IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), and Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharm.") (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,481,663 ("the 663 Patent" or the "Patent-In-Suit").

2. This action relates to the submission of Abbreviated New Drug Application No. 217084 ("the ANDA") by Defendants to the United States Food and Drug Administration ("FDA") seeking approval to market a proposed generic version of Erleada® ("Proposed ANDA Product") prior to the expiration of the Patent-In-Suit.

THE PARTIES

3. Aragon is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 10990 Wilshire Boulevard, Suite 440, Los Angeles, California 90024.

4. JBI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

5. Sloan-Kettering is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

6. On information and belief, Lupin Ltd. is a corporation organized under the laws of India, having its principal place of business at Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai 400055, Maharashtra, India.

7. On information and belief, Lupin Pharm. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202.

8. On information and belief, Lupin Pharm. is a wholly-owned subsidiary of Lupin Ltd.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including § 271(e)(2), and also including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 for patent infringement arising under 35 U.S.C. § 100 *et seq.*, including § 271(a)-(c).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

12. On information and belief, Defendants cooperate, collaborate, or act in concert for the purposes of manufacturing, selling, marketing, distributing, and importing generic drug products in Delaware and throughout the United States.

13. On information and belief, Defendants hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. On information and belief, Defendants are "vertically integrated, from process development of the API to the submission of dossiers for finished dosages." *See* https://www.lupin.com/US/generics/, last accessed May 4, 2022. Defendants' "manufacturing is also integrated." *See id.*

14. On information and belief, Lupin Ltd. has substantial, continuous, and systematic contacts with Delaware.

15. On information and belief, Lupin Ltd. develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

16. On information and belief, Lupin Ltd., alone or together with Lupin Pharm., has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in Delaware.

17. On information and belief, Lupin Ltd. consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in Delaware in one or more prior litigations, for example:

Galderma Laboratories, LP et al v. Lupin Inc. et al, No. 21-1710; *Gilead Sciences, Inc. et al v. Lupin Limited et al*, No. 21-1621; *Gilead Sciences, Inc. v. Lupin Limited*, No. 21-1615; *Boehringer Ingelheim Pharmaceuticals Inc. v. Lupin Limited et al*, No. 21-1486; *Zogenix, Inc. et al v. Lupin Ltd.*, No. 21-1424; *Neurocrine Biosciences, Inc. v. Lupin Limited et al*, No. 21-1408; *Supernus Pharmaceuticals, Inc. v. Lupin Limited et al*, No. 21-1293; *Neurocrine Biosciences, Inc. v. Lupin Limited et al*, No. 21-1042; *Vertex Pharmaceuticals Incorporated v. Lupin Ltd. et al*, No. 21-1019; *Otsuka Pharmaceutical Co., Ltd. v. Lupin Ltd. et al*, No. 21-900; *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Lupin Ltd. et al*, No. 21-530; *Bayer Pharma AG et al v. Lupin Limited et al*, No. 21-314; *Otsuka Pharmaceutical Co., Ltd. et al v. Lupin Limited et al*, No. 20-1296; *Intercept Pharmaceuticals, Inc. et al v. Lupin Limited et al*, No. 20-1155; *Arbor Pharmaceuticals, LLC et al v. Lupin Limited et al*, No. 20-922; *Merck Sharp & Dohme Corp. v. Lupin Limited et al*, No. 20-776.

18. This Court has personal jurisdiction over Lupin Ltd. by virtue of, among other things, (1) its continuous and systematic contacts with Delaware; (2) its acts of patent infringement that will result in foreseeable harm in Delaware; (3) its sale of a substantial volume of prescription drugs in Delaware; and (4) its conduct by and through, and in concert with, Lupin Pharm.

19. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, this action arises from actions of Lupin Ltd. directed toward Delaware. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the 663 Patent. If FDA approval is obtained, the Proposed ANDA Product would be sold in Delaware, causing injury to Plaintiffs in Delaware.

20. Exercising personal jurisdiction over Lupin Ltd. in this district would not be unreasonable given Lupin Ltd.'s contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

21. In the alternative, this Court has personal jurisdiction over Lupin Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met because: (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing Abbreviated New Drug Applications with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process, and is consistent with the United States Constitution and Laws.

22. Venue is proper under 28 U.S.C. § 1391(c)(3) because Lupin Ltd. is a foreign corporation.

23. On information and belief, Lupin Pharm. has substantial, continuous, and systematic contacts with Delaware.

24. On information and belief, Lupin Pharm. develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of Delaware and throughout the United States.

25. On information and belief, Lupin Pharm. has substantial, continuous, and systematic contacts with Delaware, including that it is incorporated in Delaware, is registered to do business in Delaware (Entity Id. No. 5983739) and is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation (License Nos. A4-0002387 and DM-0012065).

26. On information and belief, Lupin Pharm., alone or together with Lupin Ltd., has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in Delaware.

27. On information and belief, Lupin Pharm. consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in Delaware in one or more prior litigations, for example: *Boehringer Ingelheim Pharmaceuticals Inc. v. Lupin Limited et al*, No. 21-1486; *Vertex Pharmaceuticals Inc. v. Lupin Ltd. et al*, No. 21-1019; *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Lupin Ltd. et al*, No. 21-530; *Otsuka Pharmaceutical Co., Ltd. et al v. Lupin Limited et al*, No. 20-1296; *Vifor Fresenius Medical Care Renal Pharma Ltd. et al v. Lupin Atlantis Holdings, SA et al*, No. 20-911; *Merck Sharp & Dohme Corp. v. Lupin Limited et al*, No. 20-776; *Vifor Fresenius Medical Care Renal Pharma Ltd. et al v. Lupin Atlantis Holdings, SA et al*, No. 20-697; *ViiV Healthcare Company et al v. Lupin Limited et al*, No. 20-293.

28. This Court has personal jurisdiction over Lupin Pharm. by virtue of, among other things, (1) its incorporation in Delaware, (2) its continuous and systematic contacts with Delaware; (3) its acts of patent infringement that will result in foreseeable harm in Delaware; (4) its sale of a substantial volume of prescription drugs in Delaware; and (5) its conduct by and through, and in concert with, Lupin Ltd.

29. This Court has personal jurisdiction over Lupin Pharm. because, *inter alia*, this action arises from actions of Lupin Pharm. directed toward Delaware. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the 663 Patent. If FDA approval is

obtained, the Proposed ANDA Product would be sold in Delaware, causing injury to Plaintiffs in Delaware.

30. Exercising personal jurisdiction over Lupin Pharm. in this district would not be unreasonable given Lupin Pharm.'s contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

31. Venue is proper under 28 U.S.C. § 1400(b) because Lupin Pharm. is incorporated in Delaware and thus resides in this judicial district.

ERLEADA®

32. JBI holds approved New Drug Application No. 210951 for apalutamide, which is prescribed and sold as Erleada®.

33. On information and belief, Defendants know that JBI holds approved New Drug Application No. 210951.

34. Erleada® is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Erleada® is supplied as tablets for oral administration containing the active pharmaceutical ingredient apalutamide.

THE PATENT-IN-SUIT

35. On November 1, 2016, the 663 Patent, titled "Crystalline Forms of an Androgen Receptor Modulator" was duly and legally issued to Aragon and Sloan-Kettering as assignees. A copy of the 663 Patent is attached as Exhibit A.

36. Pursuant to 21 U.S.C. § 355(b)(1), the 663 Patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering Erleada®.

37. On information and belief, Defendants know that the 663 Patent is listed in the Orange Book as covering Erleada®.

DEFENDANTS' NOTICE LETTER AND THE ANDA

38. By letter dated April 1, 2022, addressed to JBI, Sloan-Kettering, Aragon, and Johnson & Johnson, and received by Johnson & Johnson on April 4, 2022 ("Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217084 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that the ANDA seeks the FDA approval necessary to engage in activities that constitute or require the commercial manufacture, use, sale, offer for sale in, or importation into the United States, of the Proposed ANDA Product, described in the Notice Letter as "apalutamide oral tablets, 60 mg" prior to the expiration of the 663 Patent.

39. The Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

40. The ANDA includes a Paragraph IV Certification that the claims of the Patent-In-Suit are invalid, unenforceable, or not infringed.

41. The Notice Letter stated that the Proposed ANDA Product will not literally infringe the claims of the Patent-In-Suit because the Proposed ANDA Product does not contain crystalline Form B of apalutamide.

42. The Notice Letter stated that the Proposed ANDA Product will not infringe the claims of the Patent-In-Suit under the doctrine of equivalents because the Proposed ANDA Product does not contain crystalline Form B of apalutamide, and that the patent owner had disclosed apalutamide in amorphous form but did not claim the amorphous form.

43. The Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On April 21, 2022, Defendants produced documents that Defendants purported were the ANDA.

44. On April 27, 2022, Plaintiffs requested technical information regarding the Proposed ANDA Product. Defendants declined to provide any further information. By failing to provide information, Defendants impeded Plaintiffs' ability to evaluate infringement of the Patent-In-Suit. On information and belief, if Defendants had a good faith basis to contest infringement of the Patent-In-Suit, they would have provided the requested information.

45. Plaintiffs are not aware of any other means by which to obtain technical information regarding the Proposed ANDA Product.

46. On information and belief, the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

47. On information and belief, the drug substance in and used for the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

48. Plaintiffs are commencing this action within 45 days of the date of receipt of the Notice Letter.

CLAIM FOR INFRINGEMENT OF THE 663 PATENT

49. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

50. An actual controversy exists between the parties as to whether Defendants proposed sale of the Proposed ANDA Product infringes the claims of the 663 Patent, including at least claims 1, 13, and 17.

51. Because, on information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product contain some amount of crystalline Form

B of apalutamide, the Proposed ANDA Product and the drug substance infringe at least claims 1, 13, and 17.

52. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe claim 1 because they contain crystalline Form B of apalutamide that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

53. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe claim 13 because they are a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

54. On information and belief, the use of the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product will infringe claim 17 because physicians and patients will practice a method of treating prostate cancer in a mammal by administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction

(XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

55. On information and belief, Defendants will actively induce infringement of claim 17 by actively inducing the use of the Proposed ANDA Product to treat prostate cancer in a mammal by administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

56. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 663 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 663 Patent.

57. On information and belief, Defendants have actual knowledge of the 663 Patent, at least as shown by the Notice Letter.

58. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 663 Patent, including at least claims 1, 13, and 17, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 663 Patent.

59. On information and belief, the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 663 Patent, including at least claims 1, 13, and 17, under at least one of 35 U.S.C. § 271(a), (b), or (c).

60. On information and belief, the manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17.

61. On information and belief, physicians or patients will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17 by the use of the Proposed ANDA Product upon approval.

62. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians or patients, in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17, for the pecuniary benefit of Defendants.

63. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will actively induce the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

64. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 663 Patent, including at least claims 1, 13, and 17, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label

provided by Defendants in practicing the claims of the 663 Patent, including at least claims 1, 13, and 17, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. On information and belief, Defendants Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will thus contribute to the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

65. On information and belief, the actions described in this Complaint relating to the ANDA were done by and for the benefit of Defendants.

66. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

67. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the Patent-In-Suit through the submission of the ANDA to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell the Proposed ANDA Product in the United States before the expiration of the Patent-In-Suit;

B. Enter a declaratory judgment that pursuant to 35 U.S.C. § 271(a), (b), and/or (c), the commercial manufacture, use, offer for sale, or sale within the United States, or importation

into the United States of the Proposed ANDA Product, prior to the expiration of the Patent-In-Suit, would constitute infringement of one or more claims of the Patent-In-Suit under 35 U.S.C. § 271 (a), (b), and/or (c);

C. Order that pursuant to 35 U.S.C. § 271(e)(4)(A) the effective date of any approval of the ANDA be a date that is not earlier than the expiration date of the Patent-In-Suit, or such later date as the Court may determine;

D. Order that Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with Defendants, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling the Proposed ANDA Product, and any other product that infringes or induces or contributes to the infringement of the Patent-In-Suit, prior to the expiration of the Patent-In-Suit, or such later date as the Court may determine;

E. If Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product prior to the expiration of the Patent-In-Suit, a judgment awarding damages to Plaintiffs resulting from such infringement together with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees; and

G. Award such further and other relief as this Court deems proper and just.

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