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

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 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. 12,168,063 (the "'063 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 Curium US LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 111 West Port Plaza Drive Suite 800, St. Louis, MO 63146.

6. Upon information and belief, Defendant Curium US Holdings LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 111 West Port Plaza Drive Suite 800, St. Louis, MO 63146.

7. Upon information and belief, Defendant Curium Netherlands BV is a Dutch besloten vennootschap organized and existing under the laws of the Netherlands, having a principal place of business at Westerduinweg 3, 1755 LE, Petten, Netherlands.

8. Upon information and belief, Defendant Curium International Trading BV is a Dutch besloten vennootschap organized and existing under the laws of the Netherlands, having a principal place of business at Westerduinweg 3, 1755 LE, Petten, Netherlands.

9. Upon information and belief, Curium US Holdings LLC wholly owns and controls Curium US LLC.

10. Upon information and belief, Curium Netherlands BV wholly owns and controls Curium US Holdings LLC.

11. Upon information and belief, Curium International Trading BV wholly owns and controls Curium Netherlands BV.

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

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

14. 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).

15. 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 U.S. Patent No. 10,596,276 (the "'276 patent"), U.S. Patent No. 10,596,278 (the "'278 patent"), and U.S. Patent No. 11,904,027 (the "'027 patent").

16. 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. Upon information and belief, Maarten de Jong and other scientists at Curium Netherlands have expertise in the formulation and manufacture of radiopharmaceuticals for diagnostics and therapeutic use. Upon information and belief, de Jong and other scientists at Curium Netherlands were directly involved in the design, research, and development of the formulation and the manufacturing process for producing the drug product that is the subject of Curium Application No. 218525.

17. Upon information and belief, Curium Netherlands recently opened a new Lutetium-177 production facility to supply Lutetium-177 to cancer patients worldwide. *See* *https://www.curiumpharma.com/2024/09/24/netherlands-lutetium-177/* (last accessed October 16, 2024) (Exhibit D). 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.

18. 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.

19. 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

20. 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).

21. 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.

22. 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).

23. Defendants have committed an act of infringement of the ’063 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.

24. 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.

25. Moreover, in Curium's September 5, 2024 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 the '276, '278, and '027 patents asserting that all three 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.

26. Based on Curium's Notice Letter, on October 17, 2024, ADACAP brought a patent infringement action against Curium in this District, asserting infringement of the '276, '278, and '027 patents under the Hatch-Waxman Act and 35 U.S.C. §§ 271(a), (b), and (c). C.A. No. 24-1161-MN.

27. Subsequently, U.S. Patent Nos. 12,144,873 (the "'873 patent"); 12,151,003 (the "'003 patent"); and 12,161,732 (the "'732 patent") were issued and soon listed in the FDA's Orange Book associated with LUTATHERA®. U.S. Patent No. 12,168,063, issued on December 17, 2024, was just listed in the FDA's Orange Book associated with LUTATHERA®.

28. On December 13, 2024, ADACAP filed a First Amended Complaint in C.A. No. 24-1161-MN, asserting infringement of the '276, '278, '027, '873, '003, and '732 patents under the Hatch-Waxman Act and 35 U.S.C. §§ 271(a), (b), and (c) as well as claims of trade secrets misappropriation, breach of contract, breach of covenant of good faith and fair dealing, and conversion. C.A. No. 24-1161-MN (D.I. 28).

29. In Civil Action No. 24-1161-MN, Defendants have already stipulated to venue and personal jurisdiction in this District. C.A. No. 24-1161-MN (D.I. 14) (resolving any "issues between the parties with respect to venue and personal jurisdiction").

30. 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 '063 PATENT AND LUTATHERA®

31. On December 17, 2024, the U.S. Patent and Trademark Office duly and legally issued the '063 patent, entitled "Stable, Concentrated Radionuclide Complex Solutions." A true and correct copy of the '063 patent is attached hereto as Exhibit A.

32. The claims of the '063 patent are valid and enforceable. The '063 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 '063 patent.

33. 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.

34. LUTATHERA® and the use of LUTATHERA® is covered by one or more claims of each of the '063 patent.

35. The FDA's official publication of approved drugs (the "Orange Book") will soon list the '063 patent in connection with LUTATHERA®.

COUNT I: INFRINGEMENT BY EACH DEFENDANT OF THE '063 PATENT UNDER 35 U.S.C. § 271(e)

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

37. 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®.

38. Curium's Paragraph IV notice letter states that Curium had filed its Curium Application No. 218525 seeking approval to manufacture, use, and sell a generic version of Lutathera before the expiration of the '276, '278, and '027 patents. Curium therefore necessarily seeks to sell a generic version before the expiration of the '063 patent.

39. 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 '063 patent constitutes infringement of one or more of the claims of the '063 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Defendants had actual and constructive knowledge of the '063 patent at least as of December 13, 2024, and have since been aware that filing of the aforementioned Curium Application No. 218525 with the FDA constituted an act of infringement of the '063 patent.

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' 505(b)(2) Product with its proposed labeling immediately and imminently upon approval of Curium Application No. 218525.

42. 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 '063 patent.

43. Upon information and belief, 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 '063 patent.

44. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '063 patent when Curium Application No. 218525 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

45. Upon information and belief, Defendants know that Defendants' 505(b)(2) Product is especially made or adapted for use in infringing the '063 patent, and that Defendants' 505(b)(2) Product is not suitable for any substantial non-infringing use.

46. The foregoing acts by Defendants constitute and/or will constitute direct and indirect infringement of the '063 patent.

47. In particular, under cases from this District and others, service of a Paragraph IV notice letter alone is sufficient to support a claim under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A). *See, e.g.*, *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326 (D. Del. 2019); *Silvergate Pharms., Inc. v. Bionpharma Inc.*, No. 18-CV-1962, 2024 WL 4417104 (D. Del. Oct. 4, 2024); *Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, No. CV 22-1395-RGA, 2023 WL 6387975 (D. Del. Sept. 29, 2023); *Abraxis Bioscience, LLC v. HBT Labs, Inc.*, No. CV 18-2019-RGA, 2019 WL 2270440 (D. Del. May 28, 2019); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409 (D. Del. 2010); *Endo Par Innovation Co., LLC v. BPI Labs, LLC*, No. 8:23-CV-1953-WFJ-TGW, 2024 WL 730478

(M.D. Fla. Feb. 22, 2024); *Bristol-Myers Squibb Co. v. Xspray Pharma AB*, No. CV 22-964 (RMB/MJS), 2023 WL 3354261 (D.N.J. Apr. 25, 2023); *Encore Dermatology Inc. v. Glenmark Pharms. Ltd.*, No. CV2002509KMESK, 2020 WL 7586958 (D.N.J. Dec. 22, 2020); *Celgene Corp. v. Sun Pharma Glob. FZE*, No. CV1910099SDWLDW, 2020 WL 1921700 (D.N.J. Apr. 6, 2020); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. CV 18-3632-SDW-CLW, 2018 WL 5263278 (D.N.J. Oct. 23, 2018); *Celgene Corp. v. KV Pharm. Co.*, 2008 WL 2856469 (D.N.J. July 22, 2008).

48. If Defendants' infringement of the '063 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 BY EACH DEFENDANT OF THE '063 PATENT UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

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

50. Upon information and belief, 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 or group of Defendants and ADACAP as to infringement of the '063 patent.

51. 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®.

52. Curium's Paragraph IV notice letter states that Curium had filed its Curium Application No. 218525 seeking approval to manufacture, use, and sell a generic version of

Lutathera before the expiration of the ’276, ’278, and ’027 patents. Curium therefore necessarily seeks to sell a generic version before the expiration of the ’063 patent.

53. 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 ’063 patent.

54. Upon information and belief, each of Curium US LLC, Curium US Holdings LLC, Curium Netherlands BV, and Curium International Trading BV 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 ’063 patent.

55. Upon information and belief, Curium US LLC, Curium US Holdings LLC, Curium Netherlands BV, and Curium International Trading BV will each have actual and constructive knowledge of the ’063 patent, and each will actively induce the other to infringe the ’063 patent when Curium Application No. 218525 is approved, and will each do so immediately and imminently upon final approval.

56. Upon information and belief, each of Curium US LLC, Curium US Holdings LLC, Curium Netherlands BV, and Curium International Trading BV will know that Defendants’ 505(b)(2) Product is especially made or adapted for use in infringing the ’063 patent, and that Defendants’ 505(b)(2) Product is not suitable for any substantial non-infringing use. Upon information and belief, each of Curium US LLC, Curium US Holdings LLC, Curium Netherlands BV, and Curium International Trading BV will contribute to the infringement of the ’063 patent immediately and imminently upon approval of Curium Application No. 218525.

57. The foregoing acts by Defendants constitute and/or will constitute direct infringement of the ’063 patent, active inducement of infringement of the ’063 patent, and/or

contribution to the infringement by others of the ’063 patent under 35 U.S.C. §§ 271(a), (b), and (c).

58. If Defendants’ infringement of the ’063 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 the ’063 patent.

2. A judgment that one or more claims of the ’063 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 the ’063 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 ’063 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 ’063 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 of the '063 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: December 20, 2024

MCCARTER & ENGLISH, LLP

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