

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

Avion Pharmaceuticals, LLC and Albion
Laboratories, Inc.,

Plaintiffs,

v.

Lupin Limited and Lupin Pharmaceuticals,
Inc.,

Defendants.

Civil Action No.:

COMPLAINT

Plaintiffs Avion Pharmaceuticals, LLC (“Avion”) and Albion Laboratories, Inc. (“Albion”) (collectively, “Plaintiffs”) bring this action for patent infringement against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin Pharma.”) (collectively, “Defendants”).

NATURE OF THE ACTION

1. This is an action by Plaintiffs for infringement of United States Patent No. 7,838,042 (“’042 patent” or the “Patent-In-Suit”).
2. This action arises from the filing of Abbreviated New Drug Application (“ANDA”) No. 217087 by Defendants seeking approval by the United States Food and Drug Administration (“FDA”) to sell a proposed generic version of BALCOLTRA[®] (“Proposed ANDA Product”) prior to the expiration of the Patent-in-Suit.

THE PARTIES

Plaintiffs

3. Avion is a limited liability corporation with its principal place of business at 1880 McFarland Parkway, Suite 105, Alpharetta, Georgia 30005.

4. Albion is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 67 South Main Street, Suite 200, Layton, Utah 84041.

Defendants

5. 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.

6. On information and belief, Lupin Pharma. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 11 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Pharma. is a wholly-owned subsidiary of Lupin Ltd.

8. On information and belief, Lupin Pharma. is an agent 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), (g).

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

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

12. On information and belief, Lupin Ltd. purposefully conducted and continues to conduct business in this judicial district.

13. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, this action arises from actions of Lupin Ltd. directed toward Delaware. On information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. On information and belief, Lupin Ltd. directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' Proposed ANDA Product. 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 '042 patent. If FDA approval is obtained, the Proposed ANDA Product would be sold in Delaware, causing injury to Plaintiffs in Delaware.

14. On information and belief, Lupin Ltd. has previously availed itself of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at least the following civil actions initiated in this district: *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.

15. On information and belief, Lupin Pharma. has substantial, continuous, and systematic contacts in Delaware.

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

17. On information and belief, Lupin Pharma. 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).

18. On information and belief, Lupin Pharma., alone or together with Lupin Ltd., has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of the 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 Delaware.

19. On information and belief, Lupin Pharma. 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.

20. This Court has personal jurisdiction over Lupin Pharma. by virtue of, among other things, (1) its incorporation in Delaware; (2) its continuous and systematic contacts in 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.

21. This Court has personal jurisdiction over Lupin Pharma., because *inter alia*, this action arises from actions of Lupin Pharma. 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 '042 patent. If FDA approval is obtained, the Proposed ANDA Product would be sold in Delaware, causing injury to Plaintiffs in Delaware.

22. Exercising personal jurisdiction over Lupin Pharma. in this judicial district would not be unreasonable given Lupin Pharma.'s incorporation in Delaware, contacts in this judicial district, and the interest in this district of resolving disputes related to products to be sold herein.

23. Venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) because Lupin Ltd. is a foreign corporation.

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

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