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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

AMGEN'S COMPLAINT

1 Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, “Plaintiffs”),
2 by and through their undersigned attorneys, for their Complaint against Defendants Sandoz
3 Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, “Defendants”) hereby
4 allege as follows:

5 **NATURE OF THE ACTION**

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

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

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

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

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

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

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

1 seq. and conversion under California common law. Defendants have also committed a
2 statutory act of patent infringement under the United States patent law, 35 U.S.C.
3 § 271(e)(2)(C)(ii), by submitting an application for approval of a biological product and
4 failing to provide the BLA and manufacturing information as required by the BPCIA.
5 Despite Amgen's requests, Defendants refuse to honor their obligations under the BPCIA.
6 Accordingly, Plaintiffs turn to this Court for protection of their legal rights. Plaintiffs seek
7 injunctive relief, restitution, attorneys' fees, costs, and expenses.

8 **THE PARTIES**

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

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

17 10. Upon information and belief, Sandoz Inc. is a corporation existing under the
18 laws of the state of New Jersey, with its principal place of business at 506 Carnegie Drive,
19 Suite 400, Princeton, New Jersey 08540. Upon information and belief, acting in concert with
20 Defendants Sandoz International GmbH and Sandoz GmbH, Sandoz Inc. is in the business of
21 developing, manufacturing, and marketing biopharmaceutical products that are distributed
22 and sold in the State of California and throughout the United States. Upon information and
23 belief, Sandoz Inc. is also the United States agent for Sandoz International GmbH and
24 Sandoz GmbH for purposes including, but not limited to, filing regulatory submissions to and
25 corresponding with the FDA.

26 11. Upon information and belief, Sandoz International GmbH is a corporation
27 existing under the laws of Germany with its principal place of business at Industriestrasse 25,
28 83607 Holzkirchen, Germany. Upon information and belief, acting in concert with

1 Defendants Sandoz Inc. and Sandoz GmbH, Sandoz International GmbH is in the business of
2 developing, manufacturing, and marketing biopharmaceutical products that are distributed
3 and sold in the State of California and throughout the United States.

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

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

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

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

19 **JURISDICTION AND VENUE**

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

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

24 18. In the alternative, this Court has subject matter over the case under 28 U.S.C.
25 § 1332 because there is diversity among the parties and the amount in controversy, without
26 interest and costs, exceeds \$75,000.

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

1 manufacture, seek regulatory approval for, import, market, distribute, and sell
2 biopharmaceutical products for sale and use throughout the United States, including in this
3 federal judicial District.

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

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

8 **A. Sandoz Inc.**

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

12 23. This Court has personal specific jurisdiction over Sandoz Inc. because Sandoz
13 Inc. has committed, or aided, abetted, contributed to and/or participated in the commission
14 of, the tortious act of patent infringement and the tortious acts of unfair competition and
15 conversion that have led to foreseeable harm and injury to Amgen, a corporation with its
16 principal place of business in California. In particular, Sandoz, Inc. collaborates to develop,
17 manufacture, seek approval for, and sell the disputed biosimilar product, which will cause
18 tortious injury to Plaintiffs. For example, Amgen received a letter from in-house counsel for
19 Sandoz Inc. dated July 25, 2014, that informed Amgen that Defendants' application for the
20 Sandoz biosimilar product had been accepted by the FDA for review. Moreover, upon
21 information and belief, Sandoz Inc., following any FDA approval of the biosimilar product,
22 will sell the Sandoz biosimilar product that is the subject of the patent infringement, unfair
23 competition, and conversion claims in this action in California and throughout the United
24 States.

25 24. This Court has personal general jurisdiction over Sandoz Inc. by virtue of,
26 *inter alia*, its having conducted business in this District, having availed itself of the rights and
27 benefits of California law, and having engaged in substantial and continuing contacts with
28 California. Upon information and belief, Sandoz has regular and continuous commercial

1 business dealings with representatives, agents, distributors, and customers located in
2 California and this district. In addition, Sandoz has availed itself of this Court as a patent
3 infringement plaintiff, *see, e.g., Sandoz Inc. v. Amgen Inc.*, 3:13-cv-02904-MMC (N.D. Cal.)
4 (appeal pending, Fed. Cir. Appeal No. 2014-1693), and consented to the personal jurisdiction
5 of this Court in numerous other legal proceedings. *See, e.g., Genentech, Inc. v. Sandoz Inc.*,
6 3:11-cv-01925-JSW (N.D. Cal.); *Takeda Pharmaceutical, Co., Ltd. v. Sandoz Inc.*, 5:13-cv-
7 02418-LHK (N.D. Cal.); *Takeda Pharmaceutical, Co., Ltd. v. Sandoz Inc.*, 3:12-cv-00446-
8 JCS (N.D. Cal.).

9 **B. Sandoz International GmbH (Germany)**

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

14 26. Upon information and belief, Sandoz International GmbH exercises
15 considerable control over Sandoz Inc. with respect to biosimilar products, and approves
16 significant decisions of Sandoz Inc. such as allowing Sandoz Inc. to act as the agent for
17 Sandoz International GmbH in connection with preparing and filing the Sandoz BLA, and
18 acting as Sandoz International GmbH's agent in the United States. For example, the Sandoz
19 Management Team includes "Richard Francis, the Global Head of Sandoz," and "Peter
20 Goldschmidt, President of Sandoz US and Head of North America." Upon information and
21 belief, Mr. Francis is the head of Sandoz International GmbH, Mr. Goldschmidt is the
22 President of Sandoz Inc. as well as the Head of North American Operations at Sandoz
23 International GmbH, and Mr. Goldschmidt directly or indirectly reports to Mr. Francis.

24 27. In addition, Sandoz International GmbH and Sandoz Inc. hold themselves out
25 as a unitary entity and have represented to the public that the activities of Sandoz
26 International GmbH and Sandoz Inc. are directed, controlled, and carried out by a single
27 entity, namely, Sandoz. For example, Sandoz maintains an Internet website at the URL
28 www.sandoz.com attached hereto as Ex. A, which states that it is "the website of Sandoz

1 International” and on which Sandoz states that all of the worldwide generic pharmaceutical
2 businesses owned by Novartis operate “under one single global brand as known today:
3 Sandoz.”

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

8 29. Upon information and belief, Sandoz International GmbH acted in concert with
9 Sandoz Inc. to develop a biosimilar version of Plaintiffs’ NEUPOGEN® (filgrastim). Upon
10 information and belief, Sandoz International GmbH acted in concert with, directed, and/or
11 authorized Sandoz Inc. to file a BLA seeking approval from the FDA to market and sell the
12 Sandoz biosimilar product in the State of California and throughout the United States, which
13 directly gives rise to Plaintiffs’ claims of patent infringement. For example, Novartis AG, the
14 ultimate corporate parent of both Sandoz International GmbH and Sandoz Inc., issued a press
15 release on July 24, 2014 from Holzkirchen, Germany announcing that the FDA had accepted
16 Sandoz’s application for biosimilar filgrastim. *See* Press Release, Novartis, FDA Accepts
17 Sandoz Application For Biosimilar Filgrastim (July 24, 2014),
18 <http://www.novartis.com/newsroom/media-releases/en/2014/1835571.shtml>, attached hereto as
19 Ex. B. Upon information and belief, the press release announcing the FDA’s acceptance of the
20 Sandoz’s BLA, which is the subject of Plaintiffs’ claims, was issued on behalf of Sandoz
21 International GmbH.
22
23

24 30. Upon information and belief, Sandoz International GmbH acted in concert
25 with, directed, and/or authorized Sandoz Inc. to communicate with Amgen after receiving
26 FDA notification of the FDA’s acceptance and to unlawfully withhold the BLA for the
27 Sandoz biosimilar product from Amgen while at the same time obtaining the benefits of the
28

1 § 262(k) pathway (such as making use of the FDA’s prior determinations as to the safety,
2 purity, and potency of Plaintiffs’ NEUPOGEN® (filgrastim)), which directly gives rise to
3 Plaintiffs’ claims of unfair competition and conversion. For example, Amgen received
4 correspondence from Sandoz International GmbH dated September 4, 2014 that refers to
5 “**our** decision not to disclose our application to Amgen.” (emphasis added). Similarly,
6 Amgen received further correspondence from Sandoz International, GmbH dated October 20,
7 2014 that refers to an earlier communication from Sandoz, Inc. as “our July 8, 2014 letter”
8 and to an appeal filed by Sandoz, Inc. in co-pending litigation with Amgen as “our appeal.”
9 Letter from Julia Pike, Head, Global IP Litigation, Sandoz Int’l GmbH, to Wendy A.
10 Whiteford, Vice President Law, Amgen Inc. (Oct. 20, 2014). These communications
11 evidence that Sandoz International, GmbH and Sandoz, Inc. are working in concert in their
12 scheme to unlawfully withhold from Amgen the information concerning the Sandoz
13 biosimilar product that is required to be provided under 42 U.S.C. § 262(l)(2)(A).

14 31. Upon information and belief, the acts of Sandoz Inc. complained of herein were
15 done, in part, for the benefit of Sandoz International GmbH. Upon information and belief,
16 Sandoz International GmbH, following any FDA approval, will directly or indirectly
17 manufacture and/or sell the Sandoz biosimilar product that is the subject of the infringement,
18 unfair competition, and conversion claims in this action in California and throughout the United
19 States.

20 32. This Court has personal specific jurisdiction over Sandoz International GmbH
21 because Sandoz International GmbH has directly, or through its agent, committed, or aided,
22 abetted, contributed to and/or participated in the commission of, the tortious act of patent
23 infringement and the tortious acts of unfair competition and conversion that have led to
24 foreseeable harm and injury to Amgen, a corporation with its principal place of business in
25 California.

26 33. Additionally, and in the alternative, Plaintiffs allege that to the extent Sandoz
27 International GmbH is not subject to the jurisdiction of the courts of general jurisdiction of
28 the State of California, Sandoz International GmbH likewise is not subject to the jurisdiction

1 of the courts of general jurisdiction of any state, and accordingly is amenable to service of
2 process based on its aggregate contacts with the United States, including but not limited to
3 the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil
4 Procedure.

5 **B. Sandoz GmbH (Austria)**

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

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

16 36. Upon information and belief, Sandoz GmbH is actively involved with planning
17 Sandoz Inc.’s new biosimilar filgrastim products and filing Defendants’ BLA for the biosimilar
18 product in dispute. 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted
19 to the FDA under the § 262(k) pathway “shall include” information demonstrating “the facility in
20 which the biological product is manufactured, processed, packed, or held meets standards
21 designed to assure that the biological product continues to be safe, pure, and potent.” Upon
22 information and belief, the Sandoz biosimilar product that is the subject of Defendants’ BLA is
23 manufactured at Sandoz GmbH facilities. Therefore, upon information and belief, Sandoz
24 GmbH actively participated in the preparation of Defendants’ BLA, for example by providing
25 information regarding the facilities in which the Sandoz biosimilar product is manufactured,
26 processed, packed, or held. Upon information and belief, Sandoz GmbH has provided similar
27 information for biosimilar filgrastim products in Europe and manufactures those European
28 products. For example, Sandoz GmbH applied for approval to market biosimilar filgrastim in

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

4 37. Upon information and belief, Sandoz GmbH acted in concert with Sandoz Inc.
5 to develop a biosimilar version of Plaintiffs’ NEUPOGEN® (filgrastim). Upon information
6 and belief, Sandoz GmbH acted in concert with, directed, and/or authorized Sandoz Inc. to
7 file a BLA seeking approval from the FDA to market and sell the Sandoz biosimilar product
8 in the State of California and throughout the United States, which directly gives rise to
9 Plaintiffs’ claims of patent infringement. For example, Sandoz GmbH provided ZARZIO®
10 to the then-Global Medical Director at Sandoz International GmbH, Michael Muenzberg, to
11 assess ZARZIO®’s biosimilarity to Plaintiffs’ NEUPOGEN® (filgrastim) product. *See* M.
12 Muenzberg et al., *Development of a New G-CSF Product Based on Biosimilarity Assessment*,
13 21 ANNALS OF ONCOLOGY 1419 (2010), attached hereto as Ex. D.

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

21 39. Upon information and belief, the acts of Sandoz Inc. complained of herein were
22 done, in part, for the benefit of Sandoz GmbH. Upon information and belief, Sandoz GmbH,
23 following any FDA approval, will directly or indirectly manufacture and/or sell the Sandoz
24 biosimilar product that is the subject of the infringement, unfair competition and conversion
25 claims in this action in California and throughout the United States.

26 40. This Court has personal specific jurisdiction over Sandoz GmbH because
27 Sandoz GmbH has directly, or through its agent, committed, or aided, abetted, contributed to
28 and/or participated in the commission of, the tortious act of patent infringement and the

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

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

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

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

23 43. After submission of the BLA, innovative developers must pass demanding
24 stages of clearance. For example, innovative developers are required to demonstrate to the
25 FDA that “the biological product that is the subject of the application is safe, pure, and
26 potent” (42 U.S.C. § 262(a)(2)(C)(i)(I)); and “the facility in which the biological product is
27 manufactured, processed, packed, or held meets standards designed to assure that the
28 biological product continues to be safe, pure, and potent.” 42 U.S.C. § 262(a)(2)(C)(i)(II). If

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

3 44. Not surprisingly, the development of innovative pharmaceutical products
4 requires the investment of enormous amounts of time and money. For example, the time to
5 develop a drug is ten to fifteen years, and the average cost to develop a drug (including the
6 cost of failures) was \$1.2 billion or higher in the early 2000s. See PHARMACEUTICAL
7 RESEARCH AND MANUFACTURERS OF AMERICA, 2013 PROFILE: BIOPHARMACEUTICAL
8 RESEARCH INDUSTRY, at 32, attached hereto as Ex. E; Christopher Paul Adams & Van Vu
9 Brantner, *Spending on New Drug Development*, 19 HEALTH ECONOMICS 130, 139, 141
10 (2010), attached hereto at Ex. F (finding that the cost of drug development (or the net
11 revenue needed to make investment in new drugs profitable) is over \$1 billion: “a firm
12 would need expected net revenue of over \$1 billion to develop one more drug for the
13 market”).

14 45. Amgen went through each of the requirements of 42 U.S.C. § 262(a) (the
15 “§ 262(a) pathway”) to obtain a license from the FDA for its innovative biological product
16 NEUPOGEN® (filgrastim). In 1991, the FDA approved NEUPOGEN® (filgrastim), pursuant to
17 BLA No. 103353, for decreasing the incidence of infection, as manifested by febrile neutropenia,
18 in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs
19 associated with a significant incidence of severe neutropenia with fever. The FDA later
20 approved a series of additional indications for the therapeutic use of NEUPOGEN® (filgrastim),
21 including the treatment of patients with severe chronic neutropenia, patients with acute myeloid
22 leukemia receiving induction or consolidation chemotherapy, patients receiving bone marrow
23 transplant, and patients undergoing peripheral blood progenitor cell collection and therapy. Each
24 of these new indications necessitated Amgen’s further investment to conduct additional clinical
25 testing, submit a supplemental BLA, and prove to the FDA’s satisfaction that NEUPOGEN®
26 (filgrastim) was safe, pure, and potent for each new indication. These approvals are the direct
27 result of very significant investments by Amgen in the development and clinical trials of
28

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

3 46. The active ingredient in NEUPOGEN® is filgrastim, a recombinantly
4 expressed, 175-amino acid form of a protein known as human granulocyte-colony
5 stimulating factor or “G-CSF.” NEUPOGEN® (filgrastim) is also known as recombinant
6 methionyl human granulocyte-colony stimulating factor. By binding to specific receptors on
7 the surface of certain types of cells, NEUPOGEN® (filgrastim) stimulates the production of
8 a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of
9 white blood cells and form a vital part of the human immune system. A deficiency in
10 neutrophils is known as neutropenia, a condition which makes the individual highly
11 susceptible to infection. Neutropenia can result from a number of causes; it is a common
12 side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEUPOGEN®
13 (filgrastim) counteracts neutropenia. The availability of NEUPOGEN® (filgrastim)
14 represented a major advance in cancer treatment by protecting chemotherapy patients from
15 the harmful effects of neutropenia and by thus facilitating more effective chemotherapy
16 regimes.

17 47. Another major advance provided by NEUPOGEN® (filgrastim) is for patients
18 undergoing peripheral blood progenitor cell collection and transplant. In order to
19 successfully treat certain forms of blood cancer, patients undergo hematopoietic progenitor
20 cell transplants. NEUPOGEN® (filgrastim) is indicated for the mobilization of
21 hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
22 Mobilization with NEUPOGEN® (filgrastim) allows for the collection of increased numbers
23 of hematopoietic progenitor cells capable of engraftment compared with collection without
24 the use of NEUPOGEN® (filgrastim) or from bone marrow harvest. Furthermore,
25 transplantation with an increased number of hematopoietic progenitor cells can lead to faster
26 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**

1
2
3 48. On March 23, 2010, the BPCIA was enacted, creating an abbreviated approval
4 pathway for FDA licensure of biological products upon a determination that the biological
5 product is “biosimilar” to a previously licensed “reference product.” 42 U.S.C. § 262(k). The
6 BPCIA defines a “biosimilar” to be a biological product that is (1) “highly similar to the
7 reference product notwithstanding minor differences in clinically inactive components”; and (2)
8 has “no clinically meaningful differences between the biological product and the reference
9 product in terms of the safety, purity, and potency of the product.” 42 U.S.C. §§ 262(i)(2)(A),
10 (B). The BPCIA defines a “reference product” to be “a single biological product licensed under
11 subsection (a) against which the biological product is evaluated in an application submitted
12 under subsection (k).” 42 U.S.C. §§ 262(i)(4).

13 49. As opposed to applicants under the § 262(a) pathway, biosimilar applicants are
14 permitted to make use of the FDA’s prior determinations as to the safety, purity, and potency of
15 the reference product that was already approved by the FDA. Specifically, the § 262(k) pathway
16 may only be used where the prior applicant of the reference product has submitted an application
17 under 42 U.S.C. § 262(a) for approval of a “reference product,” and FDA has determined that the
18 reference product sponsor has demonstrated that “the biological product that is the subject of the
19 application is safe, pure, and potent.” 42 U.S.C. § 262(a)(2)(C)(i)(I). A biosimilar applicant
20 may only request FDA evaluation for biosimilarity under the § 262(k) pathway with respect to
21 no more than one reference product § 262(k)(5)(A) and must submit to the FDA “publicly-
22 available information regarding the Secretary’s previous determination that the reference product
23 is safe, pure, and potent.” 42 U.S.C. § 262(k)(2)(A)(iii)(I). Consequently, the § 262(k) pathway
24 allows the biosimilar applicant to cut short the time and expensive cost of clinical testing, and
25 gain licensure to commercialize its biological product in the market sooner as a biosimilar than it
26 could have done through an independent demonstration of safety, purity, and potency under the
27 § 262(a) pathway. The § 262(k) pathway is thus referred to as an “abbreviated” approval
28 pathway.

1 50. The purpose of the BPCIA is to establish “a biosimilars pathway balancing
2 innovation and consumer interests.” Biologics Price Competition and Innovation Act of 2009,
3 Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) (amending 42 U.S.C. § 262). The
4 statutory provisions of the BPCIA reflect Congressional intent to achieve this balance. In
5 addition to saving the time and expense of the traditional approval pathway under § 262(a),
6 approval under the § 262(k) pathway offers other benefits to the biosimilar applicant. A product
7 that is approved as a biosimilar can take advantage of the existing market for the reference
8 product created by the reference product sponsor. Specifically, the the Patient Protection and
9 Affordable Care Act (PPACA) created a higher Medicare payment rate for biosimilars in the
10 physician clinic setting. Pub. L. No. 111-148, § 3139(a), 124 Stat. 119, 439 (2010) (amending
11 42 U.S.C. § 1395w-3a). In the case of drugs (both biologics and small molecule drugs) other
12 than biosimilars, the Medicare payment rate is the Average Sales Price (ASP)^[1] of the drug plus
13 6 percent of that ASP. 42 U.S.C. § 1395w-3a(b)(1). Under the PPACA amendments, the
14 Medicare payment rate for biosimilars is the ASP of the biosimilar, plus 6 percent of the
15 *reference product’s* ASP. 42 U.S.C. § 1395w-3a(b)(8). This results in a higher payment rate for
16 physicians, assuming the ASP of the reference product is higher than that of the biosimilar. *See*
17 Michael McCaughan, *Biosimilar Reimbursement Under The Sequester: The Lower The Price,*
18 *The Bigger The Spread*, THE PINK SHEET DAILY (Aug. 8, 2014), attached hereto as Ex. G.

21
22 51. Further, a biosimilar product can be approved as “interchangeable” if it meets
23 certain criteria, *i.e.*, the biosimilar product “can be expected to produce the same clinical
24 result as the reference product in any given patient” and “for a biological product that is
25 administered more than once to an individual, the risk in terms of safety or diminished
26 efficacy of alternating or switching between use of the biological product and the reference

27 ^[1] ASP is calculated by the Centers for Medicare & Medicaid Services based on sales
28 information reported to the agency by manufacturers. 42 U.S.C. § 1395w-3a(c).

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

8 52. On the other hand, the BPCIA also sets forth a detailed and elaborate
9 procedure adopted by Congress as a way of balancing the interests of reference product
10 sponsors and biosimilar applicants under the § 262(k) pathway. Of particular relevance to
11 this lawsuit, the BPCIA sets forth particular requirements that the biosimilar applicant must
12 follow in order to obtain the benefits of filing its BLA under the § 262(k) pathway. 42
13 U.S.C. § 262(l). Among other things, these provisions require the biosimilar applicant to
14 provide a copy of its BLA, together with other information necessary to describe the
15 process(es) for manufacturing the biosimilar product to the reference product sponsor. *See*
16 42 U.S.C. § 262(l)(2). This permits the reference product sponsor to evaluate whether it can
17 assert patent claims against the biosimilar applicant for making, using, offering to sell,
18 selling, or importing into the United States the biosimilar product.

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

- 23 a. ***Within 20 days*** after the FDA has accepted its abbreviated application, the biosimilar
24 applicant must provide the reference product sponsor: (i) a copy of the biosimilar
25 application and (ii) other information describing the process(es) for manufacturing the
26 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).
- 27 b. ***Within 60 days*** after receiving the BLA and manufacturing information, the reference
28 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

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

- 5 c. **Within 60 days** after receiving the foregoing list from the reference product sponsor,
6 the biosimilar applicant may provide to the reference product sponsor a list of patents
7 that the biosimilar applicant believes could be subject to a claim of patent
8 infringement. 42 U.S.C. § 262(l)(3)(B)(i). **Within the same 60 days**, regarding any
9 patents listed by the reference product sponsor or the biosimilar applicant, the
10 biosimilar applicant must also provide: (I) a statement describing, on a claim by
11 claim basis, a factual and legal basis for an opinion that a patent is invalid,
12 unenforceable, or not infringed; or (II) a statement that the biosimilar applicant does
13 not intend to market until the patent expires. 42 U.S.C. § 262(l)(3)(B)(ii). The
14 biosimilar applicant must also provide a response to the reference product sponsor's
15 identification of any patents it would be prepared to license. 42 U.S.C.
16 § 262(l)(3)(B)(iii).
- 17 d. **Within 60 days** after receiving the information described immediately above, the
18 reference product sponsor must provide, regarding each patent discussed in (I) above,
19 a reciprocal statement describing, on a claim by claim basis, a factual and legal basis
20 for an opinion that a patent will be infringed as well as a response to any statement
21 regarding validity and enforceability. 42 U.S.C. § 262(l)(3)(C).
- 22 e. After this exchange of information, both parties must engage in good faith
23 negotiations to identify which patents, if any, should be subject to patent infringement
24 litigation. 42 U.S.C. § 262(l)(4)(A). If the parties reach agreement **within 15 days**
25 of starting negotiations, the reference product sponsor must bring an "immediate" patent
26 infringement action against the biosimilar applicant on the negotiated list of patents
27 **within 30 days** of such agreement. 42 U.S.C. § 262(l)(6)(A). If the parties do not
28 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

1 manufacturing information, the biosimilar applicant's contentions, and the biosimilar
2 applicant's response to initial licensing opportunities to consider patent infringement before
3 filing a lawsuit against the biosimilar applicant. Specifically, 42 U.S.C. § 262(l) provides the
4 reference product sponsor with 225 days after receiving the BLA and manufacturing
5 information to exchange patent lists, provide detailed statements of infringement, validity,
6 and enforceability, and engage in good faith negotiations regarding such patent lists prior to
7 filing the "immediate" patent infringement action against the biosimilar applicant. *See*
8 ¶¶ 53(b), (c), (d), (e), *supra*. These procedures provide the reference product sponsor with
9 the benefit of certainty, both as to the scope of the patent disputes and also the characteristics
10 of the biosimilar product.

11 55. 42 U.S.C. § 262(l) also requires the biosimilar applicant provide the reference
12 product sponsor notice at least 180 days before the biosimilar applicant's first commercial
13 marketing of the biosimilar. 42 U.S.C. § 262(l)(8)(A). The biosimilar applicant's obligation
14 to provide this advanced notice of commercial marketing is not conditioned on performance
15 of any act by the reference product sponsor nor exempted in the circumstance of a biosimilar
16 applicant having failed to make the initial disclosures pursuant to 42 USC § 262(l)(2)(A).
17 Rather, 42 U.S.C. § 262(l)(8)(A) simply provides that the "subsection (k) applicant shall
18 provide notice to the reference product sponsor not later than 180 days before the date of first
19 commercial marketing of the biological product licensed under subsection (k)."

20 56. The advanced notice of commercial marketing does, however, enable the
21 reference product sponsor to seek a preliminary injunction before commercial marketing of the
22 biosimilar product has commenced. 42 U.S.C. § 262(l)(8)(B) permits the reference product
23 sponsor to seek a preliminary injunction enjoining the biosimilar applicant from commercially
24 manufacturing or selling the biosimilar product until the court decides the disputed patent issues
25 with respect to any patent that is on the exchanged patent lists, but which were not listed, by
26 negotiation or exchange, for immediate litigation. Accordingly, this provision gives the courts
27 an opportunity to consider the reference product sponsor's motion for preliminary injunction
28

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

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

9 58. After receiving the notice of commercial marketing and before such date of
10 first commercial marketing of such biological product, the reference product sponsor may
11 seek a preliminary injunction prohibiting the biosimilar applicant from engaging in the
12 commercial manufacture or sale of such biological product until the court decides the issue of
13 patent validity, enforcement, and infringement with respect to any patent identified for
14 immediate patent litigation in the lists described above (*see* ¶ 53(e), *supra*). 42 U.S.C.
15 § 262(l)(8)(B). This provision gives the courts an opportunity to consider the reference
16 product sponsor’s motion for preliminary injunction before the status quo has changed and
17 gives the reference product sponsor the opportunity to stop the biosimilar applicant from
18 launching its product before the patent issues are resolved.

19 **DEFENDANTS’ BIOSIMILAR**
20 **APPLICATION UNDER 42 U.S.C. 262(k)**

21 59. Upon information and belief, Defendants filed a BLA with the FDA under
22 § 351(k) of the Public Health Service Act, codified as 42 U.S.C. § 262(k), to obtain approval
23 to commercially market, manufacture, import and sell a biosimilar version of NEUPOGEN®
24 (filgrastim) for treating particular diseases in the United States.

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

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

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

6 62. Upon information and belief, Defendants have not and do not seek to
7 independently demonstrate to the FDA that their biological product is "safe, pure, and
8 potent" pursuant to 42 U.S.C. 262(a), as Amgen did in its BLA for its innovative biological
9 product NEUPOGEN® (filgrastim). Rather, upon information and belief, Defendants have
10 requested that FDA evaluate the suitability of their biological product for licensure, expressly
11 electing and seeking reliance on Amgen's FDA license for NEUPOGEN® (filgrastim).
12 Accordingly, Defendants submitted to the FDA publicly-available information regarding the
13 FDA's previous licensure determination that NEUPOGEN® (filgrastim) is "safe, pure, and
14 potent." 42 U.S.C. 262(k)(2)(A)(iii)(I).

15 63. Upon information and belief, Defendants "received notification from the FDA on
16 July 7, 2014" that the FDA had accepted their BLA for the Sandoz biosimilar product. Letter
17 from Robin Adelstein, Vice President, Legal, IP & Compliance, Sandoz Inc., to Wendy A.
18 Whiteford, Vice President Law, Amgen Inc. (July 25, 2014). Pursuant to the Biosimilar
19 Biological Product Authorization Performance Goal and Procedures, which sets forth FDA goals
20 for fiscal years 2013-2017, the FDA is committed to reviewing and acting "on 70 percent of
21 original biosimilar biological product application submissions within 10 months of receipt" for
22 biosimilar biological product applications filed in 2014.¹ Therefore, the FDA will complete its
23 final review of Sandoz's biosimilar product at least by May 2015. Upon information and belief,
24 Defendants believe that they may secure FDA approval of the Sandoz biosimilar product before

25 ¹ FDA, Biosimilar Biological Product Authorization Performance Goals and Procedures Fiscal
26 Years 2013 through 2017,
27 <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/%20HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf>, attached as Ex. I.
28

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

6 64. Defendants’ receipt of FDA notification that their BLA had been accepted for
 7 review triggered the mandatory obligations set forth in 42 U.S.C. § 262(l). Specifically, the
 8 following provisions are required of Defendants, and would have been required of Amgen
 9 and FDA but for Defendants’ failure to timely comply with their initial disclosure pursuant to
 10 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
<u>Subsection (k) application information.</u> Not later than 20 days after Defendants’ receipt of FDA notification: <ul style="list-style-type: none"> • 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
<u>List and description of patents.</u> Not later than 60 days after Amgen’s receipt of Defendants’ BLA and manufacturing information: <ul style="list-style-type: none"> • 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
<u>List and description by subsection (k) applicant.</u> Not later than 60 days after Defendants’ receipt of Amgen’s patent list: <ul style="list-style-type: none"> • 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
<p>Amgen. 42 U.S.C. § 262(l)(3)(B)(i).</p> <ul style="list-style-type: none"> 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). 	
<p><u>Description by reference product sponsor.</u> Not later than 60 days after Amgen’s receipt of Defendants’ list and statement:</p> <ul style="list-style-type: none"> 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). 	<p>On or before Monday, January 26, 2015</p>
<p><u>Patent resolution negotiations.</u> After Defendants receive Plaintiffs’ detailed statement:</p> <ul style="list-style-type: none"> 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). 	
<p><u>Immediate patent infringement action if agreement on patent list.</u> If there is agreement, then not later than 30 days after such agreement:</p> <ul style="list-style-type: none"> Amgen “shall bring” an action for patent infringement with respect to each patent. 42 U.S.C. § 262(l)(6)(A). 	<p>On or before Wednesday, February 25, 2015, assuming negotiations began on Monday, January 26, 2015.</p>
<p><u>Patent resolution if no agreement.</u> If there is no agreement, then within 15 days of beginning negotiations:</p>	<p>On or before Monday, February 16, 2015,</p>

Provision	Date
<ul style="list-style-type: none"> • 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). 	<p>assuming that Defendants notified Amgen on Tuesday, February 10, 2015.</p>
<p><u>Immediate patent infringement action if no agreement on patent list.</u> Not later than 30 days after the exchange of second patent lists if there is no agreement:</p> <ul style="list-style-type: none"> • 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). 	<p>On or before Wednesday, March 18, 2015</p>
<p><u>Notification and publication of the Complaint.</u> 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):</p> <ul style="list-style-type: none"> • 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). 	<p>On or before Friday, March 27, 2015 if there were agreement</p> <p>On or before Friday, April 17, 2015 if there were no agreement</p>

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

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

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

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

1 69. In addition, Defendants proposed in July 8, 2014 and July 21, 2014 Letters that
2 they provide Amgen with their BLA pursuant to an Offer of Confidential Access. Letter (July
3 25, 2014), *supra* ¶ 63; *see also* Letter (July 8, 2014), *supra* ¶ 63 (also proposing an Offer of
4 Confidential Access). In both letters, Defendants proposed exchanging their BLA, but not
5 manufacturing information. In the July 8, 2014 Letter, Defendants also proposed that Amgen
6 forfeit its right to use the exchanged BLA information as a basis to allege infringement under 35
7 § 271(g), which provides that “[w]hoever without authority imports into the United States or
8 offers to sell, sells, or uses within the United States a product which is made by a process
9 patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale,
10 or use of the product occurs during the term of such process patent.” 42 U.S.C. § 262(l)(1)(A)
11 permits the biosimilar applicant and the reference product sponsor to agree to alternative
12 provisions for the exchange of confidential information. But, this provision applies only to the
13 confidentiality terms that will apply to the information exchanged. The sequence and content of
14 the exchanges, and the obligations imposed on the biosimilar applicant and reference product
15 sponsor, by 42 U.S.C. § 262(l)(2) through 42 U.S.C. § 262(l)(8) are mandatory regardless of
16 what confidentiality provisions may be agreed under 42 U.S.C. § 262(l)(1). Further, in the
17 absence of agreement (“unless otherwise agreed to” by the biosimilar applicant and the reference
18 product), the statute requires that the parties proceed with the confidentiality provisions provided
19 in 42 U.S.C. § 262(l)(1)(A). Defendants’ Offer of Confidential Access purported to replace the
20 requirements of 42 U.S.C. § 262(l)(2) through 42 U.S.C. § 262(l)(8) with an entirely different
21 procedure under which Amgen would have been obligated to commence any patent infringement
22 litigation within 60 days of its receipt of Defendants’ BLA information; attempted to limit the
23 exchange of information to Defendants’ BLA and not include any manufacturing information;
24 and in the July 8, 2014 Letter, attempted to limit Amgen’s cause of actions for patent
25 infringement to exclude process patents. Defendants’ attempts to modify the statutory provisions
26 is not legally permissible.

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

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

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

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

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

6 73. One patent which Amgen believes could have been identified on its list
7 pursuant to 42 U.S.C. § 262(l)(3)(A)(i), is U.S. Patent No. 6,162,427 (“the ‘427 patent”),
8 which covers a method of using NEUPOGEN® (filgrastim) to treat a disease requiring
9 peripheral stem cell transplantation in a patient in need of such treatment. However, Amgen
10 holds numerous other patents directed to processes for manufacturing products such as the
11 Sandoz biosimilar product. As noted above, had Defendants provided Amgen with a copy of
12 their BLA and information necessary to describe the process(es) for manufacturing the
13 Sandoz biosimilar product, Amgen would have complied with its obligations under 42 U.S.C.
14 § 262(l)(3) and identified any patents to which a claim of patent infringement could
15 reasonably be asserted. Amgen therefore reserves the right to seek leave to assert additional
16 patents following eventual receipt of Defendants’ BLA and manufacturing information and
17 other relevant information to be produced in discovery in this action under the Federal Rules.

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

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

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

11 76. Each of Defendants' unlawful acts (violation of 42 U.S.C. § 262(l)(2)(A) and
12 violation of 42 U.S.C. § 262(l)(8)(A)) independently deprive Amgen of the benefits afforded
13 under the statute and which Congress provided to reference product sponsors. Defendants'
14 failure to provide the BLA and manufacturing information to Amgen under 42 U.S.C. §
15 262(l)(2)(A) deprives Plaintiffs of the opportunity to seek a preliminary injunction enjoining
16 Defendants from engaging in the commercial manufacture or sale of the Sandoz biosimilar
17 product in time to prevent irreparable harm to Plaintiffs, *i.e.*, after FDA approval of the
18 Sandoz biosimilar product but before Defendants' commercial marketing of the biosimilar
19 product. In addition, Defendants' failure to provide a legally operative notice of commercial
20 marketing deprives Plaintiffs of the opportunity to seek a court intervention to prevent
21 Plaintiffs from suffering irreparable harm. This too prevents Plaintiffs from enjoining
22 Defendants in time to prevent irreparable harm.

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

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

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

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

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

12 80. In addition and as a separate and independent unlawful act, Defendants have
13 failed and/or will imminently fail to meet its statutory obligation under 42 U.S.C.
14 § 262(l)(8)(A) to provide notice of commercial marketing to Amgen upon or after FDA
15 approval. Defendants' violations of the BPCIA satisfy the "unlawful" prong of § 17200.

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

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

1 that was spent to monitor and respond to Defendants' acts of unfair competition. Plaintiffs
2 will also suffer lost profits and increased costs if Defendants are permitted to commercially
3 market the Sandoz biosimilar product without satisfying their obligations under 42 U.S.C.
4 § 262(l). In addition, Plaintiffs will suffer loss of value of their patents as a result of
5 Defendants' actions by forcing Plaintiffs to assert one or more of their patents (including
6 process patents) after Defendants' commercial entry into the market as discussed in ¶ 74
7 above.

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

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

17 85. Plaintiffs are entitled to an order enjoining Defendants from commercially
18 marketing the biosimilar product until Plaintiffs are restored to the position they would have
19 been had Defendants met their obligations under the BPCIA, *e.g.*, providing Amgen with the
20 BLA and manufacturing information and the equivalent information and time required under
21 42 U.S.C. § 262(l) for evaluating Defendants' BLA and manufacturing information so that
22 Plaintiffs may bring a patent infringement action and/or preliminary injunction in time to
23 prevent irreparable harm to Plaintiffs (after FDA approval of the Sandoz biosimilar product
24 but before Defendants' commercial marketing of the biosimilar product).

25 86. Plaintiffs are entitled to an order compelling Defendants to provide Amgen
26 with notice of commercial marketing on or after FDA licensure of its biosimilar product, and
27 no later than 180 days before Defendants' first commercial marketing of that product.
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SECOND CAUSE OF ACTION
(CONVERSION)

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

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

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

23 90. The biological license for NEUPOGEN® (filgrastim) is owned by Amgen and
24 exclusively licensed to AML. Plaintiffs have a legitimate claim to exclusivity in the license
25 because of the significant effort, investment, and expertise required to obtain the license:
26 Amgen expended considerable time, expense, and resources in research and design; Amgen
27 conducted the appropriate tests and compiled the necessary data; Amgen prepared the BLA
28

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

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

22 92. By reason of and as a direct and proximate cause of Defendants’ wrongful
23 acts of conversion, Plaintiffs have suffered and will continue to suffer damages due to the
24 lost value of Amgen’s biological license for NEUPOGEN® (filgrastim). The detriment
25 caused by Defendants’ conversion is presumed to include the value of Plaintiffs’ property at
26 the time of conversion. *See* Cal. Civ. Code § 3336. Here, Defendants have derived and will
27 continue to derive value from Amgen’s license by seeking approval under the abbreviated
28 § 262(k) pathway rather than the § 262(a) pathway. Had Defendants not wrongfully

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

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

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

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

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

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

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

4 **THIRD CAUSE OF ACTION**
5 **(PATENT INFRINGEMENT)**

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

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

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

12 101. Upon information and belief, the purpose of Defendants’ BLA for the Sandoz
13 biosimilar product is to obtain approval to engage in the commercial marketing, manufacture,
14 import, and sale of a biological product for treating particular diseases in the United States,
15 one use of which is claimed in the ’427 patent before the expiration of such patent. Upon
16 information and belief, Defendants seek to market, manufacture, import, distribute, sell,
17 and/or offer to sell the Sandoz biosimilar product for treating particular diseases in the
18 United States immediately upon receipt of FDA approval and prior to the expiration of the
19 ’427 patent.

20 102. Defendants have committed a statutory act of infringement under 35 U.S.C.
21 § 271(e)(2)(C)(ii) of the ’427 patent by virtue of their submission of the BLA for the Sandoz
22 biosimilar product and failure to provide the required BLA and manufacturing information to
23 Amgen within 20 days after the FDA notified Defendants on July 7, 2014 that their BLA was
24 accepted for review.

25 103. Upon information and belief, Defendants intended to violate the statute by
26 failing to disclose the required BLA and manufacturing information to Amgen within 20
27 days after the FDA accepted Defendants’ BLA, and Defendants chose to disclose their non-
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1 compliance to Amgen one day after the 20 day period had expired. Defendants' actions
2 constitute a knowing and willful infringement under 35 U.S.C. § 271(e)(2)(C)(ii).

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

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

17 106. As set forth in ¶¶ 72-73 above, Plaintiffs reserve the right to seek leave to
18 assert additional patents following eventual receipt of Defendants' BLA and manufacturing
19 information and other relevant information to be produced in discovery in this action under
20 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;

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

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

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

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

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

16 **DEMAND FOR A JURY TRIAL**

17 Plaintiffs hereby demand a jury trial on all issues so triable.
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1 Date: October 24, 2014

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