UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. and PFIZER INC., Defendants.	DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Hospira, Inc. and Pfizer Inc. (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen is a pioneer in the development of biological human therapeutics. Today, Amgen is one of the largest biotechnology companies in the world, fueled in part by the success of NEUPOGEN® (filgrastim).

2. 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. AML is a wholly-owned subsidiary of Amgen.

3. On information and belief, Hospira, Inc. ("Hospira") is a corporation existing under the laws of the State of Delaware, with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. On information and belief, Pfizer Inc. ("Pfizer") is a corporation existing under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, Hospira is a wholly-owned subsidiary of Pfizer.

6. On 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 this judicial District and throughout the United States.

NATURE OF THE ACTION

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

8. By amendment to the Public Health Service Act, the BPCIA created a new, abbreviated pathway for the approval of biological products that are highly similar to previously-licensed innovative biological products. Codified at 42 U.S.C. § 262(k), the new abbreviated pathway, often referred to as "the subsection (k) pathway," allows a biosimilar applicant to secure a license from the Food and Drug Administration ("the FDA") by relying on a prior license granted to an innovator company ("the Reference Product Sponsor" or "RPS") for its innovative biological product ("the reference product"). The reference product must have been licensed by the FDA under the innovator pathway of 42 U.S.C. § 262(a), often referred to as "the

subsection (a) pathway," which requires proof of safety and efficacy through a series of phased clinical trials.

9. In this case, Hospira is a biosimilar applicant acting in concert with Pfizer, its corporate parent, and Amgen is a Reference Product Sponsor. Hospira seeks FDA licensure under the subsection (k) pathway for a biosimilar version of Amgen's NEUPOGEN® (filgrastim) product.

10. Seeking the benefits of the subsection (k) pathway, Hospira, acting in concert with Pfizer, submitted its abbreviated Biologic License Application ("aBLA") No. 761080 ("the Hospira aBLA") to the FDA, requesting that its biological product ("the Hospira Filgrastim Biosimilar Product") be licensed by relying on Amgen's demonstration of the safety and efficacy of NEUPOGEN® (filgrastim).

11. The asserted patent is U.S. Patent No. 9,643,997 ("the '997 Patent"). The '997 Patent is directed to methods of purifying proteins used in the manufacture of a biological product.

12. On information and belief, Hospira, acting in concert with Pfizer, submitted the Hospira aBLA to the FDA before the expiration of the '997 Patent.

13. Amgen included the '997 Patent on its February 8, 2018 disclosure under 42 U.S.C. § 262(*l*)(3)(A).

14. Here, Defendants committed an act of infringement of one or more of the claims of the '997 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Hospira to submit the Hospira aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Hospira Filgrastim Biosimilar Product.

15. If the FDA issues a license to Hospira for the Hospira Filgrastim Biosimilar Product, and Defendants import that product into the United States, or offer to sell, sell, or use that product within the United States, Defendants will also infringe one or more claims of the '997 Patent under 35 U.S.C. § 271(g).

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

17. This Court has personal jurisdiction over Hospira because, among other things, on information and belief, Hospira is a Delaware corporation, has conducted business in this District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

18. This Court has personal jurisdiction over Pfizer because, among other things, on information and belief, Pfizer is a Delaware corporation, has conducted business in this District, has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with Delaware.

19. Amgen is a Delaware corporation and has suffered injury in Delaware as a result of the Defendants' infringement of Amgen's patent.

20. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b) at least because, on information and belief, each Defendant is a corporation incorporated in the State of Delaware.

BACKGROUND

A. Amgen's innovative biological product, NEUPOGEN® (filgrastim)

21. The active ingredient in Amgen's NEUPOGEN® is filgrastim, a recombinantly expressed, 175-amino-acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF"). NEUPOGEN® is indicated to (1) decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs; (2) reduce the time to neutrophil recovery and duration of fever, following induction or consolidation chemotherapy treatment of adults with Acute Myeloid Leukemia (AML); (3) reduce the duration of neutropenia and neutropenia-related clinical sequelae in cancer patients undergoing bone marrow transplantation; (4) mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; (5) reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital neutropenia, cyclic neutropenia, and idiopathic neutropenia; and (6) increase survival in patients acutely exposed to myelosuppressive doses of radiation.

22. By binding to specific receptors on the surface of certain types of cells, NEUPOGEN® stimulates the production of a type of white blood cell 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® counteracts neutropenia.

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

B. Defendants seek approval to market a biosimilar version of NEUPOGEN® (filgrastim) by taking advantage of the abbreviated subsection (k) pathway of the BPCIA

24. Defendants are seeking approval from the FDA to sell a "biosimilar" version of NEUPOGEN® (filgrastim) by taking advantage of a new, abbreviated approval pathway under the BPCIA.

25. Congress enacted the BPCIA on March 23, 2010. 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 requirements of the BPCIA reflect Congress's intent to achieve this balance.

26. The BPCIA created the subsection (k) pathway, 42 U.S.C. § 262(k), for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously-licensed "reference product." The BPCIA defines a "biosimilar" to be a biological product that: (1) is "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A) and (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).

27. As opposed to applicants following the § 262(a) pathway, biosimilar applicants following the § 262(k) pathway have the advantage of referencing the innovator's license—the FDA evaluates the safety and efficacy of the applicant's biological product by relying on the innovator's prior demonstration of safety, purity, and potency of the reference product.

Specifically, the § 262(k) pathway may only be used where the prior applicant for the reference product has submitted an application under 42 U.S.C. § 262(a) for approval of a reference product, and the 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).

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

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

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

31. On information and belief, Hospira, acting in concert with Pfizer, submitted the Hospira aBLA to the FDA under the subsection (k) pathway. The Hospira aBLA seeks approval to commercially manufacture, use, offer to sell, and sell, and import into the United States, the

Hospira Filgrastim Biosimilar Product, a biosimilar version of Plaintiffs' NEUPOGEN® (filgrastim) product.

32. The applicant named in the Hospira aBLA is "Hospira, Inc., a Pfizer Company." The Hospira Filgrastim Biosimilar Product is described in the Hospira aBLA as PF-06881893.

33. On information and belief, the FDA has not yet approved the Hospira aBLA. The FDA has stated that the agency's goal is to act on the majority of subsection (k) applications within 10 months of submission. On information and belief, the FDA may complete its review of the Hospira aBLA and issue a license to Hospira for the Hospira Filgrastim Biosimilar Product by about the end of July 2018.

34. The Hospira Filgrastim Biosimilar Product is designed to copy and compete with Amgen's NEUPOGEN® (filgrastim). Hospira will instruct or direct others to administer the Hospira Filgrastim Biosimilar Product to certain patients in the U.S. to treat particular diseases in the same way that Amgen's NEUPOGEN® (filgrastim) is administered. Hospira is seeking FDA approval for one or more indications for which NEUPOGEN® (filgrastim) is already approved.

35. Amgen holds Biologic License Application ("BLA") No. 103353 for filgrastim and is therefore the Reference Product Sponsor with respect to any biosimilar versions of filgrastim. Hospira does not seek to independently demonstrate to the FDA that its 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, Hospira has requested that the FDA evaluate the suitability of its biological product for licensure by expressly referencing NEUPOGEN® (filgrastim) and thereby relying on the data supporting Amgen's FDA license for NEUPOGEN® (filgrastim). 42 U.S.C. § 262(k)(2)(A)(iii)(I).

C. The information exchange under 42 U.S.C. § 262(*l*)

36. In addition to creating an abbreviated pathway for the approval of biosimilars, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2) through (*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

37. On December 4, 2017, Defendants, through their counsel, sent a letter to Amgen providing notice that the Hospira aBLA "was recently accepted for filing by FDA" and that "Pfizer intends to provide [Amgen], as the holder of BLA No. 103353 for filgrastim and the 'reference product sponsor,' a copy of the [Hospira aBLA]." Through its counsel, Amgen responded on December 8, 2017, designating outside counsel and in-house counsel to have access to the Hospira aBLA.

38. Under 42 U.S.C. § 262(*l*)(2)(A), Defendants were required to provide to Amgen "a copy of the application submitted to [the FDA] under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."

39. On December 11, 2017, Defendants produced some sections of the Hospira aBLA to Amgen with a cover letter indicating that Defendants were providing "the full" Hospira aBLA.

40. Following a brief review of Defendants' December 11 production, counsel for Amgen suspected that Defendants had not produced their entire aBLA, and on December 12, 2017, counsel for Amgen asked Defendants' counsel to "confirm whether Pfizer has produced its entire ABLA, or whether it has redacted or withheld any portions of it." Defendants' counsel responded on December 15, 2017 indicating that Amgen "should have the entire ABLA."

41. Following further review of Defendants' production, however, it was apparent to Amgen that Defendants had not produced the entirety of the Hospira aBLA. Amgen promptly brought this concern to Defendants' attention in a letter on December 21, 2017. In response, Defendants produced additional portions of the Hospira aBLA on December 22, 2017, and January 4, 2018, which Defendants characterized as a "few minor additional sections" of the Hospira aBLA that "were inadvertently not included with" Defendants' production on December 11, including "a couple minor items that were not included as part of module 1.1."

42. Yet, despite these repeated assurances that Defendants had produced a complete copy of the Hospira aBLA, and Defendants' supplemental productions of additional portions thereof, after continued review of Defendants' production, Amgen concluded that Defendants still had not produced numerous sections of the Hospira aBLA to Amgen. In part, Amgen concluded that some sections were missing from the production because some of the missing sections were cross-referenced in the limited sections of the aBLA that Defendants had produced. Counsel for Amgen once again brought this failure to comply with § 262(*l*)(2)(A) to Defendants' attention in a letter dated January 30, 2018, which provided examples of numerous sections that were referenced in the Hospira aBLA, but had not been produced to Amgen.

43. On February 13, 2018, over a week after the deadline for Amgen to serve its disclosure under § 262(*l*)(3)(A), Defendants responded to Amgen's January 30, 2018 letter by producing additional documents that Defendants claimed "were inadvertently not included in [Defendants'] original production." This late production included over 70,000 additional pages of the Hospira aBLA, far exceeding the approximately 10,000 pages that Defendants had previously produced.

44. Despite Defendants' deficient and/or untimely disclosure under § 262(*l*)(2)(A), Amgen has nevertheless engaged in the statutory process to the extent possible. On February 8, 2018, Amgen provided its disclosure under 42 U.S.C. § 262(*l*)(3)(A) to Defendants identifying six patents that, based on the information Defendants had provided to date, Amgen believed a claim of patent infringement could reasonably be asserted if a person not licensed by Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the Hospira aBLA (as described in the portions of the Hospira aBLA provided to Amgen on December 11 and 22, 2017, and January 4, 2018). On March 5, 2018, Amgen disclosed a newly-issued patent to Defendants under § 262(*l*)(7).

45. On April 4, 2018, Defendants provided to Amgen a statement under 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), and on June 1, 2018, Amgen provided to Defendants a statement under 42 U.S.C. § 262(*l*)(3)(C).

46. Beginning with a telephone conference on June 7, 2018, the parties engaged in a negotiation under 42 U.S.C. § 262(*l*)(4)(A), which requires the parties to engage in "good-faith negotiations" in an effort to "agree on which, if any, patents . . . shall be the subject of an action for patent infringement under [42 U.S.C. § 262(*l*)(6)]."

47. After additional communications among counsel, on June 22, 2018, the parties agreed that only the '997 Patent would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). The parties reached this agreement within 15 days of beginning their negotiations under 42 U.S.C. § 262(*l*)(4)(A).

48. Amgen filed this Complaint within the timeframe required under 42 U.S.C. § 262(*l*)(6) because Amgen filed this Complaint within 30 days after the parties reached

agreement that only the ’997 Patent would be the subject of an action for patent infringement under § 262(*l*)(6).

THE PATENT-IN-SUIT

49. Amgen Inc. is the owner of all rights, title, and interest in U.S. Patent No. 9,643,997 (“the ’997 Patent”).

50. AML holds an exclusive license to the ’997 Patent.

51. The ’997 Patent is titled “Capture Purification Processes for Proteins Expressed in a Non-Mammalian System.” The ’997 Patent was duly and legally issued on May 9, 2017 by the United States Patent and Trademark Office (“USPTO”). A true and correct copy of the ’997 Patent is attached to this Complaint as Exhibit A.

52. The ’997 Patent is directed to a process for purifying proteins.

CAUSES OF ACTION

FIRST COUNT
INFRINGEMENT OF U.S. PATENT NO. 9,643,997 UNDER 35 U.S.C. § 271(e)(2)(C)

53. Amgen incorporates by reference the foregoing paragraphs as if fully set forth herein.

54. On information and belief, Defendants seek FDA approval under the subsection (k) pathway to engage in the commercial manufacture, use, or sale of the Hospira Filgrastim Biosimilar Product, a proposed biosimilar version of Amgen’s NEUPOGEN® (filgrastim) product.

55. Amgen included the ’997 Patent on its disclosure under 42 U.S.C. § 262(*l*)(3)(A).

56. Defendants committed an act of infringement with respect to the ’997 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Hospira to submit the Hospira aBLA for the

purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Hospira Filgrastim Biosimilar Product.

57. On information and belief, Defendants intend to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Hospira Filgrastim Biosimilar Product before the expiration of the ’997 Patent.

58. On information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Hospira Filgrastim Biosimilar Product will infringe, literally or under the doctrine of equivalents, one or more claims of the ’997 Patent.

59. Representative claim 9 of the ’997 Patent recites:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (d) washing the separation matrix; and
>
> (e) eluting the protein from the separation matrix.

’997 Patent at 22:36-55.

60. On information and belief, the process by which Defendants manufacture the Hospira Filgrastim Biosimilar Product satisfies each limitation of at least independent claim 9 and also certain dependent claims, literally or equivalently. With respect to the requirement that

the protein is expressed in a non-native limited solubility form in a non-mammalian expression system, Defendants practice a process for purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system. With respect to the requirement of the "solubilizing" step, in the Defendants' process, Defendants solubilize the protein in a solubilization solution comprising one or more of a denaturant, reductant, and surfactant. With respect to the requirement of the "forming" step, in the Defendants' process, Defendants form a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of a denaturant, aggregation suppressor, protein stabilizer, and redox component. With respect to the requirement of the "applying" step, Defendants apply the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix. With respect to the requirement of the "washing" step, Defendants wash the separation matrix. With respect to the requirement of the "eluting" step, Defendants elute the protein from the separation matrix.

61. Under 42 U.S.C. § 262(*l*)(3)(C), Amgen has provided Defendants with a detailed statement describing the factual and legal bases of Amgen's opinion that Defendants will infringe the '997 Patent through the commercial marketing of the biological product that is the subject of the Hospira aBLA. That statement provides additional details to Defendants about Amgen's assertion of infringement of the '997 Patent including references to confidential information that Defendants provided to Amgen under 42 U.S.C. § 262(*l*)(2). Amgen does not repeat its detailed statement here because under 42 U.S.C. § 262(*l*)(1)(F), Amgen is not permitted to include Defendants' confidential information provided under § 262(*l*)(2) "in any publicly-available complaint or other pleading."

62. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’997 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

63. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Hospira Filgrastim Biosimilar Product before the expiration of the ’997 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND COUNT
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’997 PATENT UNDER 35 U.S.C. § 271(g)

64. Plaintiffs incorporate by reference the foregoing paragraphs as if fully set forth herein.

65. On information and belief, Defendants seek FDA approval under the subsection (k) pathway to manufacture and sell the Hospira Filgrastim Biosimilar Product, a biosimilar version of Amgen’s NEUPOGEN® (filgrastim) product.

66. On information and belief, the FDA may act on the Hospira aBLA as soon as July 2018 leading to Defendants’ commercial launch of the Hospira Filgrastim Biosimilar Product.

67. The FDA has stated publicly that the agency’s goal is to act on the majority of subsection (k) applications within 10 months of submission. *See* https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/ucm311121.htm. This 10-month date is sometimes called a “BsUFA date,” which is an abbreviation for Biosimilar User Fee Act date. On information and belief, the anticipated BsUFA date for the Hospira Filgrastim Biosimilar Product is in July 2018.

68. On information and belief, Defendants intend to, and will upon FDA licensure of the Hospira Filgrastim Biosimilar Product, import into the United States, and offer to sell, sell, and use within the United States, the Hospira Filgrastim Biosimilar Product, which will infringe one or more claims of the ’997 Patent under 35 U.S.C. § 271(g).

69. An actual controversy has arisen and now exists between the parties concerning whether the Hospira Filgrastim Biosimilar Product has or will infringe one or more claims of the ’997 Patent.

70. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the ’997 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, the Hospira Filgrastim Biosimilar Product before the expiration of the ’997 Patent.

71. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’997 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, the Hospira Filgrastim Biosimilar Product before the expiration of the ’997 Patent.

72. Defendants’ manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Hospira Filgrastim Biosimilar Product before the expiration of the ’997 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284 or other monetary relief.

PRAYER FOR RELIEF

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

A. A judgment that Defendants have infringed one or more claims of the ’997 Patent under 35 U.S.C. § 271(e)(2)(C)(i);

B. A judgment that Defendants have infringed and will infringe one or more claims of the ’997 Patent under 35 U.S.C. § 271(g);

C. An order enjoining Defendants, their officers, partners, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, other related business entities, and those persons in active concert or participation with any of them, from infringing the ’997 Patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any current or future versions of the Hospira Filgrastim Biosimilar Product, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

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

E. A declaration that this is an exceptional case and awarding to Amgen its attorneys’ fees and costs pursuant to 35 U.S.C. § 285; and

F. Such other relief as this Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Amgen hereby demands a jury trial on all issues so triable.

July 18, 2018

Respectfully submitted,

/s/ Robert W. Whetzel

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