring a motion for preliminary injunction, then Plaintiffs are entitled to restitution for the period of time between Defendants' market entry and a court's decision on Plaintiffs' motion for preliminary injunction.

84. The unlawful conduct alleged herein is continuing and there is no indication that Defendants will cease the conduct.

85. Plaintiffs are entitled to an order enjoining Defendants from commercially marketing the biosimilar product until Plaintiffs are restored to the position they would have been had Defendants met their obligations under the BPCIA, *e.g.,* providing Amgen with the BLA and manufacturing information and the equivalent information and time required under 42 U.S.C. § 262(l) for evaluating Defendants' BLA and manufacturing information so that Plaintiffs may bring a patent infringement action and/or preliminary injunction in time to prevent irreparable harm to Plaintiffs (after FDA approval of the Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar product).

86. Plaintiffs are entitled to an order compelling Defendants to provide Amgen with notice of commercial marketing on or after FDA licensure of its biosimilar product, and no later than 180 days before Defendants' first commercial marketing of that product.

SECOND CAUSE OF ACTION
(CONVERSION)

87. The allegations of ¶¶ 1-86 are repeated and incorporated herein by reference.

88. The FDA is charged by Congress with promoting "the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393. The FDA pursues this mission vigorously and effectively in cooperation with applicants who market or seek to market regulated products. One important function of the FDA is to prescribe standards and measure compliance with a multistep process for approval for drugs and biological products.

89. As discussed above in ¶ 43, for reference products, FDA approval requires a demonstration that the "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). The same demonstration is not required for FDA approval of biosimilar products under the § 262(k) pathway. Rather, a biosimilar applicant under the § 262(k) pathway selects a single reference product for which it seeks FDA evaluation of its biological product as a biosimilar, and submits to the FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). In order to obtain the benefit of the BPCIA's abbreviated approval pathway for biosimilar products, § 262(k) pathway, including reliance of the reference product sponsor's prior FDA licensure, applicants must follow the BPCIA's procedures set forth in 42 U.S.C. § 262(l) regarding the disclosure of information to the reference product sponsor, the exchange of contentions, the negotiation of disputes for resolution or litigation, and notice of commercial marketing to the reference product sponsor.

90. The biological license for NEUPOGEN® (filgrastim) is owned by Amgen and exclusively licensed to AML. Plaintiffs have a legitimate claim to exclusivity in the license because of the significant effort, investment, and expertise required to obtain the license: Amgen expended considerable time, expense, and resources in research and design; Amgen conducted the appropriate tests and compiled the necessary data; Amgen prepared the BLA

for NEUPOGEN® (filgrastim) and engaged in negotiations with the FDA regarding the BLA; Amgen demonstrated to the FDA that NEUPOGEN® (filgrastim) is safe, pure, and potent; and Amgen supplemented its BLA with the FDA. In addition, Amgen's license has value because it enables biosimilar applicants, such as Defendants, to secure approval of a biological product as biosimilar NEUPOGEN® (filgrastim) without the delay, burden, or expense of demonstrating to the FDA that such biosimilar product is independently "safe, pure, and potent." Thus, the license to NEUPOGEN® (filgrastim) owned by Amgen and exclusively licensed to AML is a property right that is recognized by the law in that Plaintiffs' interest is precisely defined and capable of exclusive possession.

91. Defendants' use of the license for NEUPOGEN® (filgrastim) to obtain a governmental privilege (FDA approval to market, manufacture, import, and sell the Sandoz biosimilar product for use in the United States) for Defendants' own benefit and profit is an act of conversion. Specifically, Defendants filed a BLA for the Sandoz biosimilar product that intentionally uses Amgen's prior demonstration of the safety, purity, and potency of NEUPOGEN® (filgrastim), but without Plaintiffs' authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(l) that apply to biosimilar applicants. By filing their BLA for the Sandoz biosimilar product under the § 262(k) pathway rather than the § 262(a) pathway, Defendants seek to obtain a valuable benefit from the license for NEUPOGEN® (filgrastim). Without Amgen's efforts, the information relied on by Defendants for the safety, purity, and potency of the Sandoz biosimilar product would not exist. As a result, Defendants have converted property belonging to Plaintiffs.

92. By reason of and as a direct and proximate cause of Defendants' wrongful acts of conversion, Plaintiffs have suffered and will continue to suffer damages due to the lost value of Amgen's biological license for NEUPOGEN® (filgrastim). The detriment caused by Defendants' conversion is presumed to include the value of Plaintiffs' property at the time of conversion. *See* Cal. Civ. Code § 3336. Here, Defendants have derived and will continue to derive value from Amgen's license by seeking approval under the abbreviated § 262(k) pathway rather than the § 262(a) pathway. Had Defendants not wrongfully

converted Plaintiffs' property, Defendants would have had to incur the time and money for filing a BLA under the § 262(a) pathway, just as Amgen did to obtain its license for NEUPOGEN® (filgrastim).

93. In addition, Defendants' conduct will diminish the value of the NEUPOGEN® (filgrastim) license that is owned by Amgen and exclusively licensed to AML. If Defendants are permitted to convert Plaintiffs' property—without authorization or permission and without satisfying the mandatory provisions of 42 U.S.C. § 262(l) that apply to biosimilar applicants—and obtain FDA approval to launch the Sandoz biosimilar product, then the biological license will no longer be exclusive. Consequently, Plaintiffs will suffer economic injury to their business in the form of lost sales, revenue, market share, and asset value.

94. By reason of and as a direct and proximate cause of Defendants' wrongful acts of conversion, Plaintiffs have suffered economic injury to their business in the form of lost money that was spent to monitor and respond to Defendants' acts of conversion. The detriment caused by Defendants' conversion is presumed to include fair compensation for the time and money properly expended by Plaintiffs in pursuit of their property. *See* Cal. Civ. Code § 3336.

95. Upon information and belief, Defendants' conversion of Plaintiffs' property is oppressive and malicious. As a result of such conduct, Plaintiffs are entitled to punitive damages. *See* California Civil Code § 3294.

96. The unlawful conduct alleged herein is continuing and there is no indication that Defendants will cease the conduct.

97. Plaintiffs are entitled to an order enjoining Defendants from continuing to seek FDA review of their § 262(k) application and/or compelling Defendants to suspend FDA review of their § 262(k) application until Defendants have obtained permission from Plaintiffs to use the NEUPOGEN® (filgrastim) license or require Defendants to restore to Amgen the benefits afforded to reference product sponsors in the statute, *e.g.,* providing Amgen with the equivalent information and time required under the statute for evaluating

Sandoz's BLA and manufacturing information, exchanging patent lists and information, negotiating patent lists, receiving Defendants' notice of commercial marketing, and bringing patent infringement actions and preliminary injunction motions.

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT)

98. The allegations of ¶¶ 1-97 are repeated and incorporated herein by reference.

99. Amgen is the owner of all right, title and interest in the '427 patent.

100. The '427 patent is titled "Combination of G-CSF With a Chemotherapeutic Agent for Stem Cell Mobilization" and was duly and legally issued by the USPTO on December 19, 2000. The inventors of the '427 patent are Matthias Baumann and Peter-Paul Ochlich. A true and correct copy of the '427 patent is attached hereto as Ex. H.

101. Upon information and belief, the purpose of Defendants' BLA for the Sandoz biosimilar product is to obtain approval to engage in the commercial marketing, manufacture, import, and sale of a biological product for treating particular diseases in the United States, one use of which is claimed in the '427 patent before the expiration of such patent. Upon information and belief, Defendants seek to market, manufacture, import, distribute, sell, and/or offer to sell the Sandoz biosimilar product for treating particular diseases in the United States immediately upon receipt of FDA approval and prior to the expiration of the '427 patent.

102. Defendants have committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) of the '427 patent by virtue of their submission of the BLA for the Sandoz biosimilar product and failure to provide the required BLA and manufacturing information to Amgen within 20 days after the FDA notified Defendants on July 7, 2014 that their BLA was accepted for review.

103. Upon information and belief, Defendants intended to violate the statute by failing to disclose the required BLA and manufacturing information to Amgen within 20 days after the FDA accepted Defendants' BLA, and Defendants chose to disclose their non-

compliance to Amgen one day after the 20 day period had expired. Defendants' actions constitute a knowing and willful infringement under 35 U.S.C. § 271(e)(2)(C)(ii).

104. Plaintiffs are entitled to injunctive relief under 35 U.S.C. § 271(e)(4)(B) preventing Defendants' from profiting by their deliberate non-compliance with the mandatory provisions of 42 U.S.C. § 262(l) by issuing an appropriately tailored injunction against the commercial manufacture, import, offer for sale, or sale of Sandoz's biosimilar product, and restoring Plaintiffs to the position in which they would have been but for such non-compliance. Defendants must restore to Amgen the benefits afforded to reference product sponsors in the statute, *e.g.,* providing Amgen with the equivalent information and time required under the statute for evaluating Sandoz's BLA and manufacturing information, exchanging patent lists and information, negotiating patent lists, receiving Defendants' notice of commercial marketing, and bringing patent infringement actions and preliminary injunction motions.

105. Plaintiffs are further entitled to injunctive relief against Defendants to prevent the commercial manufacture, use, offer to sell, or sale within the United States of the Sandoz biosimilar product. *See* 35 U.S.C. § 271(e)(4)(B).

106. As set forth in ¶¶ 72-73 above, Plaintiffs reserve the right to seek leave to assert additional patents following eventual receipt of Defendants' BLA and manufacturing information and other relevant information to be produced in discovery in this action under the Federal Rules.

PRAYER FOR RELIEF

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

A. Declaring that Defendants have engaged in unfair competition under Cal. Bus. & Prof. Code § 17200 et seq.;

B. Awarding Plaintiffs restitution for Defendants' acts of unfair competition, including Defendants' unlawful proceeds such as gross profits;

C. Enjoining Defendants from commercially marketing the biosimilar product until Amgen is restored to the position it would have been had Defendants met their obligations under the BPCIA;

D. Enjoining Defendants from commercially marketing the biosimilar product until Defendants have provided Amgen with notice of commercial marketing on or after FDA licensure of its biosimilar product, and no later than 180 days before Defendants' first commercial marketing of that product;

E. Enjoining Defendants from continuing to seek FDA review of their § 262(k) application and/or compelling Defendants to suspend FDA review of their § 262(k) application until Defendants have obtained permission from Plaintiffs to use the NEUPOGEN® (filgrastim) license or require Defendants to restore to Amgen the benefits afforded to reference product sponsors in the statute;

F. Awarding Plaintiffs compensatory damages for Defendants' acts of conversion;

G. Awarding Plaintiffs restitution for Defendants' acts of conversion, including Defendants' unlawful proceeds such as gross profits;

H. Awarding Plaintiffs punitive damages for Defendants' acts of conversion;

I. Adjudging and decreeing that Defendants have committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) of the'427 patent by submitting their BLA to the FDA for approval of the Sandoz biosimilar product without providing the required BLA and manufacturing information to Amgen;

J. Declaring that Defendants' infringement under 35 U.S.C. § 271(e)(2)(C)(ii) is and/or will be willful and that this is an exceptional case under 35 U.S.C. § 285;

K. Enjoining Defendants, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '427 patent, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the Sandoz biosimilar product described in Defendants' BLA while the litigation is pending;

L. Permanently enjoining Defendants, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '427 patent, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, importation or distribution of any current or future versions of the Sandoz biosimilar product described in Defendants' BLA;

M. Awarding Plaintiffs their attorneys' fees, costs, and expenses; and

N. Awarding Plaintiffs such other and further relief as this Court may deem to be just and proper.

DEMAND FOR A JURY TRIAL

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

Date: October 24, 2014

___/s/ Vernon M. Winters_____
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