IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBOR PHARMACEUTICALS, LLC and TAKEDA PHARMACEUTICAL COMPANY LIMITED,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Arbor Pharmaceuticals, LLC ("Arbor") and Takeda Pharmaceutical Company Limited ("Takeda) (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") (collectively, "Defendants" or "Lupin"), hereby allege as follows:

THE PARTIES

1. Arbor is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

2. Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

3. Upon information and belief, Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Upon information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Pharma, develops, manufactures, markets,

sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

4. Upon information and belief, Lupin Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Lupin Pharma is a wholly owned subsidiary of Lupin Ltd. and acts as its authorized agent in the United States. Upon information and belief, Lupin Pharma sells various drug products in the United States, including in this judicial district.

NATURE OF THE ACTION

5. This is a civil action for infringement of United States Patent Nos. 7,157,584 ("the '584 patent"), 7,572,920 ("the '920 patent"), and 9,066,936 ("the '936 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION & VENUE

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

7. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, the incorporation of Lupin Pharma in the State of Delaware, the fact that they have availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware, and because they intend to market, sell, and/or distribute generic pharmaceutical drug products to residents of this State, including the generic drug product that is the subject of Abbreviated New Drug Application ("ANDA") No. 214489. This Court has personal jurisdiction over Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court also has personal jurisdiction over Defendants by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including Arbor, a Delaware corporation.

9. This Court also has personal jurisdiction over Defendants because they have previously been sued in this Judicial District and have not challenged personal jurisdiction, and they have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing claims and counterclaims in this Judicial District. *See*, *e.g.*, *Merck Sharp & Dohme Corp. v. Lupin Limited and Lupin Pharmaceuticals, Inc.*, No. 19-347-RGA (D. Del. Feb. 19, 2019) (Lupin Ltd. and Lupin Pharma); *Anacor Pharm., Inc. v. Lupin Ltd.*, No. 18-1606-RGA, D.I. 16 (D. Del. Nov. 8, 2018) (Lupin Ltd.); *H. Lundbeck A/S v. Lupin Ltd.*, No. 18-777-LPS, D.I. 11 (D. Del. Jun. 12, 2018) (Lupin Ltd.); *Bial-Portela & CA S.A. v. Lupin Ltd.*, No. 18-312-VAC-MPT, D.I. 8 (D. Del. Apr. 18, 2018) (Lupin Ltd.); *Bayer Intellectual Prop. GmbH v. Lupin Ltd.*, No. 17-1047-RGA, D.I. 9 (D. Del. Aug. 22, 2017) (Lupin Ltd. and Lupin Pharma); *ViiV Healthcare Co. v. Lupin Ltd.*, 17-1576-VAC-CJB, D.I. 17 (D. Del. Dec. 19, 2017) (Lupin Ltd. and Lupin Pharma); *Astellas Pharma Inc. v. Lupin Ltd.*, No. 16-908, D.I. 20 (D. Del. Jan. 17, 2017) (Lupin Ltd. and Lupin Pharma); *Arena Pharm., Inc. v. Lupin Ltd.*, No. 16-887, D.I. 12 (D. Del. Jan. 11, 2017) (Lupin Ltd. and Lupin Pharma).

10. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Lupin Ltd. in this action, this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is 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, submitting various ANDAs to the FDA and manufacturing and selling pharmaceutical products distributed throughout the United States such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

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

THE PATENTS-IN-SUIT

12. On January 2, 2007, the '584 patent, entitled "Benzimidazole derivative and use thereof" was duly and legally issued. A copy of the '584 patent is attached as Exhibit A.

13. Takeda owns the '584 patent. Arbor holds an exclusive license to the '584 patent in the United States.

14. On August 11, 2009, the '920 patent, entitled "Benzimidazole derivative and use as A II receptor antagonist" was duly and legally issued. A copy of the '920 patent is attached as Exhibit B.

15. Takeda owns the '920 patent. Arbor holds an exclusive license to the '920 patent in the United States.

16. On June 30, 2015, the '936 patent, entitled "Solid pharmaceutical composition comprising a benzimidazole-7-carboxylate derivative and a pH control agent" was duly and legally issued. A copy of the '936 patent is attached as Exhibit C.

17. Takeda owns the '936 patent. Arbor holds an exclusive license to the '936 patent in the United States.

ACTS GIVING RISE TO THIS ACTION

18. Arbor holds New Drug Application ("NDA") No. 200796 for oral tablets containing 40/80 mg of azilsartan medoxomil as the active ingredient. Arbor markets and sells these oral tablets in the United States under the brand name EDARBI®.

19. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering EDARBI® or its use.

20. Upon information and belief Lupin submitted ANDA No. 214489 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, Lupin's ANDA No. 214489 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of an oral tablet containing 40 mg or 80 mg of azilsartan medoxomil ("the Lupin Generic Product") prior to the expiration of the patents-in-suit.

21. Upon information and belief, by filing ANDA No. 214489, Lupin has certified to the FDA that the Lupin Generic Product has the same active ingredient as EDARBI® and the same or substantially the same proposed labeling as EDARBI®.

22. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Lupin certified in ANDA No. 214489 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Lupin Generic Product.

23. Plaintiffs received written notification of Lupin's ANDA No. 214489 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx® Priority Overnight dated May 23, 2020 ("Lupin's Notice Letter").

24. Lupin's Notice letter contained an Offer of Confidential Access ("OCA") to certain confidential information regarding the Lupin Generic Product. Plaintiffs and Lupin subsequently exchanged markups of the OCA in an attempt to reach agreement on the terms for

confidential access. As of the filing of this Complaint, however, the parties have not been able to reach an agreement.

25. To date, Lupin has not provided Plaintiffs with a copy of any portions of ANDA No. 214489 or any information regarding the Lupin Generic Product, beyond the information set forth in Lupin's Notice Letter.

26. The limited information relating to the Lupin Generic Product that was provided in Lupin's Notice Letter does not demonstrate that the Lupin Generic Product, which Lupin has asked the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

27. This action was commenced within 45 days of Plaintiffs receiving Lupin's Notice Letter.

COUNT I
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 7,157,584

28. Plaintiffs re-allege paragraphs 1-27 as if fully set for herein.

29. Lupin's submission of ANDA No. 214489 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '584 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, use, offer for sell, sale, or import of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '584 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '584 patent.

31. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the '584 patent.

32. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Lupin's ANDA No. 214489 be a date that is not earlier than the expiration of the '584 patent, or any later expiration of exclusivity for the '584 patent to which Plaintiffs are or become entitled.

33. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

34. Upon information and belief, Defendants were aware of the existence of the '584 patent and were aware that the filing of ANDA No. 214489 and the certification with respect to the '584 patent constituted an act of infringement of that patent.

COUNT II
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 7,572,920

35. Plaintiffs re-allege paragraphs 1-34 as if fully set for herein.

36. Lupin's submission of ANDA No. 214489 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '920 patent under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, the commercial manufacture, use, offer for sell, sale, or import of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '920 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '920 patent.

38. Separate and apart from certain contentions regarding patent validity, Lupin's Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of claims 1-4, 7, and 8 of the '920 patent.

39. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Lupin's ANDA No. 214489 be a

date that is not earlier than the expiration of the '920 patent, or any later expiration of exclusivity for the '920 patent to which Plaintiffs are or become entitled.

40. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

41. Upon information and belief, Defendants were aware of the existence of the '920 patent and were aware that the filing of ANDA No. 214489 and the certification with respect to the '920 patent constituted an act of infringement of that patent.

COUNT III
INFRINGEMENT BY LUPIN OF U.S. PATENT NO. 9,066,936

42. Plaintiffs re-allege paragraphs 1-41 as if fully set for herein.

43. Lupin's submission of ANDA No. 214489 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, the commercial manufacture, use, offer for sell, sale, or import of the Lupin Generic Product—if approved by the FDA, prior to the expiration of the '584 patent, and for use in accordance with its proposed labeling—would infringe and/or induce and/or contribute to the infringement of the '936 patent.

45. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Lupin's ANDA No. 214489 be a date that is not earlier than the expiration of the '936 patent, or any later expiration of exclusivity for the '936 patent to which Plaintiffs are or become entitled.

46. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

47. Upon information and belief, Defendants were aware of the existence of the '936 patent and were aware that the filing of ANDA No. 214489 and the certification with respect to the '936 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment that:

A. Lupin has infringed one or more claims of the '584 patent;

B. Lupin has infringed one or more claims of the '920 patent;

C. Lupin has infringed one or more claims of the '936 patent;

D. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Lupin's ANDA No. 214489 will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs are or become entitled;

E. Lupin, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the Lupin Generic Product and any other product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which Plaintiffs are or become entitled;

F. Plaintiffs be awarded monetary relief to the extent Lupin commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the patents-in-suit within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extensions or exclusivities for the patents-in-suit to which Plaintiffs

are or will become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

G. Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur in litigating this action; and

H. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: July 8, 2020

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