IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED ACCELERATOR APPLICATIONS USA, INC. and ADVANCED ACCELERATOR APPLICATIONS SA, Plaintiffs, v. LANTHEUS MEDICAL IMAGING, INC., LANTHEUS HOLDINGS, INC., POINT BIOPHARMA USA INC., and POINT BIOPHARMA GLOBAL INC., Defendants.	C.A. No. __

COMPLAINT

Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA (collectively, "ADACAP" or "Plaintiffs") by their attorneys hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, et seq. This action relates to an Abbreviated New Drug Application ("ANDA") No. 217060 filed by the above-named defendants with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import of a generic version of ADACAP's LUTATHERA® (lutetium Lu 177 dotatate) injection, prior to expiration of U.S. Patent No. 10,596,276 ("the '276 patent").

PARTIES

A. Plaintiffs

2. Advanced Accelerator Applications USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 57 E. Willow Street, Millburn, NJ 07041.

3. Advanced Accelerator Applications SA is a corporation organized and existing under the laws of France, with its principal place of business in France.

4. ADACAP is in the business of creating, developing, and bringing to market new drug therapies to benefit patients against serious diseases, including targeted radioligand therapy for the treatment for cancer. LUTATHERA® is one such treatment. ADACAP markets and sells LUTATHERA® in this judicial district and throughout the United States.

B. Defendants

5. Upon information and belief, Defendant Lantheus Medical Imaging, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 331 Treble Cove Road B300-2, N. Billerica, MA 01862.

6. Upon information and belief, Defendant Lantheus Holdings, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 201 Burlington Road, South Building, Bedford, MA 01730.

7. Upon information and belief, Lantheus Medical Imaging, Inc. is a wholly owned subsidiary of Lantheus Holdings, Inc. (collectively, “Lantheus”).

8. Upon information and belief, Lantheus is in the business of, inter alia, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling pharmaceutical products throughout the United States (including in the State of Delaware).

9. Upon information and belief, Defendant POINT Biopharma Global Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 4850 West 78th Street, Indianapolis, IN 46268.

10. Upon information and belief, Defendant POINT Biopharma USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 4850 West 78th Street, Indianapolis, IN 46268.

11. Upon information and belief, POINT Biopharma USA Inc. is a wholly owned subsidiary of POINT Biopharma Global Inc. (collectively, "POINT").

12. Upon information and belief, POINT is in the business of, inter alia, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling pharmaceutical products throughout the United States (including in the State of Delaware).

13. Lantheus and POINT are collectively referred to hereafter as "Defendants" unless otherwise noted.

14. By a letter dated December 12, 2023, Lantheus notified ADACAP that Defendants had submitted to the FDA ANDA No. 217060 for Lutetium Lu-177 Dotatate injection solution, a generic version of LUTATHERA® ("Defendants' ANDA Product"), seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' ANDA Product prior to the expiration of the '276 patent.

15. In its Notice Letter, Lantheus notified ADACAP that, as a part of Defendants' ANDA, Defendants had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '276 patent asserting that the '276 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' ANDA Product.

16. Upon information and belief, Lantheus and POINT have entered into "strategic collaboration agreements" under which Lantheus and POINT will collaborate in seeking FDA approval of Defendants' ANDA Product, and, following any such approval Lantheus and POINT will collaborate to manufacture and commercialize in the United States Defendants' ANDA Product. *See https://www.globenewswire.com/news-release/2022/11/14/2554779/0/en/Lantheus-and-POINT-Biopharma-Announce-Strategic-Collaboration-and-Exclusive-License-Agreements-for-the-Commercialization-of-PNT2002-PNT2003.html* (last accessed January 22, 2024).

17. Upon information and belief, Lantheus and POINT acted collaboratively in the preparation and submission of ANDA No. 217060.

18. Upon information and belief, following any FDA approval of ANDA No. 217060, Lantheus and POINT will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 217060 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

JURISDICTION AND VENUE

19. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

20. Upon information and belief, Defendants are each organized and existing under the laws of the State of Delaware.

21. Defendants have committed an act of infringement of the '276 patent in this judicial district by filing ANDA No. 217060 with the intent to make, use, offer to sell, sell, and/or import the generic drug products that are the subject of ANDA No. 217060 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, selling, and/or importing the same, acts of infringement that will lead to foreseeable harm and injury to ADACAP, including through Advanced Accelerator Applications USA, Inc., a Delaware corporation.

22. Upon information and belief, Defendants have extensive contacts with Delaware, regularly conduct business in Delaware, have purposefully availed themselves of the privilege of doing business in Delaware, and intend to sell in Delaware the product described in ANDA No. 217060 upon approval.

23. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Defendants.

THE ’276 PATENT AND LUTATHERA®

24. On March 24, 2020, the U.S. Patent and Trademark Office duly and legally issued the ’276 patent, entitled “Stable, Concentrated Radionuclide Complex Solutions.” A true and correct copy of the ’276 patent is attached hereto as Exhibit A.

25. The claims of the ’276 patent are valid and enforceable. The ’276 patent is wholly owned by Advanced Accelerator Applications SA, which therefore has the right to sue for and obtain equitable relief and damages for infringement of the ’276 patent.

26. Advanced Accelerator Applications USA, Inc. is the holder of New Drug Application (“NDA”) No. 208700 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of LUTATHERA®. LUTATHERA® is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

27. LUTATHERA® and the use of LUTATHERA® is covered by one or more claims of the ’276 patent.

28. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’276 patent in connection with LUTATHERA®.

COUNT I: INFRINGEMENT BY EACH DEFENDANT OF THE ’276 PATENT UNDER 35 U.S.C. § 271(e)

29. ADACAP incorporates each of the proceeding paragraphs 1–28 as if fully set forth herein.

30. By filing their ANDA, Defendants have necessarily represented to the FDA that, upon approval, Defendants’ ANDA Product will have the same active ingredient,

method of administration, dosage form, and strength as LUTATHERA®, and will be bioequivalent to LUTATHERA®.

31. Defendants' submission of ANDA No. 217060 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Defendants' ANDA Product, prior to the expiration of the '276 patent constitutes infringement of one or more of the claims of the '276 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, Defendants had actual and constructive knowledge of the '276 patent at least as of December 12, 2023 and have since been aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '276 patent.

33. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 217060.

34. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product would infringe one or more claims of the '276 patent.

35. Upon information and belief, Defendants know that the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product would infringe one or more claims of the '276 patent.

36. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '276 patent when their ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

37. Upon information and belief, Defendants know that Defendants' ANDA Product is especially made or adapted for use in infringing the '276 patent, and that Defendants' ANDA Product is not suitable for any substantial non-infringing use.

38. The foregoing acts by Defendants constitute and/or will constitute direct and indirect infringement of the '276 patent.

39. If Defendants' infringement of the '276 patent is not permanently enjoined, ADACAP will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT INFRINGEMENT BY EACH DEFENDANT OF THE '276 PATENT UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

40. ADACAP incorporates each of the proceeding paragraphs 1–39 as if fully set forth herein.

41. Upon information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product immediately and imminently upon final approval of ANDA No. 217060. Therefore a case or controversy exists between each Defendant or group of Defendants and ADACAP as to infringement of the '276 patent.

42. By filing their ANDA, Defendants have necessarily represented to the FDA that, upon approval, Defendants' ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as LUTATHERA®, and will be bioequivalent to LUTATHERA®.

43. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product would infringe one or more claims of the '276 patent.

44. Upon information and belief, each of Lantheus and POINT will know that the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' ANDA Product would infringe one or more claims of the '276 patent.

45. Upon information and belief, Lantheus and POINT will each have actual and constructive knowledge of the '276 patent, and each will actively induce the other to infringe the '276 patent when ANDA No. 217060 is approved, and will each do so immediately and imminently upon final approval.

46. Upon information and belief, each of Lantheus and POINT will know that Defendants' ANDA Product is especially made or adapted for use in infringing the '276 patent, and that Defendants' ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, each of Lantheus and POINT will contribute to the infringement of the '276 patent immediately and imminently upon approval of NDA No. 217060.

47. The foregoing acts by Defendants constitute and/or will constitute direct infringement of the '276 patent, active inducement of infringement of the '276 patent, and/or contribution to the infringement by others of the '276 patent under 35 U.S.C. §§ 271(a), (b), and (c).

48. If Defendants' infringement of the '276 patent is not permanently enjoined, ADACAP will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ADACAP prays that this Court grant the following relief:

1. A declaration and judgment that Defendants' imminent making, using, offering to sell, or selling in the United States, or importing into the United States, or inducing or contributing to the same, of Defendants' ANDA Product will infringe the '276 patent;

2. A judgment that one or more claims of the '276 patent is not invalid, is enforceable, and is infringed by Defendants' submission of ANDA No. 217060, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States of Defendants' ANDA Product, will infringe the '276 patent.

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 217060 shall be a date which is not earlier than the expiration date of the '276 patent, including any extensions and/or additional periods of exclusivity to which ADACAP is or becomes entitled.

4. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendants' ANDA Product, until after the expiration date of the '276 patent, including any extensions and/or additional periods of exclusivity to which ADACAP is or becomes entitled.

5. Damages or other monetary relief to ADACAP if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendants' ANDA Product, prior to the expiration date of the '276 patent, including any extensions and/or additional periods of exclusivity to which ADACAP is or becomes entitled.

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: January 25, 2024

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