IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. AND AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. HOSPIRA, INC. AND PFIZER INC., Defendants.	Case No. 1:18-cv-01064-VAC-MPT

DEFENDANTS HOSPIRA, INC. AND PFIZER INC.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Pfizer Inc. ("Pfizer") and Hospira, Inc. ("Hospira," and together with Pfizer, "Defendants"), by and through their attorneys, hereby submit this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen" or "Plaintiffs") on July 18, 2018 (the "Complaint").

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a "Paragraph") in the Complaint. Defendants deny all allegations in the 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. Moreover, to the extent that any of Plaintiffs' allegations are vague and/or ambiguous, Defendants deny said allegations. To the extent that any of the Complaint's headings or footnotes constitute allegations, Defendants specifically deny each and every

one of them. Defendants reserve the right to amend this Answer or to assert other defenses as this action proceeds. Defendants deny that Amgen is entitled to the relief requested or any other relief. Defendants respond to the Complaint as follows:

THE PARTIES

1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 and, therefore, deny the same.

2. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and, therefore, deny the same.

3. Admitted.

4. Admitted.

5. Admitted.

6. Defendants admit that Hospira develops biopharmaceutical products. Defendants otherwise deny the allegations in Paragraph 6.

NATURE OF THE ACTION

7. Defendants admit that the Complaint purports to bring a civil action for patent infringement under 35 U.S.C. § 271(e)(2)(C). Defendants further admit that 35 U.S.C. § 271(e)(2)(C), was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"). The remaining allegations in Paragraph 7 contain conclusions of law to which no response is required. To the extent that a response is required, Defendants deny the allegations.

8. Paragraph 8 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 8.

9. Defendants admit that Hospira is a biosimilar applicant and sought FDA licensure under 35 U.S.C. § 262(k) ("the subsection (k) pathway") for a biosimilar version of Amgen's Neupogen® (filgrastim) product ("Hospira Filgrastim Product"). Defendants otherwise deny the allegations in Paragraph 9.

10. Defendants admit that Hospira submitted Biologic License Application No. 761080 ("Hospira aBLA") to the FDA requesting licensure for the Hospira Filgrastim Product. Defendants otherwise deny the allegations in Paragraph 10.

11. Defendants admit that, in the Complaint, Amgen purports to assert U.S. Patent No. 9,643,997 (the "'997 Patent"). To the extent that the allegations in Paragraph 11 purport to describe or characterize a publicly available document, Defendants object to such characterization or description of that document and note that such document speaks for itself and no response is required. Defendants deny the remaining allegations in Paragraph 11.

12. Defendants admit that Hospira submitted the Hospira aBLA to the FDA. Paragraph 12 otherwise contains legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations.

13. Defendants admit that, on or about February 8, 2018, Amgen provided Hospira with a list of patents, purporting to be in accordance with 42 U.S.C. § 262(l)(3)(A), and that the '997 Patent was included on that list. Defendants otherwise deny the allegations in Paragraph 13.

14. Defendants deny the allegations in Paragraph 14.

15. Defendants deny the allegations in paragraph 15.

JURISDICTION AND VENUE

16. Defendants admit that the Complaint purports to bring an action under 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. Paragraph 16 otherwise contains conclusions of law to which no response is required. To the extent that a response is required, Defendants deny the allegations.

17. Defendants admit that Hospira is incorporated in Delaware. Paragraph 17 otherwise contains conclusions of law to which no response is required. Hospira does not contest personal jurisdiction for purposes of this action only.

18. Defendants admit that Pfizer is incorporated in Delaware. Paragraph 18 otherwise contains conclusions of law to which no response is required. Pfizer does not contest personal jurisdiction for purposes of this action only.

19. Defendants deny that Amgen has suffered any injury as the result of Defendants' actions. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19 and, therefore, deny the same.

20. Defendants admit that Pfizer and Hospira are incorporated in Delaware. Paragraph 20 otherwise contains conclusions of law to which no response is required. Defendants do not contest venue for purposes of this action only.

BACKGROUND

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

21. Upon information and belief, Defendants admit that the active ingredient in Neupogen® is filgrastim. Defendants lack knowledge or information sufficient to form a

belief about the truth of the remaining allegations in Paragraph 21 and, therefore, deny the same.

22. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22 and, therefore, deny the same.

23. Defendants lack knowledge or information sufficient to form a belief about the about the truth of the allegations in Paragraph 23 and, therefore, deny the same.

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 admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product. Paragraph 24 otherwise contains Amgen's characterizations of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations.

25. Defendants admit that Congress enacted the BPCIA on March 23, 2010. Paragraph 25 otherwise contains Amgen's characterizations of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations.

26. To the extent that the allegations in Paragraph 26 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. Paragraph 26 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is

required. To the extent that a response is required, Defendants deny the allegations in Paragraph 26.

27. To the extent that the allegations in Paragraph 27 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. Paragraph 27 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 27.

28. Paragraph 28 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 28.

29. Paragraph 29 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 29.

30. Paragraph 30 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 30.

31. Defendants admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product under the subsection (k) pathway. Defendants deny the remaining allegations in Paragraph 31.

32. Defendants admit the allegations in Paragraph 32.

33. Defendants admit that the FDA approved the Hospira aBLA on or about July 20, 2018. Defendants otherwise deny the allegations in Paragraph 33.

34. Defendants admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product as a biosimilar version of Amgen's Neupogen® (filgrastim) product. Paragraph 34 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 34.

35. Defendants admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product as a biosimilar version of Amgen's Neupogen® (filgrastim) product. Defendants further admit, on information and belief, that Amgen holds Biologic License Application No. 103353 for filgrastim. Paragraph 35 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 35.

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

36. To the extent that the allegations in Paragraph 36 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. Paragraph 36 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 36.

37. Defendants admit that, on or about December 4, 2017, Hospira provided notice to Amgen that the Hospira aBLA was accepted for review by the FDA and that Hospira intended to provide Amgen with a copy of the Hospira aBLA, and that Amgen responded on or about December 8, 2017. Defendants otherwise deny the allegations in Paragraph 37.

38. To the extent that the allegations in Paragraph 38 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. Paragraph 38 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 38.

39. Defendants admit that, on or about December 11, 2017, Hospira produced information pursuant to 42 U.S.C. § 262(l)(2)(A) including relevant portions of the Hospira aBLA to Amgen. Paragraph 39 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 39.

40. Defendants lack knowledge or information sufficient to form a belief as to the truth of the first sentence in Paragraph 40 and, therefore, deny the same. Paragraph 40 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 40.

41. Defendants lack knowledge or information sufficient to form a belief as to the truth of the first two sentences in Paragraph 41 and, therefore, deny the same. Defendants admit that, on or about December 22, 2017, and also on or about January 4, 2018, Hospira produced additional portions of the Hospira aBLA to Amgen. Paragraph 41 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 41.

42. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 and, therefore, deny the same. To the extent that Paragraph 42 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 42.

43. Defendants admit that, on or about February 13, 2018, Hospira produced additional portions of the Hospira aBLA to Amgen. Paragraph 43 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 43.

44. Defendants lack knowledge or information sufficient to form a belief as to the truth of the first sentence in Paragraph 44 and, therefore, deny the same. Defendants admit that, on or about February 8, 2018, Amgen provided Hospira with a list of patents, purporting to be in accordance with 42 U.S.C. § 262(l)(3)(A). Defendants further admit that, on or about March 5, 2018, Amgen disclosed an additional patent to Hospira purportedly in accordance with 42 U.S.C. § 262(l)(7). Paragraph 44 otherwise contains

Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 44.

45. Defendants admit that, on or around April 4, 2018, Hospira provided Amgen with a statement pursuant to 42 U.S.C. § 262(l)(3)(B). Defendants further admit that, on or about June 1, 2018, they received a statement from Amgen, purporting to be in accordance with 42 U.S.C. § 262(l)(3)(C). Defendants deny the remaining allegations in Paragraph 45.

46. Defendants admit that, beginning on or about June 7, 2018, the parties engaged in negotiations pursuant to 42 U.S.C. § 262(l)(4). To the extent that the allegations in Paragraph 46 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. To the extent that Paragraph 46 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, no response is required. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 46.

47. Defendants admit that, on or about June 22, 2018, the parties reached an agreement that should Amgen sue Hospira for patent infringement with respect to the filing of the Hospira aBLA, only the '997 Patent would be the subject of an action for patent infringement under 42 U.S.C. § 262(l)(6). Defendants further admit that the parties reached this agreement within 15 days of beginning negotiations pursuant to 42 U.S.C. § 262(l)(4). Defendants deny the remaining allegations in Paragraph 47.

48. Paragraph 48 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 48.

THE PATENT-IN-SUIT

49. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49 and, therefore, deny the same. To the extent that Paragraph 49 contains Amgen's characterization of their claims and/or legal conclusions, no response is required.

50. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 and, therefore, deny the same. To the extent that Paragraph 50 contains Amgen's characterization of their claims and/or legal conclusions, no response is required.

51. Defendants admit that the '997 Patent is titled "Capture Purification Processes for Proteins Expressed in Non-Mammalian System," that the United States Patent and Trademark Office issued the '997 Patent on or about May 9, 2017, and that what purports to be a copy of the '997 Patent is attached to the Complaint as Exhibit A. Paragraph 51 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 51.

52. To the extent that the allegations in Paragraph 52 purport to describe or characterize publicly available documents, Defendants object to such characterization or description of those documents and note that such documents speak for themselves and no response is required. To the extent that Paragraph 52 contains Amgen's characterization

of their claims, applicable law and regulations, and/or legal conclusions no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 52.

CAUSES OF ACTION

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

53. Defendants incorporate by reference their responses to Paragraphs 1-52 as if fully set forth herein.

54. Defendants admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product as a biosimilar version of Amgen's Neupogen® (filgrastim) product under the subsection (k) pathway. Defendants deny the remaining allegations in Paragraph 54.

55. Defendants admit that Amgen's disclosure purporting to be in accordance with 42 U.S.C. § 262(l)(3)(A) included the '997 Patent.

56. Defendants deny the allegations in Paragraph 56.

57. Defendants admit the allegations in Paragraph 57, but deny that any such manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Hospira Filgrastim Product before the expiration of the '997 Patent will infringe any valid and enforceable claim of the '997 Patent.

58. Defendants deny the allegations in Paragraph 58.

59. Defendants admit that claim 9 of the '997 Patent is recited in Paragraph 59. To the extent that the allegations in Paragraph 59 purport to describe or characterize a publicly available document, Defendants object to such characterization or description of that document and note that such document speaks for itself and no response is required.

To the extent that Paragraph 59 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, no response is required. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 59.

60. Paragraph 60 contains Amgen's characterization of their claims and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 60. Defendants specifically deny any allegation of infringement based on Defendants' activities relating to the manufacture, use, sale, offer for sale, and/or importation of the Hospira Filgrastim Product.

61. Defendants admit that Amgen provided a statement purporting to be in accordance with 42 U.S.C. § 262(l)(3)(C). Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 61 and, therefore, deny the same.

62. Paragraph 62 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 62. Defendants specifically deny that the manufacture, use, sale, and/or offer for sale within the United States, and/or import in the United States, of the Hospira Filgrastim Product will infringe any valid and enforceable claim of the '997 Patent.

63. Defendants deny the allegations in Paragraph 63.

SECOND COUNT
DECLARATORY JUDGEMENT OF INFRINGMENT OF THE '997 PATENT UNDER 35 U.S.C. § 271(g)

64. Defendants incorporate by reference their responses to Paragraphs 1-63 as if fully set forth herein.

65. Defendants admit that Hospira submitted the Hospira aBLA to the FDA seeking licensure for the Hospira Filgrastim Product as a biosimilar version of Amgen's Neupogen® (filgrastim) product under the subsection (k) pathway.

66. Defendants admit that the FDA approved the Hospira aBLA on or about July 20, 2018. Paragraph 66 otherwise contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 66.

67. Defendants admit that the FDA approved the Hospira aBLA on or about July 20, 2018. Paragraph 67 otherwise contains Amgen's characterizations of applicable law and regulations, to which no response is required.

68. Paragraph 68 contains Amgen's characterization of their claims and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the remaining allegations in Paragraph 68. Defendants specifically deny any allegation of infringement based on Defendants' activities relating to the manufacture, use, sale, offer for sale, use and/or importation of the Hospira Filgrastim Product.

69. Paragraph 69 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 69. Defendants specifically deny that the manufacture, use, sale, and/or offer for sale within the United States, and/or import in the United States, of the Hospira Filgrastim Product will infringe any valid and enforceable claim of the '997 Patent.

70. Defendants deny the allegations in Paragraph 70.

71. Paragraph 71 contains Amgen's characterization of their claims, applicable law and regulations, and/or legal conclusions, to which no response is required. To the extent that a response is required, Defendants deny the allegations in Paragraph 71. Defendants specifically deny that the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the Hospira Filgrastim Product will infringe any valid and enforceable claim of the '997 Patent.

72. Defendants deny the allegations in Paragraph 72.

PRAYER FOR RELIEF

The remainder of the Complaint recites a prayer for relief to which no response is required. To the extent that any response is required, Defendants deny that Amgen is entitled to any remedy or relief, and deny any allegations therein.

DEMAND FOR A JURY TRIAL

To the extent that the jury demand is a legal conclusion, no response is required. To the extent that a response is required, Defendants deny that Amgen is entitled to a jury trial based on the allegations in the Complaint.

ADDITIONAL DENIAL

To the extent that there are any allegations in the Complaint directed to Defendants to which Defendants did not respond specifically, such omission was inadvertent, and Defendants hereby deny 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 Complaint, Defendants assert the following additional defenses:

FIRST DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

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

THIRD DEFENSE

At least claim 9 of the asserted patent, and its dependent claims, 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, and/or any judicially-created doctrine of invalidity including obviousness-type double patenting.

FOURTH DEFENSE

The manufacture, use, offer for sale, sale and/or importation into the United States of the Hospira Filgrastim Product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

FIFTH DEFENSE

The filing of the Hospira aBLA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

SIXTH 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 and/Pfizer, their 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 Pfizer, and/or their 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 the asserted patent.

SEVENTH DEFENSE

Defendants' 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.

EIGHTH DEFENSE

Defendants have not willfully infringed any claim of the asserted patent.

NINTH DEFENSE

Defendants' activities fall within the safe harbor provisions of 35 U.S.C. § 271(e)(1).

TENTH DEFENSE

Plaintiffs cannot maintain a cause of action for the asserted patent because they have not complied with the BPCIA.

ELEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

RESERVATION OF DEFENSES

Defendants reserve their rights to assert any additional defenses or counterclaims, at law or equity, which may exist.

HOSPIRA AND PFIZER'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counterclaim-Plaintiffs Hospira, Inc. and Pfizer Inc. (collectively, "Defendants") by and through their attorneys, hereby submit these Counterclaims against Counterclaim-Defendants Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen" or "Plaintiffs").

1. These are Defendants' Counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of the asserted patent under 35 U.S.C. § 271(e)(2)(C)(i) and 28 U.S.C. §§ 2201 and 2202.

2. Defendants repeat and incorporate by reference each of the foregoing Paragraphs of Defendants' Answer and Affirmative Defenses to the Complaint.

THE PARTIES

3. Hospira, Inc. 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. Pfizer Inc. 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. Pfizer is one of the world's premier biopharmaceutical companies. Pfizer applies science and global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development, and manufacture of healthcare products. Pfizer's global portfolio includes medicines, vaccines, and medical devices, as well as many of the world's best-known consumer healthcare products. Pfizer works across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Pfizer

collaborates with healthcare providers, governments, and local communities to support and expand access to reliable, affordable healthcare around the world.

6. Hospira, Inc. is a wholly owned subsidiary of Pfizer Inc.

7. As pled in Amgen's 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.

8. As pled in Amgen's 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

9. These counterclaims are for declaratory judgement of invalidity and non-infringement, which arise under the patent laws of the United States, 35 U.S.C. § 1, et seq., 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").

10. 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).

11. This Court has personal jurisdiction over each of Amgen Inc. and AML at least because they have subjected themselves to the jurisdiction of the Court in this case by filing the Complaint.

12. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and § 1400(b) and by virtue of Amgen's filing of this action in this Court.

FACTUAL BACKGROUND

A. Amgen's BLA for Neupogen® (filgrastim)

13. According to the FDA's "Purple Book," Amgen obtained a license from the FDA for Neupogen® (filgrastim), BLA No. 761080, on or about February 20, 1991.

14. According to the current product label, Neupogen® (filgrastim) is indicated to, among other things, decrease incidence of infection in patients at risk of chemotherapy-induced febrile neutropenia.

15. Upon information and belief, Amgen has marketed and sold Neupogen® (filgrastim) in the United States since 1991. Therefore, under 42 U.S.C. § 262(k)(7), Amgen's 12-year market exclusivity for Neupogen® (filgrastim) expired fifteen years ago in 2003.

16. Now, Amgen seeks to extend Amgen's exclusivity even further beyond that contemplated by Congress in the BPCIA, and delay patient access to a more affordable version of this drug.

B. Hospira's aBLA No. 761080

17. In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the BPCIA. The BPCIA established an abbreviated pathway ("the subsection (k) 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 "biosimilars pathway balancing innovation and consumer interests."

18. On or about September 21, 2017, Hospira submitted Hospira's aBLA No. 761080 ("Hospira aBLA") to the FDA seeking licensure for the drug product PF-06881893

("Hospira Filgrastim Product") pursuant to the subsection (k) pathway. The reference product for the Hospira Filgrastim Product is Neupogen® (filgrastim).

19. On or about November 20, 2017, the FDA accepted the Hospira aBLA for review.

20. On or about July 20, 2018, the FDA approved Hospira's aBLA.

21. The Hospira Filgrastim Product will be commercially marketed as NIVESTYM ® (filgrastim-aafi). NIVESTYM® is indicated to (1) decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; (2) reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia; (3) reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation; (4) mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and (5) reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

C. Defendants Complied with the Requirements of the BPCIA

22. In addition to the subsection (k) pathway, 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 application has been submitted to the FDA but before any court-enforced confidentiality protections are in place.

23. On or about December 11, 2017, Defendants provided Amgen with what it believed was the entire Hospira aBLA under 42 U.S.C. § 262(l)(3)(A). Due to inadvertent technical difficulties, Defendants were unaware that the initial disclosure of the aBLA was incomplete. Defendants worked to promptly remedy deficiencies noted by Amgen, and provided the remaining aBLA documents to Amgen on or before February 13, 2018.

24. The documents included in the initial December 11, 2017, disclosure included a substantial number of documents detailing how the Hospira Filgrastim Product is manufactured. These documents included: Module 3.2.S.2.2 "Description of Manufacturing Process and Process Controls"; Module 3.2.S.2.6 "Manufacturing Process Development"; Module 3.2.S.2.5 "Process Validation and/or Evaluation; and Module 2.3.S.1.3 "General Properties". These documents were heavily cited in Amgen's statement purporting to be in accordance with 42 U.S.C. § 262(l)(3)(C). Following Defendants' completion of the production of the full Hospira aBLA on or about February 13, 2018, the parties continued to engage in the information exchange procedure contemplated by the BPCIA, including good faith negotiations beginning on or about June 7, 2018. On or about June 22, 2018, the parties agreed that should Amgen bring a claim of patent infringement with respect to the filing of the Hospira aBLA, only U.S. Patent No. 9,643,997 would be the subject of an infringement action.

THE PATENT-IN-SUIT

25. U.S. Patent No. 9,643,997 (the "'997 Patent") is titled "Capture Purification Processes for Proteins Expressed in a Non-Mammalian System" and lists Joseph Edward Shultz and Roger Hart as the inventors. The '997 Patent, on its face, is assigned to Amgen,

Inc. According to the Complaint, Amgen is the owner of all rights, title, and interest in the '997 Patent.

COUNT I

Declaratory Judgment of Non-infringement of U.S. Patent No. 9,643,997

26. Defendants hereby incorporate by reference each and every allegation set forth in their Answer and Affirmative Defenses to the Complaint and Paragraphs 1 to 25 of the Counterclaims above.

27. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Hospira aBLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of the Hospira Filgrastim Product infringes, has infringed, or will infringe any valid and enforceable claim of the '997 Patent either directly or indirectly, and either literally or under the doctrine of equivalents.

28. Defendants have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '997 Patent either literally or under the doctrine of equivalents and are not liable for such infringement. For example, Defendants have not, do not, and will not infringe at least the following limitation of claim 9 of the '997 Patent and its dependent claims: "applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix."

29. Defendants are entitled to a declaration that they have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '997 Patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Hospira Filgrastim

Product that is the subject of the Hospira aBLA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '997 Patent.

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

31. The Hospira aBLA and additional documents provided to Amgen clearly establish that Amgen does not have a reasonable basis to assert the '997 Patent against the Defendants. Therefore, Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT II

Declaratory Judgment of Invalidity of U.S. Patent No. 9,643,997

32. Defendants hereby incorporate by reference each and every allegation set forth in their Answer and Defenses to the Complaint and Paragraphs 1 to 25 of the Counterclaims above.

33. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '997 Patent, based on Amgen's allegation in its Complaint that Hospira has infringed or will infringe the '997 Patent.

34. At least claim 9 of the '997 Patent, and its dependent claims, are 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. §§ 101, 102, 103, and/or 112, and/or any judicially-created doctrine of invalidity including obviousness-type double patenting.

35. Defendants are entitled to a judicial declaration that at least claim 9 of the '997 Patent, and its dependent claims, are invalid.

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

PRAYER FOR RELIEF

WHEREFORE, Defendants pray that the Court enter judgement in their favor and against Plaintiffs as follows:

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

B. Declaring that Defendants have not and will not infringe any valid and enforceable claim of the asserted patent;

C. Declaring that at least claim 9 and its dependent claims of the asserted patent are invalid;

D. 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 Defendants or their actual or prospective customers, sellers, dealers, or suppliers, or charging them either orally or in writing with infringement of the patent asserted herein against Defendants;

E. Granting Defendants Judgment in their favor on Plaintiff's Complaint;

F. Denying Plaintiffs' request for injunctive relief;

G. Denying Plaintiffs' request for any monetary damages;

H. Finding that Plaintiffs did not have a good-faith basis for bringing this action;

I. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Defendants' their costs and reasonable attorneys' fees;

J. An award of costs, expenses, and attorney fees pursuant to 28 U.S.C. § 1927;

K. An award of taxable costs;

L. An award of interest; and

M. Awarding any other such relief as it is just and proper.

Dated: August 9, 2018
Wilmington, Delaware

Respectfully submitted,

By: */s/ Arthur G. Connolly, III*

Arthur G. Connolly III (#2667)
Ryan P. Newell (#4744)
Mary Akhimien (#5448)
CONNOLLY GALLAGHER LLP
The Brandywine Building
1000 West Street
Suite 1400
Wilmington, Delaware 19801
Telephone: (302) 757-7300
Facsimile: (302) 757-7299
aconnolly@connollygallagher.com
rnewell@connollygallagher.com
makhimien@connollygallagher.com

OF COUNSEL:

Dimitrios T. Drivas
John Scheibeler
Alison Hanstead
Amit Thakore
White & Case LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Attorneys for Hospira, Inc. and Pfizer Inc.