IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. Defendant.	C.A. No. 1:15-cv-00839-RGA [redacted]

DEFENDANT HOSPIRA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Hospira, Inc. ("Hospira"), by and through its attorneys, hereby submits this Answer, Affirmative Defenses, and Counterclaims to the Amended Complaint filed by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") on November 6, 2015 (the "Amended Complaint").

ANSWER TO AMENDED COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a "Paragraph") in the Amended Complaint. Hospira denies all allegations in the Amended Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Hospira denies that Amgen is entitled to the relief requested or any other relief. Hospira responds to the Amended Complaint as follows:

THE PARTIES

1. Hospira lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 and, therefore, denies the same.

2. Hospira lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and, therefore, denies the same.

3. Hospira lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 and, therefore, denies the same.

4. Admitted.

5. Hospira admits that Hospira, Inc. was formed in 2004 and that it manufactures and sells certain pharmaceutical injectable products. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Hospira Product") described in Hospira's BLA No. 125-545 ("Hospira's BLA"). Hospira otherwise denies the allegations of Paragraph 5.

NATURE OF THE ACTION

6. Hospira admits that the Amended Complaint purports to bring a civil action for patent infringement under 35 U.S.C. § 271(e)(2)(C). Hospira further admits that § 271(e)(2)(C) was enacted in 2010 in the part of the Patient Protection and Affordable Care Act known as the Biologics Price Competition and Innovation Act (the "BPCIA"). Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 6 and, therefore, denies the same.

7. Hospira admits that the Amended Complaint purports to bring a civil action for declaratory judgment of violation of 42 U.S.C. § 262(*l*)(8)(A). Hospira denies that the BPCIA provides for a private right of action to enforce these provisions and denies that Amgen is entitled to any relief in

this action. Hospira denies the remaining allegations of Paragraph 7.

8. The allegations of Paragraph 8 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (*see* Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010)), establishing an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilar pathway balancing innovation and consumer interests." *Id.* at 804. The Food and Drug Administration ("FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a). *Id.* The BPCIA, by contrast and design, allows an applicant to file an abbreviated biologics license application ("aBLA" or "subsection (k) application"), to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)-(5); *see also id.* § 262(i). The BPCIA thus authorizes a biosimilar applicant to rely in part on the approved license of a reference product.

9. Hospira admits that the BPCIA amended the PHSA to create an abbreviated pathway for approval and an intricate and carefully orchestrated set of procedures between the subsection (k) applicant and the reference product sponsor if the subsection (k) applicant chooses to make such disclosures. The remaining allegations of Paragraph 9 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

10. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 10.

11. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA, including the disclosure and notice provisions (42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(8)(A), respectively). Hospira otherwise denies the allegations of Paragraph 11.

12. The allegations of Paragraph 12 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies the allegations of Paragraph 12. Hospira has fully complied with all relevant provisions of 42 U.S.C. § 262(*l*)(2)(A), including by producing to Amgen over 4,200 documents totaling over 747,000 pages of detailed information that completely describes the Hospira Product and the process or processes used to manufacture the biological product that is the subject of such application. Hospira denies that the information provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(1)-(2) was in any way incomplete or otherwise deficient, or that Amgen's ability to identify patents in accordance with 42 U.S.C. § 262(*l*)(3)(A) was limited in any way by Hospira.

13. The allegations of Paragraph 13 contain conclusions of law for which no response is required. Furthermore, the allegations of Paragraph 13 are not relevant to any of the Counts in the Amended Complaint and therefore no response is required. To the extent an answer is required, Hospira denies the allegations of Paragraph 13. Hospira has fully complied with all provisions of 42 U.S.C. § 262(*l*)(4), including by engaging in negotiations that concluded on August 19, 2015

when Hospira accepted the patents listed in Amgen's § 262(*l*)(3)(A) disclosure as constituting the list of patents required to be litigated by § 262(*l*)(6). This negotiation resulted in Amgen filing an initial Complaint and subsequently this Amended Complaint alleging patent infringement on two of the patents included in Amgen's § 262(*l*)(3)(A) list. Amgen's assertion that Hospira has refused to negotiate under 42 U.S.C. § 262(*l*)(4) is incorrect, and reflects a flawed view of the statutory provisions. Furthermore, Hospira denies that the BPCIA provides for a private right of action to enforce the negotiation provisions of the BPCIA and denies that Amgen is entitled to any relief in this action.

14. The allegations of Paragraph 14 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies the allegations of Paragraph 14. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA.

15. The allegations of Paragraph 15 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies the allegations of Paragraph 15. The manufacture, use, offer for sale, sale and/or import of the Hospira Product do not and will not infringe any valid claim of any patent identified under 42 U.S.C. § 262(*l*)(3)(A).

JURISDICTION AND VENUE

16. Hospira admits that the Amended Complaint purports to bring an action to declare the rights and obligations of the parties under Section 262 of the PHSA, Title 42, United States Code, and for patent infringement under the patent laws of the United States, Title 35, United States Code. Hospira denies that Amgen is entitled to any relief in this action. Hospira denies that this Court has subject-matter jurisdiction over Count 1 because that Count does not allege a civil action arising under any law. The remaining allegations of Paragraph 16 contain conclusions of law for which no response is required.

17. Hospira admits that it manufactures, seeks regulatory approval to market, distribute, and sell pharmaceutical products, and markets, distributes, and sells pharmaceutical products for use throughout the United States. Hospira does not contest venue for purposes of this action only. The remaining allegations of Paragraph 17 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies the remaining allegations of Paragraph 17.

18. Hospira admits that it is a corporation incorporated in Delaware. Hospira does not contest personal jurisdiction for purposes of this action only. The remaining allegations of Paragraph 18 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies the remaining allegations of Paragraph 18.

BACKGROUND

A. Amgen's innovative biological product, EPOGEN® (epoetin alfa)

19. Upon information and belief, Hospira admits that the label for EPOGEN® states that the active ingredient is epoetin alfa, a 165-amino-acid glycoprotein that is produced by mammalian cells into which the human erythropoietin gene has been introduced. Upon information and belief, Hospira admits that the label for EPOGEN® states that EPOGEN® stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. Upon information and belief, Hospira admits that the EPOGEN® label states that it is indicated for the treatment of anemia due to chronic kidney disease in patients on dialysis and not on dialysis. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 19 and, therefore, denies the same.

20. Upon information and belief, Hospira admits that Amgen is engaged in the development of biologic drugs, including EPOGEN®. Upon information and belief, Hospira admits that EPOGEN® may be used in the treatment of anemia. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 20 and,

therefore, denies the same.

21. Hospira admits that biological products for human therapeutic use are regulated by the FDA under the PHSA. The remaining allegations contained in Paragraph 21 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and, therefore, denies the same.

22. The allegations contained in Paragraph 22 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and, therefore, Hospira denies the same.

23. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 23 and, therefore, denies the same.

24. Upon information and belief, Hospira admits that the FDA approved EPOGEN® (epoetin alfa) pursuant to BLA No. 103234 in 1989. Upon information and belief, Hospira admits that the label for EPOGEN® states that EPOGEN® is indicated for the treatment of anemia due to chronic kidney disease in patients on dialysis and not on dialysis; zidovudine in HIV-infected patients; the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; and reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 24 and, therefore, denies the same.

B. Hospira seeks approval to market a biosimilar version of EPOGEN® (epoetin alfa) by taking advantage of the abbreviated subsection (k) pathway of the BPCIA

25. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described

in Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 25.

26. Denied. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA.

C. The BPCIA reflects Congress's balancing of the interests of innovators and biosimilar applicants

27. Admitted.

28. The allegations of Paragraph 28 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

29. The allegations of Paragraph 29 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

30. The allegations of Paragraph 30 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

31. The allegations of Paragraph 31 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

32. The allegations of Paragraph 32 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

33. Hospira denies the allegations contained in Paragraph 33. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. The BPCIA offers a biosimilar applicant the option either to comply with the provisions of 42 U.S.C. § 262(*l*) or absorb

the consequences set forth in 42 U.S.C. § 262(*l*)(9), including an action under 28 U.S.C. § 2201 for a declaration of patent infringement.

34. The allegations of Paragraph 34 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. The BPCIA established a streamlined patent-dispute-resolution regime by amending Titles 28, 35, and 42 of the United States Code to create an artificial "act of infringement" that allows infringement suits based on a biosimilar application prior to FDA approval and prior to marketing of the biological product. This process encourages the biosimilar applicant and the RPS to resolve patent disputes. As a first step, the applicant may choose to grant the RPS with confidential access to its aBLA and the manufacturing information regarding its biosimilar product no later than 20 days after the FDA accepts the applicant's aBLA for review. The parties may then exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted by the RPS. Following their exchanges, the parties may then negotiate a list of patents (the "listed patents") that would be the subject of an immediate infringement action (*see* 42 U.S.C. § 262(*l*)(4)-(5)). The RPS may then sue the biosimilar applicant within 30 days. *Id.* at § 262(*l*)(6).

35. The allegations of Paragraph 35 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law, and also denies any factual allegations contained in Paragraph 35, including that the BPCIA provides for a private right of action to enforce the notice provisions of the BPCIA and denies that Amgen is entitled to any relief in this action.

36. The allegations of Paragraph 36 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

D. Hospira seeks the benefits of the BPCIA pathway under 42 U.S.C. § 262(k) but refuses to comply with all of its obligations under § 262(*l*)

1. The Hospira BLA

37. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA that was submitted to the FDA on December 16, 2014. Hospira otherwise denies the allegations of Paragraph 37.

38. Hospira admits that EPOGEN® is the reference product for Hospira's BLA. Hospira admits that it is seeking licensure of the Hospira Product for one or more indications for which EPOGEN® is already approved. Hospira otherwise denies the allegations of Paragraph 38.

39. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira also admits that EPOGEN® is the reference product for Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 39.

40. Hospira admits that in a letter dated February 23, 2015, Hospira notified Amgen that the "Hospira BLA recently was accepted for filing by FDA." Hospira admits that the FDA has not yet approved Hospira's BLA. The remaining allegations contained in Paragraph 40 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and, therefore, denies the same.

41. Hospira denies the allegations contained in Paragraph 41. There is no linkage in the BPCIA

between the patent exchange provisions and the regulatory approval pathway. The BPCIA gives a biosimilar applicant the option either to share its biosimilar application with the reference product sponsor not later than 20 days after acceptance of the BLA by the FDA for review or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement pursuant to 42 U.S.C. § 262(*l*)(9)(C).

42. Hospira denies the allegations contained in Paragraph 42. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. The BPCIA gives a biosimilar applicant the option either to share its biosimilar application with the reference product sponsor not later than 20 days after acceptance of the BLA by the FDA for review or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement pursuant to 42 U.S.C. § 262(*l*)(9)(C).

43. Hospira admits that it sent a copy of its complete BLA via hard drive on March 2, 2015, in full compliance with § 262(*l*)(2)(A). Indeed, Hospira's BLA contained over 747,000 pages of information on its product and the processes to make its product, including 507 files that were produced natively. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. Hospira otherwise denies the allegations of Paragraph 43.

2. Hospira violated § 262(*l*)(2)(A)

44. Hospira admits that it sent a copy of its complete BLA via hard drive on March 2, 2015, in full compliance with § 262(*l*)(2)(A). Indeed, Hospira's BLA contained over 747,000 pages of information on its product and the processes to make its product, including 507 files that were produced natively. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. Hospira otherwise denies the allegations of Paragraph 44.

45. Hospira admits that Amgen has requested the exact composition of four commercially available raw materials made by third parties in correspondence dated March 31, April 17, April 27, and May 1, 2015. This is the only alleged deficiency in Hospira's documents identified by Amgen in any correspondence. However, Hospira's BLA adequately describes the processes used to manufacture its biological product and Amgen's desire for additional information concerning the composition of four commercially available raw materials that were purchased from third-party suppliers is neither required to be provided under 42 U.S.C. § 262(*l*)(2)(A) nor necessary for Amgen to prepare any list it may wish to provide to Hospira under 42 U.S.C. § 262(*l*)(3)(A). Hospira otherwise denies the allegations of Paragraph 45.

46. Hospira admits that it sent a copy of its complete BLA via hard drive on March 2, 2015, containing over 747,000 pages of information on its product and the processes to make its product, including 507 files that were produced natively. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. Hospira admits that in various correspondence, Amgen unreasonably requested information about four commercially available raw materials—MAM-PF2, Trace Element Solution, Lipid Mix, and Antifoam C Solution—which Hospira purchases from third-party manufacturers. The Hospira production documents contained sufficient information regarding the commercially available raw materials to fully satisfy the provisions of § 262(*l*)(2)(A). Hospira otherwise denies the allegations of Paragraph 46.

47. Denied. Hospira incorporates by reference its responses to Paragraphs 44-46.

48. Hospira admits that it has provided documents to Amgen sufficient to completely describe the processes used to manufacture the biological product that is the subject of Hospira's BLA as detailed above. Hospira admits that it continues to seek licensure of the Hospira Product with the

FDA. Hospira otherwise denies the allegations of Paragraph 48.

49. The allegations of Paragraph 49 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. The Federal Circuit held that although the BPCIA says that the biosimilar applicant "shall provide" its application, this does not impose a mandatory requirement, because the BPCIA and Patent Act "expressly provide the only remedies as those being based on a claim of patent infringement." *Id*. at 1355, 1357. The court reasoned that paragraph (*l*)(2)(A)'s "'shall' provision . . . cannot be read in isolation" (*id*. at 1355), noting that "both 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." *Id*. at 1356. "Moreover, 35 U.S.C. § 271(e)(4) provides 'the only remedies which may be granted by a court for an act of infringement described in paragraph (2).'" *Id*. Thus, when "the BPCIA explicitly contemplates that a subsection (k) applicant might fail" to take action required by the statute and "specifically sets forth the consequence for such failure," this indicates that "'shall' . . . does not mean 'must.'" *Id*. at 1355. Otherwise, "mandating compliance [with the "shall" provision] in all circumstances would render [the consequence provisions] superfluous, and statutes are to be interpreted if possible to avoid rendering any provision superfluous." *Id*. at 1356.

50. The allegations of Paragraph 50 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. The information produced to Amgen completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. (*See, e.g.*, Hospira responses

to Paragraphs 44-46.) Indeed, the only alleged deficiency Amgen can point to is information concerning certain commercially available raw materials. Amgen has been unable or unwilling to identify any patent that could be relevant to the information sought and has not included any such patent in its § 262(*l*)(3)(A) list. Hospira denies that the information provided pursuant to 42 U.S.C. § 262(*l*)(1)-(2) was in any way incomplete or otherwise deficient, or that Amgen's ability to identify patents in accordance with 42 U.S.C. § 262(*l*)(3)(A) was improperly limited.

51. Denied. The information produced to Amgen completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. (*See, e.g.*, Hospira responses to Paragraphs 44-46.) Hospira denies that the information provided pursuant to 42 U.S.C. § 262(*l*)(1)-(2) was in any way incomplete or otherwise deficient, or that Amgen's ability to identify patents in accordance with 42 U.S.C. § 262(*l*)(3)(A) was improperly limited. Amgen was required to list any of its "extensive portfolio of patents relating to various aspects of the manufacture of biological products" on its § 262(*l*)(3)(A) list, but unilaterally decided not to do so despite the comprehensive information concerning its manufacturing process and product provided by Hospira.

52. The allegations of Paragraph 52 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all allegations of Paragraph 52. Amgen was required to list any of its "extensive portfolio of patents relating to various aspects of the manufacture of biological products" on its § 262(*l*)(3)(A) list, but unilaterally decided not to do so despite the comprehensive information concerning its manufacturing process and product provided by Hospira. Pursuant to 35 U.S.C. § 271(e)(6)(C), Amgen is prohibited from asserting a claim of infringement against Hospira's Product on any patent that is not included in a timely manner on Amgen's list of patents provided pursuant to 42 U.S.C. § 262(*l*)(3)(A).

53. Denied. The information produced to Amgen completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. (*See, e.g.*, Hospira responses to Paragraphs 44-46.) Hospira denies that the information provided pursuant to 42 U.S.C. § 262(*l*)(1)-(2) was in any way incomplete or otherwise deficient, or that Amgen's ability to identify patents in accordance with 42 U.S.C. § 262(*l*)(3)(A) was improperly limited.

3. Amgen has complied with the BPCIA procedures

54. The allegations of Paragraph 54 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all allegations of Paragraph 54.

55. Hospira admits that it received what purported to be Amgen's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) on May 1, 2015. Amgen's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) included a statement that "Amgen is not prepared to license any of these patents to Hospira at this time." The remaining allegations contained in Paragraph 55 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and, therefore, denies the same.

56. Hospira admits that it provided its statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) to Amgen on June 19, 2015, which satisfied all statutory provisions. Hospira admits that it received what purported to be Amgen's statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) on August 18, 2015 ("Amgen's 3(C) Statement"). Amgen's 3(C) Statement failed to satisfy the statutory provisions, including by failing to provide substantive infringement contentions regarding the now-expired U.S. Patent No. 5,756,349 (the "'349 Patent"). The remaining allegations contained in Paragraph 56 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and,

therefore, denies the same.

4. Hospira violated § 262(*l*)(4)

57. The allegations contained in Paragraph 57 are either conclusions of law that require no response from Hospira, or allegations on which Hospira lacks knowledge or information sufficient to form a belief as to their truth or falsity and, therefore, Hospira denies the same. Hospira respectfully refers the Court to the cited statutes for their complete contents and meanings.

58. Hospira admits that in a letter dated August 19 from Mr. Meloro to Mr. Flowers, Hospira accepted and agreed that the patents identified in Amgen's list pursuant to paragraph (3)(A), U.S. Patent Nos. 5,756,349, 5,856,298, and 6,632,637, constituted the list of patents under 42 U.S.C. § 262(*l*)(3) that could be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). Because the parties were in agreement regarding the patents to be included in the suit, the negotiations under 42 U.S.C. § 262(*l*)(4)(A) concluded as of the date of that letter. Hospira has consistently maintained that the negotiations contemplated under paragraph (4)(A) were completed as of the August 19, 2015 letter, including in correspondence dated August 19, August 24, and September 15, 2015. Indeed, this negotiation and its conclusion resulted in Amgen filing this Amended Complaint alleging patent infringement on two of the patents included in Amgen's § 262(*l*)(3)(A) list. The BPCIA specifically contemplates this type of situation where the parties are able to agree on the patents to litigate. *See* 42 U.S.C. § 262(*l*)(6)(A). Hospira otherwise denies the allegations of Paragraph 58.

59. As described in Hospira's response to Paragraph 58, the parties reached agreement on the patents to litigate on August 19, 2015. Amgen's assertion that Hospira has refused to negotiate under 42 U.S.C. § 262(*l*)(4) is incorrect, and reflects a flawed view of the statutory provisions. The BPCIA specifically contemplates this type of situation where the parties are able to agree on the

patents to litigate. *See* 42 U.S.C. § 262(*l*)(6)(A). Hospira admits that Amgen sent letters to Hospira dated August 21 and September 14, 2015. Hospira otherwise denies the allegations of Paragraph 59.

5. Hospira violated § 262(*l*)(8)(A)

60. The allegations of Paragraph 60 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA. Regardless, Hospira denies that the BPCIA provides for a private right of action to enforce the notice provisions of the BPCIA and denies that Amgen is entitled to any relief in this action.

61. The allegations of Paragraph 61 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Hospira denies that the BPCIA provides for a private right of action to enforce the notice provisions of the BPCIA and denies that Amgen is entitled to any relief in this action.

62. Hospira admits that in an effort to cooperate with Amgen and prior to the ruling in *Amgen v. Sandoz*, Hospira provided notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) on April 8, 2015. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA. The remaining allegations of Paragraph 62 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

63. Hospira admits that the Federal Circuit issued a decision in *Amgen Inc. v. Sandoz Inc.* on July 21, 2015. The remaining allegations of Paragraph 63 contain conclusions of law for which no

response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law.

64. Hospira admits that in correspondence dated August 19 and September 15, 2015, Hospira stated that no notice of commercial marketing is required in this situation. Hospira otherwise denies the allegations of Paragraph 64. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA.

65. Denied. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA. Nevertheless, the patent dispute between the parties has been "crystallized" as evidenced by this litigation. Hospira otherwise denies the allegations of Paragraph 65.

66. Hospira denies the allegations of Paragraph 66. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA.

67. Hospira denies the allegations of Paragraph 67. Hospira has been and continues to be in full compliance with all relevant provisions of the BPCIA.

THE PATENTS-IN-SUIT

E. U.S. Patent No. 5,856,298

68. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 68 and, therefore, denies the same.

69. Hospira admits that the '298 Patent is entitled "Erythropoietin Isoforms." Hospira admits that the '298 Patent issued on January 5, 1999 by the United States Patent and Trademark Office ("USPTO"). Hospira admits that the face of the '298 Patent lists Thomas Strickland as an inventor. Hospira admits that what purports to be a copy of the '298 Patent was attached to the Amended Complaint as Exhibit A. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 69 and, therefore, denies the same.

70. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 70 and, therefore, denies the same.

71. Hospira admits that the Abstract of the '298 Patent states, "Erythropoietin isoforms having a specific number of sialic acids per erythropoietin molecule are disclosed. Also disclosed are mixtures of such isoforms, pharmaceutical compositions containing such isoforms or mixtures thereof and methods of obtaining the erythropoietin isoforms." Hospira otherwise denies the allegations of Paragraph 71.

B. U.S. Patent No. 5,756,349

72. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 72 and, therefore, denies the same.

73. Hospira admits that the '349 Patent is titled "Production of Erythropoietin." Hospira admits that the '349 Patent issued on May 26, 1998 by the USPTO. Hospira admits that the face of the '349 Patent lists Fu-Kuen Lin as an inventor. Hospira admits that what purports to be a copy of the '349 Patent was attached to the Amended Complaint as Exhibit B. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 73 and, therefore, denies the same.

74. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74 and, therefore, denies the same.

75. Hospira admits that the Abstract of the '349 Patent states, "Disclosed are novel polypeptides possessing part or all of the primary structural conformation and one or more of the biological properties of mammalian erythropoietin ('EPO') which are characterized in preferred forms by being the product of prokaryotic or eukaryotic host expression of an exogenous DNA sequence." Hospira otherwise denies the allegations of Paragraph 75.

CAUSES OF ACTION

FIRST COUNT

(DECLARATORY JUDGMENT THAT HOSPIRA'S REFUSAL TO GIVE LEGALLY EFFECTIVE NOTICE OF COMMERCIAL MARKETING VIOLATES 42 U.S.C. § 262(*l*)(8)(A))

76. Hospira incorporates by reference its answers to Paragraphs 1-75 as if fully set forth herein. Hospira otherwise denies the allegations of Paragraph 76.

77. Hospira admits that the Amended Complaint purports to bring a civil action arising under the BPCIA, 42 U.S.C. § 262, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202. Hospira denies that Amgen is entitled to any relief in this action. Hospira also denies that there is any private right of action to enforce the provisions of 42 U.S.C. § 262. Hospira denies the remaining allegations of Paragraph 77.

78. The allegations of Paragraph 78 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Hospira denies the remaining allegations of Paragraph 78.

79. Denied. Hospira has fully complied with all relevant provisions of 42 U.S.C. § 262(*l*)(2)(A), including by serving on Amgen over 4,200 documents totaling over 747,000 pages of detailed information on its product and the processes to make its product. Hospira denies that the information provided to Amgen pursuant to 42 U.S.C. § 262(*l*)(1)-(2) was in any way incomplete or otherwise deficient, or that Amgen's ability to identify patents in accordance with 42 U.S.C. § 262(*l*)(3)(A) was improperly limited.

80. The allegations of Paragraph 80 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Further, Hospira denies that

the BPCIA provides for a private right of action to enforce the notice provisions of the BPCIA and denies that Amgen is entitled to any relief in this action.

81. Hospira admits that it sent to Amgen a letter dated April 8, 2015, in which Hospira provided notice of commercial marketing of the Hospira BLA Product. Hospira admits that as of April 8, 2015, the FDA had not yet approved the Hospira BLA Product for licensure. The remaining allegations of Paragraph 81 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. In an effort to cooperate with Amgen and prior to *Amgen v. Sandoz*, Hospira provided notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) on April 8, 2015.

82. Hospira admits that it has stated to Amgen that notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) is not required. Hospira otherwise denies the allegations of Paragraph 82.

83. Hospira admits that it has stated to Amgen that notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) is not required. Unless the subsection (k) applicant has "completely fail[ed]" to provide information pursuant to § 262(*l*)(2)(A), the only remedy available for a violation of § 262(*l*)(8)(A) is that the reference product sponsor "may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A)" as stated in 42 U.S.C. § 262(*l*)(9)(B). Hospira otherwise denies the allegations of Paragraph 83.

84. The allegations of Paragraph 84 contain conclusions of law for which no response is required. To the extent an answer is required, Hospira denies all characterizations of the law that are inconsistent with the referenced statutes and pertinent case law. Further, Hospira denies that the BPCIA provides for a private right of action to enforce the notice provisions of the BPCIA and

denies that Amgen is entitled to any relief in this action.

85. Denied. There is no private right of action to injunctive relief contemplated by the statute. Indeed, the BPCIA gives a biosimilar applicant the option either to comply with the provisions of 42 U.S.C. § 262(*l*) or to face the consequences set forth in 42 U.S.C. § 262(*l*)(9), including an action under 28 U.S.C. § 2201 for a declaration of patent infringement.

SECOND COUNT

(INFRINGEMENT OF U.S. PATENT NO. 5,856,298 UNDER 35 U.S.C. § 271(e)(2)(C))

86. Hospira incorporates by reference its answers to Paragraphs 1-85 as if fully set forth herein. Hospira otherwise denies the allegations of Paragraph 86.

87. Hospira lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 87 and, therefore, denies the same.

88. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 88.

89. Admitted.

90. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira admits that it intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Hospira Product following approval of Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 90.

91. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira admits that it intends to engage in the manufacture, use, offer for sale,

sale, and/or importation of the Hospira Product following approval of Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 91.

92. Denied.

93. Denied.

94. Denied.

THIRD COUNT

(INFRINGEMENT OF THE '298 PATENT UNDER 35 U.S.C. § 271(a))

95. Hospira incorporates by reference its answers to Paragraphs 1-94 as if fully set forth herein. Hospira otherwise denies the allegations of Paragraph 95.

96. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 96.

97. Hospira admits that it is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the Hospira Product described in Hospira's BLA. Hospira admits that it intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Hospira Product following approval of Hospira's BLA. Hospira otherwise denies the allegations of Paragraph 97.

98. Denied.

99. Admitted.

100. Denied.

101. Denied.

102. Denied.

FOURTH COUNT

(INFRINGEMENT OF U.S. PATENT NO. 5,756,349 UNDER 35 U.S.C. § 271(a))

103. Hospira incorporates by reference its answers to Paragraphs 1-102 as if fully set forth herein. Hospira otherwise denies the allegations of Paragraph 103.

104. Denied.

105. Denied.

106. Denied.

PRAYER FOR RELIEF

The remainder of the Complaint recites a prayer for relief for which no response is required. To the extent any response is required, Hospira denies that Amgen is entitled to any remedy or relief.

ADDITIONAL DENIAL

To the extent that there are any allegations in the Amended Complaint directed to Hospira to which Hospira did not respond specifically, such omission was inadvertent, and Hospira hereby denies any such allegations.

AFFIRMATIVE AND OTHER DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the Amended Complaint, Hospira relies upon the following defenses:

FIRST DEFENSE

Hospira is not required to provide a notice of commercial marketing under 42 U.S.C. § 262(*l*)(8)(A).

SECOND DEFENSE

The Court lacks jurisdiction over Count 1; the BPCIA does not confer a private right of

action to enforce allegations of non-compliance with the statutory provisions of 42 U.S.C. § 262(*l*)(8)(A).

THIRD DEFENSE

Hospira has complied with the provisions of the BPCIA, including specifically 42 U.S.C. § 262(*l*)(2)(A).

FOURTH DEFENSE

All claims of the ’298 and ’349 Patents are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, or any judicially-created doctrine of invalidity including obviousness-type double patenting.

FIFTH DEFENSE

The manufacture, use, offer for sale, sale and/or importation into the United States of product described in BLA No. 125-545 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’349 and ’298 Patents directly, indirectly, by inducement, contributorily, literally under the doctrine of equivalents, or in any other manner.

SIXTH DEFENSE

The filing of BLA No. 125-545 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’349 and ’298 Patents directly, indirectly, by inducement, contributorily, literally under the doctrine of equivalents, or in any other manner.

SEVENTH DEFENSE

Amgen is not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins Hospira, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related

business entities and all other persons acting in concert, participation, or in privity with Hospira and/or its successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any product that purportedly infringes, or the use or manufacture of which purportedly infringes either of the ’298 and ’349 Patents.

EIGHTH DEFENSE

Plaintiffs’ Amended Complaint fails to state a claim upon which relief may be granted.

NINTH DEFENSE

Hospira’s actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 271(e)(4) or 35 U.S.C. § 285.

TENTH DEFENSE

Hospira has not willfully infringed any claim of the ’298 and ’349 Patents.

ELEVENTH DEFENSE

Amgen is barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

TWELFTH DEFENSE

Hospira’s activities fall within the safe harbor provisions of 35 U.S.C. § 271(e)(1).

THIRTEENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

HOSPIRA’S PRAYER FOR RELIEF

WHEREFORE, Hospira requests (a) that all claims of the ’298 and ’349 Patents are found to be invalid; (b) that Plaintiffs’ Amended Complaint be dismissed with prejudice and judgment be entered in favor of Hospira; (c) a declaration that this case is exceptional under 35 U.S.C. § 285 entitling Hospira to relief under that statute; and (d) an award of such other and further relief to

Defendants that the Court deems just and proper.

HOSPIRA'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counterclaim Plaintiff Hospira, Inc, by and through its attorneys, hereby submits these Counterclaims against Counterclaim Defendants Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen"):

1. These are Hospira's Counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent Nos. 5,856,298 and 5,756,349 (collectively, "the patents-in-suit") under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202.

2. Hospira repeats and incorporates by reference each of the foregoing Paragraphs of Hospira's Answer and Affirmative Defenses to the Amended Complaint.

THE PARTIES

3. Hospira is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. According to its Amended Complaint, Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

5. According to its Amended Complaint, Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

JURISDICTION AND VENUE

6. These counterclaims are for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for determining questions of actual controversy between the parties regarding the rights and other legal relations of the parties with respect to the Biosimilars Price Competition and Innovation Act (the "BPCIA").

7. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. § 262(k)-(*l*), 28 U.S.C. §§ 1331, 1338(a) and 1367(a), and 35 U.S.C. § 271(e)(2)(C).

8. This Court has personal jurisdiction over each of Amgen Inc. and Amgen Manufacturing, Limited at least because they have subjected themselves to the jurisdiction of this Court in this case by filing the Amended Complaint.

9. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and by virtue of Amgen's filing of this action in this Court.

THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

10. In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition and Innovation Act of 2009.

11. The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilar pathway balancing innovation and consumer interests."

12. The U.S. Food and Drug Administration ("FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a).

13. The BPCIA, by contrast and design, allows an applicant to file an abbreviated biologics license application to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is safe, pure, and potent." The BPCIA thus authorizes a biosimilar applicant to rely in part on the approved license of a reference product.

14. To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a 12-year exclusivity period to a reference product, both beginning on the date of first

licensure of the reference product. Specifically, approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to 12 years of exclusivity against follow-on products, regardless of patent protection.

15. In addition to the biosimilars pathway of 42 U.S.C. § 262(k), the BPCIA sets forth a procedure by which the biosimilar applicant and reference product sponsor may exchange information relating to potential patent disputes. *See* 42 U.S. C. § 262(*l*). These exchanges occur after the biosimilar BLA has been submitted to the FDA but before any court-enforced confidentiality protections are in place.

16. First, within 20 days after the FDA publishes a notice of acceptance for a 262(k) application, the applicant may provide a copy of the application to the reference product sponsor. 42 U.S.C. § 262(*l*)(2)(A). The BPCIA gives a biosimilar applicant the option either to share its biosimilar application with the reference product sponsor promptly after acceptance of the BLA by the FDA or to face the consequences provided by the BPCIA, specifically 42 U.S.C. § 262(*l*)(9)(C).

17. 42 U.S.C. § 262(*l*)(9)(C) governs and provides the sole consequence if the subsection (k) applicant does not share information pursuant to § 262(*l*)(2)(A):

> **(9) Limitation on declaratory judgment action**
>
> **(A) Subsection (k) application provided**
>
> If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).
>
> **(B) Subsequent failure to act by subsection (k) applicant**

> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> **(C) Subsection (k) application not provided**
>
> If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.
>
> 42 U.S.C. § 262(*l*)(9).

18. If the biosimilar applicant elects not to share its manufacturing information, then the reference product sponsor—but ***not*** the biosimilar applicant—may seek a declaration of infringement, validity, or enforceability before the biosimilar applicant provides its notice of commercial marketing. 42 U.S.C. § 262(*l*)(9)(C). Any other interpretation would render superfluous both BPCIA subsection (*l*)(9)(C) and the BPCIA conforming amendment codified at 35 U.S.C. § 271(e)(2)(C)(ii).

19. The BPCIA does not provide for injunctive relief, declaratory judgment of non-compliance or damages for failing to provide the disclosures pursuant to subsection (*l*)(2)(A). Instead, the BPCIA and/or 35 U.S.C. § 271(e)(4) precludes and preempts any and all such claims and remedies.

20. If the subsection (k) applicant chooses to provide its subsection (k) application to the reference product sponsor, the reference product sponsor may provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted . . ." not later than 60 days after receipt of the application. 42 U.S.C. § 262(*l*)(3)(A). The reference product sponsor may also identify which of the listed patents it would be willing to license

to the subsection (k) applicant.

21. The subsection (k) applicant then has 60 days after receipt of the list pursuant to § 262(*l*)(3)(A) to provide "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application[.]" 42 U.S.C. § 262(*l*)(3)(B). The subsection (k) applicant may also provide a response regarding any patents that the reference product sponsor would be willing to license.

22. The reference product sponsor then has 60 days after receipt of the list pursuant to § 262(l)(3)(B) to provide "a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)."

23. After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant engage in "good faith negotiations" to agree on which, if any, patents listed under paragraph (3) to litigate. If the parties reach agreement, the reference product sponsor has 30 days to bring suit.

24. In addition, under certain circumstances, the subsection (k) applicant may provide notice of commercial marketing to the reference product sponsor.

FACTUAL BACKGROUND

A. Amgen's BLA for EPOGEN®

25. According to Amgen's Amended Complaint, Amgen obtained a license from the FDA for EPOGEN® (epoetin alfa) ("Epogen") pursuant to 42 U.S.C. § 262(a).

26. According to the label, EPOGEN® is indicated for the treatment of anemia due to chronic kidney disease in patients on dialysis and not on dialysis; zidovudine in HIV-infected patients; the effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; and reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

27. Amgen has marketed and sold EPOGEN® since 1989. Therefore, under the BPCIA, Amgen's exclusivity period for Epogen has long since expired.

B. Hospira's BLA

28. Hospira is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Epoetin Hospira") described in Hospira's BLA No. 125-545 ("Hospira's BLA") submitted on December 15, 2014. The reference product to Hospira's BLA is EPOGEN®.

29. Now, Amgen seeks to delay Hospira's BLA application for a biosimilar epoetin, extend its exclusivity even further beyond that contemplated by Congress in the BPCIA, and delay patient access to a more affordable version of this drug.

C. Exchanges Pursuant to the BPCIA

30. Hospira notified Amgen on February 23, 2015 that Hospira's BLA had been recently accepted for filing by the FDA and provided Amgen with Hospira's complete BLA in full compliance with 42 U.S.C. § (*l*)(2)(A).

31. Hospira sent a copy of its complete BLA via hard drive on March 2, 2015. Hospira's BLA contained over 747,000 pages of information on its product and the processes to make its product, including 507 files that were produced natively. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA.

32. Hospira's BLA as produced to Amgen provided certificates of analysis for the MAM-PF2, Trace Element Solution, Lipid Mix, and Antifoam C Solution components, showing that these media were all commercially available products purchased from third party suppliers.

33. On May 1, 2015, Amgen provided to Hospira its list pursuant to § 262(*l*)(3)(A). Amgen's § 262(*l*)(3)(A) list identified the following patents: U.S. Patent No. 5,756,349 (the "'349 Patent"); U.S. Patent No. 5,856,298 (the "'298 Patent"); and U.S. Patent No. 6,632,637 (the "'637 Patent". In addition, Amgen stated that it was "not prepared to license any of these patents to Hospira at this time." Amgen's § 262(*l*)(3)(A) list did not identify any alleged deficiencies in the information provided by Hospira pursuant to § 262(*l*)(2)(A).

34. On June 19, 2015 Hospira provided to Amgen a detailed statement that described on a claim by claim basis, the factual and legal bases for its opinion that the '298 and '637 Patents are invalid, unenforceable, and will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the biological product that is the subject of Hospira's BLA, in full compliance with § 262(*l*)(3)(B)(ii)(I). Hospira also provided to Amgen a statement that Hospira does not intend to begin commercial marketing of the biological product that is the subject of Hospira's BLA before the date that the '349 Patent will expire, in full compliance with § 262(*l*)(3)(B)(ii)(II).

35. On August 18, 2015, Amgen purported to provide Hospira with its statement of Amgen's opinion that the '298, '637 and '349 Patents will be infringed by the commercial marketing of the biological product that is the subject of Hospira's BLA, and Amgen's response to Hospira's statement concerning validity and enforceability provided under § 262(*l*)(3)(B)(ii)(I).

36. On August 19, 2015, Hospira notified Amgen that Hospira accepted and agreed that the patents identified in Amgen's U.S.C. § 262(*l*)(3)(A) list constitute the list of patents under 42 U.S.C. § 262(*l*)(3) that shall be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

37. Amgen filed the instant Amended Complaint on September 18, 2015 alleging, *inter alia*, infringement of the '298 Patent under 35 U.S.C. § 271(e)(2)(C) and 35 U.S.C. § 271(a) and infringement of the '349 Patent under 35 U.S.C. § 271(a). Amgen did not allege infringement of the '637 Patent.

THE PATENTS-IN-SUIT

A. The '298 Patent

38. The '298 patent is entitled "Erythropoietin Isoforms" and lists Thomas Wayne Strickland as the inventor.

39. The '298 patent is assigned on its face to Amgen Inc. According to the Amended Complaint, Amgen Inc. is the owner of all rights, title and interest in the '298 Patent. According to the Amended Complaint, Amgen Manufacturing Limited is an exclusive licensee under the '298 Patent.

40. The '298 patent expired on January 5, 2016.

B. The '349 Patent

41. The '349 Patent is titled "Production of Erythropoietin" and lists Fu-Kuen Lin as the inventor.

42. The '349 Patent is assigned on its face to Amgen Inc. According to the Amended Complaint, Amgen Inc. is the owner of all rights, title and interest in the '349 Patent. According to the Amended Complaint, Amgen Manufacturing Limited is an exclusive licensee under the '349 Patent.

43. The '349 Patent expired on May 26, 2015.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-infringement of the '298 Patent

44. Hospira hereby incorporates by reference each and every allegation set forth in its Answer

and Affirmative Defenses to the Amended Complaint and Paragraphs 1-43 of the Counterclaims above.

45. Hospira has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’298 Patent either literally or under the doctrine of equivalents and is not liable for such infringement.

46. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the filing of the Hospira BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the Hospira Product infringes, has infringed, or will infringe any valid and enforceable claim of the ’298 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

47. Hospira is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’298 Patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Hospira Product that is the subject of the Hospira BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’298 Patent.

48. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity of the ’298 Patent

49. Hospira hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Amended Complaint and Paragraphs 1-48 of the Counterclaims above.

50. There is an actual, substantial, continuing, and justiciable controversy between the parties

regarding the invalidity of the ’298 Patent, based on Amgen’s allegation in its Amended Complaint that Hospira has infringed or will infringe the ’298 Patent.

51. Each and every claim of the ’298 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and 103.

52. The alleged invention of the ’298 Patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

53. The alleged invention of the ’298 Patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

54. The ’298 Patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

55. The alleged invention of the ’298 Patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’298 Patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’298 Patent and would have had a reasonable expectation of success in doing so.

56. The subject matter claimed in the ’298 Patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have

been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

57. Hospira is entitled to a judicial declaration that all claims of the ’298 patent are invalid.

58. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

THIRD COUNTERCLAIM

Declaratory Judgment of Non-infringement of the ’349 Patent

59. Hospira hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Amended Complaint and Paragraphs 1-58 of the Counterclaims above.

60. Hospira has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’349 Patent either literally or under the doctrine of equivalents and is not liable for such infringement.

61. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the filing of the Hospira BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the Hospira Product infringes, has infringed, or will infringe any valid and enforceable claim of the ’349 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

62. Hospira is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’349 Patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Hospira Product that is the subject of the Hospira BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’349 Patent.

63. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

FOURTH COUNTERCLAIM

Declaratory Judgment of Invalidity of the '349 Patent

64. Hospira hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Amended Complaint and Paragraphs 1-63 of the Counterclaims above.

65. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '349 Patent, based on Amgen's allegation in its Amended Complaint that Hospira has infringed or will infringe the '349 Patent.

66. Each and every claim of the '349 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to judicially-created doctrines of invalidity such as obviousness-type double patenting.

67. The '349 Patent describes and claims an alleged invention, that is not patentably distinct from earlier claims in commonly owned patents.

68. Hospira is entitled to a judicial declaration that all claims of the '349 patent are invalid.

69. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Hospira prays that the Court enter judgment in its favor and against Plaintiffs as follows:

A. Adjudging and decreeing that Plaintiffs be denied all relief requested under their Amended Complaint;

B. Declaring that Hospira has not and will not infringe the ’298 Patent;

C. Declaring that the ’298 Patent is invalid;

D. Declaring that Hospira has not and will not infringe the ’349 Patent;

E. Declaring that the ’349 Patent is invalid;

F. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Hospira or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Hospira, or charging them either orally or in writing with infringement of any patent asserted herein against Hospira;

G. Granting Hospira Judgment in its favor on Plaintiffs’ Amended Complaint;

H. Denying Plaintiffs’ request for injunctive relief;

I. Dismissing Plaintiffs’ Amended Complaint with prejudice;

J. Finding this case to be exception under 35 U.S.C. § 285 and awarding Hospira its costs and reasonable attorneys’ fees; and

K. Awarding any other such relief as is just and proper.

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