IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED ACCELERATOR APPLICATIONS USA, INC. and ADVANCED ACCELERATOR APPLICATIONS SA, Plaintiffs, v. CURIUM US LLC, CURIUM US HOLDINGS LLC, CURIUM NETHERLANDS BV, and CURIUM INTERNATIONAL TRADING BV., Defendants.	C.A. No. __

COMPLAINT

Plaintiffs Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA (collectively, "ADACAP") 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 a New Drug Application No. 218525 filed under 21 U.S.C. § 505(b)(2) 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 version of ADACAP's LUTATHERA® (lutetium Lu 177 dotatate) injection, prior to expiration of U.S. Patent No. 12,415,003 ("the '5003 patent").

PARTIES

A. Plaintiffs

2. ADACAP USA is a Delaware corporation with a principal place of business at 57 E. Willow Street, Millburn, NJ 07041. ADACAP USA was formerly known as BioSynthema, Inc., before it was acquired by ADACAP SA in 2010.

3. ADACAP SA is a French corporation with a principal place of business in France. ADACAP SA is the ultimate parent in the Advanced Accelerator family of companies and is now an indirect wholly owned subsidiary of Novartis AG.

4. ADACAP creates, develops, and brings to market new drug therapies, including targeted radioligand therapy for the treatment of cancer. Lutathera is one such treatment. ADACAP markets and sells Lutathera in this judicial district and throughout the United States.

B. Defendants

5. Defendant Curium US LLC is a Delaware limited liability company with a principal place of business at 111 West Port Plaza Drive Suite 800, St. Louis, MO 63146.

6. Defendant Curium US Holdings LLC is a Delaware limited liability company with a principal place of business at 111 West Port Plaza Drive Suite 800, St. Louis, MO 63146. Curium US Holdings LLC wholly owns and controls Curium US LLC. Curium's management in Europe controls Curium US Holdings LLC and, through it, Curium US LLC.

7. Defendant Curium Netherlands BV is a Dutch besloten vennootschap with a principal place of business at Westerduinweg 3, 1755 LE, Petten, Netherlands. Curium Netherlands BV wholly owns and controls Curium US Holdings LLC.

8. Defendant Curium International Trading BV is a Dutch besloten vennootschap with a principal place of business at Westerduinweg 3, 1755 LE, Petten, Netherlands. Curium International Trading BV wholly owns and controls Curium Netherlands BV.

9. Curium Netherlands BV and Curium International Trading BV are collectively referred to as "Curium Netherlands" hereinafter, unless otherwise noted.

10. Curium US LLC, Curium US Holdings LLC, Curium Netherlands BV, and Curium International Trading BV are collectively referred to herein as "Curium," "Defendants," or the "Curium Defendants," unless otherwise noted. According to public documents, the ultimate owner of the Curium Defendants is a British private equity fund called "CapVest."

11. Upon information and belief, Curium 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).

12. By a letter dated September 5, 2024, Curium notified ADACAP that Curium had submitted to the FDA NDA No. 218525 ("Curium Application No. 218525") for Lutetium Lu-177 Dotatate injection solution, a version of Lutathera ("the 505(b)(2) 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 Curium's 505(b)(2) Product prior to the expiration of ADACAP's Orange Book listed patents, which then included U.S. Patent Nos. 10,596,276; 10,596,278; and 11,904,027.

13. In its Notice Letter, Curium notified ADACAP that, as a part of Curium Application No. 218525, Curium had filed a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA (21 U.S.C. § 355(b)(2)(A)(iv)), with respect to ADACAP's Orange Book patents asserting that the patents are 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 Curium's 505(b)(2) Product.

14. Upon information and belief, Curium Netherlands is in the business of the manufacture and global distribution of radioactive compounds as well as the research and development of radiopharmaceuticals for diagnostics and therapeutic use. Upon information and belief, Curium US LLC, Curium US Holdings LLC, and Curium Netherlands collaborated in the research and development of the drug product that is the subject of Curium Application No. 218525.

15. Upon information and belief, following any FDA approval of Curium Application No. 218525, Curium Netherlands will manufacture Lutetium-177 for the production of the drug product that is the subject of Curium Application No. 218525.

16. Upon information and belief, Curium US LLC, Curium US Holdings LLC, and Curium Netherlands acted collaboratively in the preparation and submission of Curium Application No. 218525.

17. Upon information and belief, following any FDA approval of Curium Application No. 218525, Curium US LLC, Curium US Holdings LLC, and Curium Netherlands will work in concert with one another to make, use, offer to sell, and/or sell the drug products that are the subject of Curium Application No. 218525 throughout the United States, and/or import such drug products into the United States, including in this judicial district.

JURISDICTION AND VENUE

18. 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).

19. Upon information and belief, Curium US LLC and Curium US Holdings LLC are each organized and existing under the laws of the State of Delaware.

20. Upon information and belief, Curium Netherlands BV and Curium International Trading BV are foreign corporations not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

21. Defendants have committed an act of infringement of the '5003 patent in this judicial district by filing Curium Application No. 218525 with the intent to make, use, offer to sell, sell, and/or import the drug products that are the subject of Curium Application No. 218525 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 drug product described in Curium Application No. 218525 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 PATENT-IN-SUIT AND LUTATHERA

24. On September 16, 2025, the U.S. Patent and Trademark Office duly and legally issued the '5003 patent, entitled "Stable, Concentrated Radionuclide Complex Solutions." A true and correct copy of the '5003 patent is attached hereto as Exhibit A.

25. The claims of the '5003 patent are valid and enforceable. The '5003 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 '5003 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 '5003 patent.

28. The FDA's official publication of approved drugs (the "Orange Book") lists or shortly after the filing of this complaint is expected to list the '5003 patent in connection with Lutathera.

CAUSES OF ACTION

29. ADACAP accordingly asserts the following causes of action, and seeks the relief set forth below.

COUNT I

(Infringement of U.S. Patent No. 12,415,003 Under 35 U.S.C. § 271(e)(2)(A))

30. ADACAP repeats and realleges each allegation set forth above as if fully set forth herein.

31. On September 16, 2025, the U.S. PTO duly and legally issued the '5003 patent, entitled "Stable, Concentrated Radionuclide Complex Solutions." A true and correct copy of the '5003 patent is attached hereto as Exhibit A.

32. The claims of the '5003 patent are valid and enforceable. The '5003 patent is wholly owned by ADACAP SA, which therefore has the right to sue for and obtain equitable relief and damages for infringement of the '5003 patent.

33. ADACAP USA is the holder of NDA No. 208700 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of Lutathera, a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive GEP-NETs, including foregut, midgut, and hindgut neuroendocrine tumors in adults. ADACAP USA holds a license to practice the '5003 patent in the United States.

34. Lutathera and the use of Lutathera is covered by one or more claims of the '5003 patent, which is listed or is expected shortly to be listed on the FDA's official publication of approved drugs (the "Orange Book").

35. By filing Curium FDA Application No. 218525, Defendants have necessarily represented to the FDA that, upon approval, Defendants' 505(b)(2) product will have the same active ingredient, method of administration, dosage form, and strength as Lutathera, and will be bioequivalent to Lutathera.

36. Defendants' submission of Curium Application No. 218525 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of Defendants' 505(b)(2) product, prior to the expiration of the '5003 patent constitutes infringement of one or more of the claims of the '5003 patent under 35 U.S.C. § 271(e)(2)(A).

37. Defendants had actual and constructive knowledge of the '5003 patent at least as September 10, 2025, and have filed the aforementioned Curium Application No. 218525 with the FDA which constitutes an act of infringement of the '5003 patent.

38. Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product with its proposed labeling immediately and imminently upon approval of Curium Application No. 218525.

39. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product would infringe one or more claims of the '5003 patent.

40. Defendants know that the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product would infringe one or more claims of the '5003 patent.

41. Defendants plan and intend to, and will, actively induce infringement of the '5003 patent when Curium Application No. 218525 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

42. Defendants know that Defendants' 505(b)(2) product is especially made or adapted for use in infringing the '5003 patent, and that Defendants' 505(b)(2) product is not suitable for any substantial non-infringing use.

43. The foregoing acts by Defendants constitute and/or will constitute direct and indirect infringement of the '5003 patent.

44. If Defendants' infringement of the '5003 patent is not permanently enjoined, ADACAP will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

(Declaratory Judgment on Infringement of U.S. Patent No. 12,415,003 Under 35 U.S.C. § 271(a), (b), and (c))

45. ADACAP repeats and realleges each allegation set forth above as if fully set forth herein.

46. Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product immediately

and imminently upon final approval of Curium Application No. 218525. Therefore, a case or controversy exists between each Defendant and ADACAP as to infringement of the '5003 patent.

47. By filing Curium Application No. 218525, Defendants have necessarily represented to the FDA that, upon approval, Defendants' 505(b)(2) product will have the same active ingredient, method of administration, dosage form, and strength as Lutathera, and will be bioequivalent to Lutathera.

48. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product would infringe one or more claims of the '5003 patent.

49. Each Defendant will know that the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Defendants' 505(b)(2) product would infringe one or more claims of the '5003 patent.

50. Each Defendant will have actual and constructive knowledge of the '5003 patent, and each will actively induce the other to infringe the '5003 patent when Curium Application No. 218525 is approved, and will each do so immediately and imminently upon final approval.

51. Each Defendant will know that Defendants' 505(b)(2) product is especially made or adapted for use in infringing the '5003 patent, and that Defendants' 505(b)(2) product is not suitable for any substantial non-infringing use. Upon information and belief, each Defendant will contribute to the infringement of the '5003 patent immediately and imminently upon approval of Curium Application No. 218525.

52. The foregoing acts by Defendants constitute and/or will constitute direct infringement of the '5003 patent, active inducement of infringement of the '5003 patent, and/or

contribution to the infringement by others of the '5003 patent under 35 U.S.C. §§ 271(a), (b), and (c).

53. If Defendants' infringement of the '5003 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' 505(b)(2) product will infringe one or more claims of the 12,415,003 patent.

2. A judgment that one or more claims of the 12,415,003 patent is not invalid, is enforceable, and is infringed by Defendants' submission of Curium Application No. 218525, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States of Defendants' 505(b)(2) product, will infringe one or more claims of the 12,415,003 patent.

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Curium Application No. 218525 shall be a date which is not earlier than the expiration of the 12,415,003 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' 505(b)(2) Product, until after the expiration of the 12,415,003 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' 505(b)(2) Product, prior to the expiration date(s) of the 12,415,003 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: September 16, 2025

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