

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC; ASTELLAS PHARMA
US, INC.; and GILEAD SCIENCES, INC.,

Plaintiff/Counterclaim Defendant,

v.

HOSPIRA, INC.,

Defendant/Counterclaim Plaintiff.

C.A. No. 20-00893

HOSPIRA, INC.’S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant Hospira, Inc. (“Hospira”), by and through its undersigned attorneys, provide the following answers and affirmative defenses to the Complaint of Plaintiffs Astellas US LLC, Astellas Pharma US, Inc., and Gilead Sciences, Inc. (collectively, “Plaintiffs”). This pleading is based upon Hospira’s knowledge as to its own activities, and upon information and belief as to the activities of others. Pursuant to Fed. R. Civ. P. 8(b)(3), Hospira denies all allegations in Plaintiffs’ Complaint, except those specifically admitted below.

NATURE OF THE ACTION¹

1. Hospira admits that the Complaint purports to bring an action for infringement arising under the patent laws of the United States, Title 35, United States Code, but denies that Plaintiffs are entitled to any such relief. Hospira admits that this action purports to relate to the submission of Abbreviated New Drug Application (“ANDA”) No. 214349 (“Hospira’s ANDA”) to the U.S. Food and Drug Administration (“FDA”).

¹ For the Court’s convenience, Hospira has incorporated the section titles that appear in the Complaint. Hospira does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

2. Hospira admits that Hospira's ANDA seeks approval to market 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson ("the Hospira ANDA Product"), which is a generic version of Plaintiffs' Lexiscan® drug product, prior to the expiration of U.S. Patent Nos. 8,106,183 ("the '183 patent"), RE 47,301 ("the '301 patent"), and 8,524,883 ("the '883 patent") (collectively, the "patents-in-suit"). Hospira otherwise denies the remaining allegations of paragraph 2.

PARTIES

3. Hospira is without sufficient knowledge and information to form a belief as to the allegations of paragraph 3, and therefore denies the same.

4. Hospira is without sufficient knowledge and information to form a belief as to the allegations of paragraph 4, and therefore denies the same.

5. Hospira is without sufficient knowledge and information to form a belief as to the allegations of paragraph 5, and therefore denies the same.

6. Hospira is without sufficient knowledge and information to form a belief as to the allegations of paragraph 6, and therefore denies the same.

7. Hospira admits that it is a corporation organized and existing under the laws of Delaware, having its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045. Hospira otherwise denies the remaining allegations of paragraph 7.

JURISDICTION AND VENUE

8. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira admits this action purports to arise under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.* Hospira does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 for the purposes of this action only. Hospira otherwise denies the remaining allegations of paragraph 8.

9. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hospira admits that it is incorporated in Delaware. Hospira otherwise denies the remaining allegations of paragraph 9.

10. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hospira otherwise denies the remaining allegations of paragraph 10.

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hospira otherwise denies the remaining allegations of paragraph 11.

12. Hospira admits that it has previously agreed not to dispute the exercise of personal jurisdiction over it by courts in the District of Delaware and has filed counterclaims in cases in the District of Delaware. Hospira otherwise denies the remaining allegations of paragraph 12.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira does not contest venue for purposes of this action only and expressly reserves the right to contest venue in any other case as to any party. Hospira otherwise denies the remaining allegations of paragraph 13.

14. Admitted.

PATENTS-IN-SUIT

15. Hospira admits that the '183 patent is titled, on its face, "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs," and bears an issuance date of January 31, 2012. Hospira admits that a purported copy of the '183 patent is attached to the Complaint as Exhibit A. Hospira denies that the '183 patent was duly and legally issued. Hospira also denies that the claims of the '183 patent are "valid, enforceable, and not expired." Hospira is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 15, and therefore denies the same.

16. Hospira admits that the '301 patent is titled, on its face, "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs," and bears a reissuance date of March 19, 2019. Hospira admits that the '301 patent, on its face, is a reissue of U.S. Patent No. 9,085,601, which bears an issuance date of July 21, 2015. Hospira admits that a purported copy of the '301 patent is attached to the Complaint as Exhibit B. Hospira denies that the '301 patent was duly and legally issued. Hospira also denies that the claims of the '301 patent are "valid, enforceable, and not expired." Hospira is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 16, and therefore denies the same.

17. Hospira admits that the '883 patent is titled, on its face, "Monohydrate of (1-[9-[4S,2R,3R,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-6-aminopurin-2-yl}pyrazol-4-yl)-N-methylcarboxamide," and bears an issuance date of September 3, 2013. Hospira admits that a purported copy of the '883 patent is attached to the Complaint as Exhibit C. Hospira denies that the '883 patent was duly and legally issued. Hospira also denies that the claims of the '883 patent are "valid, enforceable, and not expired." Hospira is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 17, and therefore denies the same.

18. Hospira admits that the “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”) identifies Astellas Pharma US, Inc. as the “Applicant Holder” for NDA No. 022161 for Lexiscan®. Hospira admits that the Orange Book identifies the dosage form of NDA No. 022161 as an intravenous solution of regadenoson at a strength of 0.4 mg/5mL (0.08 mg/mL). Hospira also admits that the Orange Book lists the ’183 and ’301 patents in connection with NDA No. 022161. Hospira further admits that the prescribing information for Lexiscan® states that it is a “pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.” Hospira is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 18, and therefore denies the same.

19. Hospira admits that the prescribing information for Lexiscan® states that it is a “pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.” Hospira admits that a purported copy of the prescribing information for Lexiscan® is attached as Exhibit D to the Complaint. Hospira is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 19, and therefore denies the same.

20. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira denies that any claim of the ’883 patent recites “processes for preparing a pharmaceutical composition of regadenoson with at least one pharmaceutically acceptable carrier.” Hospira otherwise denies the remaining allegations of paragraph 20.

INFRINGEMENT BY HOSPIRA

21. Hospira admits that it sent Plaintiffs a Notice Letter dated June 16, 2020 pursuant to 21 U.S.C. § 355(j)(2)(B), notifying Plaintiffs that Hospira’s ANDA includes a Paragraph IV Certification. Hospira otherwise denies the remaining allegations of paragraph 21.

22. Hospira admits that its Notice Letter notified Plaintiffs that pursuant to 21 U.S.C. § 355(j)(2)(B), Hospira's ANDA includes a Paragraph IV Certification with respect to the '183 and '301 patents. Hospira also admits that it submitted the Hospira ANDA to the FDA to seek approval to market a generic regadenoson product. Hospira otherwise denies the remaining allegations of paragraph 22.

23. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira admits that it represented to the FDA that the Hospira ANDA Product is an intravenous solution of regadenoson at a strength of 0.4 mg/5mL and is bioequivalent to Lexiscan®. Hospira otherwise denies the remaining allegations of paragraph 23.

24. Hospira admits that Hospira is seeking approval to market the Hospira ANDA Product for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. Hospira otherwise denies the remaining allegations of paragraph 24.

25. Hospira admits that, in its Notice Letter, Hospira notified Plaintiffs that the '183 and '301 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Hospira ANDA Product. Hospira otherwise denies the remaining allegations of paragraph 25.

26. Hospira admits that, in its Notice Letter, Hospira offered confidential access to portions of Hospira's ANDA, on terms and conditions set forth therein. Hospira otherwise denies the remaining allegations of paragraph 26.

27. Denied.

28. Denied.

29. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira is without sufficient knowledge and information to form a belief as to the allegations of paragraph 29, and therefore denies the same.

30. Denied.

31. Denied.

32. Denied.

33. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira admits it was aware of the '883 patent at the time it filed Hospira's ANDA. Hospira otherwise denies the remaining allegations of paragraph 33.

COUNT I
(INFRINGEMENT OF THE '183 PATENT)

34. Hospira repeats and incorporates by reference each of its answers to paragraphs 1 through 33 as if fully set forth herein.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

COUNT II
(INFRINGEMENT OF THE '301 PATENT)

39. Hospira repeats and incorporates by reference each of its answers to paragraphs 1 through 38 as if fully set forth herein.

40. Denied.

41. Denied

42. Denied.

43. Denied.

COUNT III
(DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE '883 PATENT)

44. Hospira repeats and incorporates by reference each of its answers to paragraphs 1 through 43 as if fully set forth herein.

45. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hospira does not dispute that, in light of Plaintiffs' allegations in the Complaint, there is a justiciable controversy regarding Hospira's non-infringement of the '883 patent. Hospira denies that Plaintiffs have any good faith basis for bringing their infringement allegations regarding the '883 patent. Hospira further denies that there is any genuine dispute regarding Hospira's non-infringement of the '883 patent and denies that the Hospira ANDA Product infringes any valid and enforceable claim of the '883 patent. Hospira otherwise denies the remaining allegations of paragraph 45.

46. Denied.

47. Hospira admits that it submitted Hospira's ANDA to the FDA in accordance with the regulatory requirements for approval. Hospira otherwise denies the remaining allegations of paragraph 47.

48. Denied.

49. Denied.

50. Denied.

RESPONSE TO PRAYER FOR RELIEF

Hospira denies that Plaintiffs are entitled to any relief sought in their Prayer for Relief or any relief at all for the allegations made in the Complaint.

AFFIRMATIVE DEFENSES

Hospira asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hospira does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Hospira reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

Hospira does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent. If the Hospira ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Hospira would not infringe any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent.

SECOND DEFENSE

Hospira has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent. If the Hospira ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Hospira would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent.

THIRD DEFENSE

The claims of the '183 patent, the '301 patent, and the '883 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTH DEFENSE

Claims of the '183 patent, the '301 patent, and the '883 patent are barred in whole or in part by the doctrine of prosecution history estoppel and/or judicial estoppel.

FIFTH DEFENSE

To the extent the Complaint purports to seek injunctive relief against Hospira, the Complaint fails to state a claim for injunctive relief because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

SIXTH DEFENSE

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Hospira's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

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

EIGHTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

HOSPIRA, INC.'S COUNTERCLAIMS

For their Counterclaims against Plaintiffs/Counterclaim Defendants Astellas US LLC, Astellas Pharma US, Inc. (collectively, “Astellas”), and Gilead Sciences, Inc. (“Gilead”) (collectively, “Counterclaim Defendants”), Counterclaim Plaintiff/Defendant Hospira, Inc. (“Hospira”) states as follows:

NATURE OF THE ACTION

1. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* (including 35 U.S.C. §271(e)(5)), and/or 21 U.S.C. § 355(j)(5)(C).

2. Hospira seeks a declaratory judgment that U.S. Patent Nos. 8,106,183 (“the ’183 patent”), RE47,301 (“the ’301 patent”), and 8,524,883 (“the ’883 patent”) (collectively, “the patents-in-suit”), are not infringed by the manufacture, use, sale, offer for sale, or importation of the 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson that is the subject of Hospira’s ANDA No. 214349 (“the Hospira ANDA Product”).

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. On information and belief, Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

5. On information and belief, Astellas Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

6. On information and belief, Gilead is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, CA 94404.

JURISDICTION AND VENUE

7. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Counterclaim Defendants on the basis of, *inter alia*, their contacts with Delaware relating to the subject matter of this action, including having filed suit.

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

10. On information and belief, Astellas Pharma US, Inc. holds approved New Drug Application (“NDA”) No. 022161 for Lexiscan®, which is an intravenous solution of regadenoson formulated at a strength of 0.4 mg/5 mL (0.08 mg/mL).

11. An NDA must include, among other things, the number of any patent that claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

12. Upon approval of the NDA, the U.S. Food and Drug Administration (“FDA”) publishes patent information for the approved drug in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. The '183 patent is titled, on its face, "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs," and bears an issuance date of January 31, 2012.

14. On information and belief, Gilead is the owner of the '183 patent and Astellas US LLC holds an exclusive license to the '183 patent.

15. The '301 patent is titled, on its face, "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs," and bears a reissuance date of March 19, 2019.

16. On information and belief, Gilead is the owner of the '301 patent and Astellas US LLC holds an exclusive license to the '301 patent.

17. The '883 patent is titled, on its face, "Monohydrate of (1-{9-[4S,2R,3R,5R]-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-6-aminopurin-2-yl}pyrazol-4-yl)-N-methylcarboxamide," and bears an issuance date of September 3, 2013.

18. On information and belief, Gilead is the owner of the '883 patent and Astellas US LLC holds an exclusive license to the '883 patent.

19. On information and belief, one or more Counterclaim Defendants caused the '183 and '301 patents to be listed in the Orange Book in connection with Lexiscan®.

20. Hospira submitted Abbreviated New Drug Application ("ANDA") No. 214349 ("Hospira's ANDA") to obtain FDA approval to market an intravenous solution of regadenoson 0.4 mg/5 mL (0.08 mg/mL) prior to the expiration of the '183 and '301 patents.

21. By letter dated June 16, 2020 (the "Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Hospira notified Counterclaim Defendants that ANDA No. 214349 includes a Paragraph IV Certification with respect to the '183 and '301 patents. The Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for

Hospira's Paragraph IV Certification that the claims of the '183 and '301 patents are invalid, not infringed, and/or unenforceable.

22. On June 30, 2020, Counterclaim Defendants filed this instant lawsuit alleging infringement of the '183, '301, and '883 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '183 Patent)

23. Hospira re-alleges and incorporates by reference the allegations in paragraphs 1 through 22 of its Counterclaims as if fully set forth herein.

24. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hospira's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Hospira ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '183 patent.

25. Hospira has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '183 patent and is not liable for such infringement.

26. Hospira is entitled to a declaration that if the Hospira ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Hospira would not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '183 patent.

COUNT II
(Declaratory Judgment of Non-Infringement of the '301 Patent)

27. Hospira re-alleges and incorporates by reference the allegations in paragraphs 1 through 26 of its Counterclaims as if fully set forth herein.

28. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hospira's ANDA and/or the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Hospira ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '301 patent.

29. Hospira has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '301 patent and is not liable for such infringement.

30. Hospira is entitled to a declaration that if the Hospira ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Hospira would not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '301 patent.

COUNT III
(Declaratory Judgment of Non-Infringement of the '883 Patent)

31. Hospira re-alleges and incorporates by reference the allegations in paragraphs 1 through 30 of its Counterclaims as if fully set forth herein.

32. In light of Counterclaim Defendants' allegations in the Complaint, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Hospira ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '883 patent.

33. Hospira has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '883 patent and is not liable for such infringement.

34. Hospira is entitled to a declaration that if the Hospira ANDA Product was manufactured, used, offered for sale, or sold within the United States, or imported into the United States, Hospira would not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '883 patent.

PRAYER FOR RELIEF

WHEREFORE, Hospira respectfully requests judgment in its favor and against Counterclaim Defendants as follows:

- A. Declaring that the filing of Hospira's ANDA has not infringed and does not infringe any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent;
- B. Declaring that the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Hospira ANDA Product does not, and would not, infringe any valid and enforceable claim of the '183 patent, the '301 patent, or the '883 patent;
- C. Declaring this an exceptional case in favor of Hospira and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;
- D. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and
- E. Awarding any and all such other relief as the Court determines to be just and proper.

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