IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VERTEX PHARMACEUTICALS INCORPORATED,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff Vertex Pharmaceuticals Incorporated ("Vertex"), by its undersigned attorneys, for its Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Defendant Lupin Limited's submission of Abbreviated New Drug Application ("ANDA") No. 217431 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Vertex's KALYDECO® (ivacaftor) oral granules prior to the expiration of patents that cover, *inter alia*, KALYDECO® and its use.

2. In ANDA No. 217431, Defendant Lupin Limited seeks approval to commercially market a generic version of Vertex's KALYDECO® prior to the expiration of United States Patent Nos. 8,883,206 (the "'206 patent"), 10,272,046 (the "'046 patent"), 10,646,481 (the "'481 patent"), 11,147,770 (the "'770 patent"), 11,564,916 (the "'916 patent"), and 11,752,106 ("the '106 patent"), which are owned by Vertex.

3. On July 22, 2022, Vertex brought an action against Lupin for infringement of the '206, '046, '481, and '770 patents (C.A. No. 1:22-cv-00966-RGA).

4. On May 26, 2023, Vertex brought an action against Lupin for infringement of the '916 patent (C.A. No. 1:23-cv-00583-RGA).

5. On July 10, 2023, these actions were consolidated for all purposes including trial under C.A. No. 1:22-cv-00966-RGA.

THE PARTIES

6. Plaintiff Vertex is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 50 Northern Avenue, Boston, MA 02210. Vertex is a biopharmaceutical company committed to improving the lives of patients worldwide. Vertex focuses on the pursuit of medical research to create transformative medicines for people with serious and life-threatening diseases, such as cystic fibrosis.

7. Upon information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, with its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

8. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202. Defendant Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary of Lupin Limited.

9. Upon information and belief, Defendant Lupin Limited is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly owned subsidiaries and agents, including Defendant Lupin Pharmaceuticals, Inc.

THE '106 PATENT

10. On September 12, 2023, the United States Patent and Trademark Office duly and legally issued the '106 patent, entitled "Pharmaceutical Composition and Administrations Thereof," to Vertex as assignee. A copy of the '106 patent is attached to this Complaint as Exhibit A.

11. Vertex is the lawful owner of and holds all right, title, and interest in the '106 patent.

KALYDECO®

12. Vertex holds approved New Drug Application ("NDA") No. 207925 ("Vertex's NDA") for the use of ivacaftor 5.8, 13.4, 25, 50, and 75 mg oral granules ("Vertex's NDA Products") for the treatment of cystic fibrosis ("CF") in patients age one month to less than 6 years old who have at least one mutation in the cystic fibrosis transmembrane conductance regulator ("CFTR") gene that is responsive to ivacaftor based on clinical and/or *in vitro* assay data. Vertex sells the ivacaftor oral granules under the trade name KALYDECO®.

13. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the '106 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Vertex's NDA.

LUPIN'S ANDA

14. Upon information and belief, Defendant Lupin Limited acted in concert with Defendant Lupin Pharmaceuticals, Inc. to prepare and submit Abbreviated New Drug Application ("ANDA") No. 217431 ("Lupin's ANDA") to the FDA. Defendants submitted Lupin's ANDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 25, 50, and 75 mg ivacaftor oral granules ("Lupin's ANDA Products"), which are based on Vertex's NDA Products, before the expiration of the '206, '046, '481, '770, '916, and '106 patents.

15. Upon information and belief, Lupin's ANDA refers to and relies upon Vertex's NDA and contains data that, according to Defendant Lupin Limited, demonstrates the bioequivalence of Lupin's ANDA Products to Vertex's NDA Products.

16. By letter to Vertex dated June 9, 2022 ("Lupin's June 9, 2022 Paragraph IV Notice Letter"), Defendant Lupin Limited stated that Lupin's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '206, '046, and '481 patents will be infringed by the manufacture, importation, use, or sale of Lupin's ANDA Products (the "June 9, 2022 Paragraph IV Certification"). Defendant Lupin Limited attached an exhibit to its June 9, 2022 letter, in which it purported to allege the factual and legal bases for its June 9, 2022 Paragraph IV Certification.

17. By letter to Vertex dated April 25, 2023 ("Lupin's April 25, 2023 Paragraph IV Notice Letter"), Defendant Lupin Limited stated that Lupin's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '916 patent will be infringed by the manufacture, importation, use, or sale of Lupin's ANDA Products (the "April 25, 2023 Paragraph IV Certification"). Defendant Lupin Limited attached an exhibit to its April 25, 2023 letter, in which it purported to allege the factual and legal bases for its April 25, 2023 Paragraph IV Certification.

18. By letter to Vertex dated February 27, 2024 ("Lupin's February 27, 2024 Paragraph IV Notice Letter"), Defendant Lupin Limited stated that Lupin's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid claim of the '106 patent will be infringed by the manufacture, importation, use, or sale of Lupin's ANDA Products (the "February 27, 2024 Paragraph IV Certification"). Defendant Lupin Limited attached an exhibit to its February 27, 2024 letter, in which it purported to allege the factual and legal bases for its February 27, 2024 Paragraph IV Certification.

19. Upon information and belief, if the FDA approves Lupin's ANDA, Defendants will manufacture, distribute, import, offer for sale and/or sell Lupin's ANDA Products throughout the United States, including within the State of Delaware.

20. This action is being filed within 45 days of Vertex's receipt of Lupin's February 27, 2024 Paragraph IV Notice Letter.

JURISDICTION AND VENUE

21. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over Defendant Lupin Limited because of its regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing its products into the stream of commerce for distribution and consumption in Delaware, and throughout the United States, Defendant Lupin Limited has engaged in the regular conduct of business within this judicial district.

23. In addition, this Court has personal jurisdiction over Defendant Lupin Limited by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc., a wholly owned subsidiary of Lupin Limited, is incorporated in Delaware.

24. Defendant Lupin Limited filed ANDA No. 217431 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Products in the United States, including in Delaware. Upon information and belief, upon approval of ANDA No. 217431, Defendant Lupin Limited will market, distribute, offer for sale, and/or sell Lupin's ANDA Products in the United States, including in Delaware.

25. This Court has personal jurisdiction over Defendant Lupin Pharmaceuticals, Inc. because, among other things, it is a corporation formed under the laws of the state of

Delaware and has appointed a registered agent in Delaware to accept service of process. Defendant Lupin Pharmaceuticals, Inc. has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

26. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc., acting as the agent of Defendant Lupin Limited, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Defendant Lupin Limited or for which Defendant Lupin Limited is the named applicant on approved ANDAs. Upon information and belief, upon approval of ANDA No. 217431, Defendant Lupin Pharmaceuticals, Inc. will market, distribute, offer for sale, and/or sell Lupin's ANDA Products in the United States, including in Delaware.

27. Upon information and belief, Defendants have previously consented to suit in this judicial district and have not challenged personal jurisdiction. Defendants have further availed themselves of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. *See, e.g.*, *Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, C.A. No. 22-0639 (D.I. 6); *Gilead Scis., Inc. v. Lupin Ltd. et al.*, C.A. No. 22-0615 (D.I. 17); *Exeltis USA, Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 22-434 (D.I. 22); *Bayer Pharma AG, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 21-314-RGA (D.I. 14); *Bayer Intellectual Property GmbH, et al., v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 17-1047-RGA (D.I. 9); *Genentech, Inc., et al. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, C.A. No. 19-109-RGA (D.I. 10).

28. Venue is proper in this Court for Defendant Lupin Limited under 28 U.S.C. § 1391(c)(3) because Lupin Limited, on information and belief, is not a resident of the United States and may thus be sued in any judicial district.

29. Venue is proper in this Court for Defendant Lupin Pharmaceuticals, Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware.

CLAIM FOR RELIEF
INFRINGEMENT OF U.S. PATENT NO. 11,752,106

30. Vertex hereby realleges and incorporates by reference the allegations of paragraphs 1 to 29 of this Complaint.

31. Defendants have infringed one or more claims of the '106 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Lupin's ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Lupin's ANDA Products prior to the expiration of the '106 patent.

32. Defendants' commercial manufacture, sale, offer for sale, or use of Lupin's ANDA Products within the United States, or importation of Lupin's ANDA Products into the United States, during the term of the '106 patent would infringe, induce the infringement, and/or contribute to the infringement of one or more claims of the '106 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Upon information and belief, Defendants have acted with full knowledge of the '106 patent and without a reasonable basis for believing that they would not be liable for infringement of the '106 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Lupin's ANDA Products with its proposed labeling immediately and imminently upon approval of Lupin's ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '106 patent.

34. Upon information and belief, if the FDA approves Lupin's ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the'106 patent, and will do so immediately and imminently upon approval.

35. Upon information and belief, Defendants know that Lupin's ANDA Products are especially made or adapted for use in infringing the '106 patent, and that Lupin's ANDA Products are not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '106 patent immediately and imminently upon approval of Lupin's ANDA.

36. Vertex will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '106 patent.

37. Vertex has no adequate remedy at law.

38. Vertex is entitled to a permanent injunction against further infringement under 35 U.S.C. § 283.

39. Vertex is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Vertex prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed the '106 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 217431;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 217431 shall be a date not earlier than the expiration of the '106 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

C. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Lupin's ANDA Products will directly infringe, induce and/or contribute to infringement of the '106 patent;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling Lupin's ANDA Products within the United States, or importing Lupin's ANDA Products into the United States, prior to the expiration of the '106 patent, or any later expiration of exclusivity to which Vertex is or becomes entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 283, enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using offering to sell, or selling Lupin's ANDA Products within the United States, or importing Lupin's ANDA Products into the United States, before the expiration or the '106 patent, including any extensions;

F. If Defendants commercially manufacture, use, offer to sell, or sell Lupin's ANDA Products within the United States, or import Lupin's ANDA Products into the United States, prior to the expiration of the '106 patent, including any extensions, a judgment awarding damages to Vertex resulting from such infringement, together with interest;

G. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Vertex its attorneys' fees incurred in this action;

H. A judgment awarding Vertex costs and expenses incurred in this action; and

I. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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