

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

NEUROCRINE BIOSCIENCES, INC.

Plaintiff,

v.

LUPIN LIMITED, LUPIN
PHARMACEUTICALS, INC., LUPIN INC.
and LUPIN ATLANTIS HOLDINGS S.A.

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Neurocrine Biosciences, Inc. (“Neurocrine”), by way of Complaint against Defendants Lupin Limited, Lupin Pharmaceuticals, Inc. (“Lupin Pharmaceuticals”), Lupin Inc., and Lupin Atlantis Holdings S.A. (“Lupin S.A.”) (collectively “Lupin” or “Defendants”), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 11,026,931 (“the ’931 patent”), 11,026,939 (“the ’939 patent”) and 11,040,029 (“the ’029 patent”) (collectively, “patents-in-suit”), arising under the United States patent laws, Title 35 United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Lupin’s filing of an Abbreviated New Drug Application (“ANDA”) No. 216064 under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, import, offer to sell and/or sell Valbenazine Tosylate Capsule, eq. 40 mg base and eq. 80 mg base (“Lupin’s generic products”) before the expiration of the patents-in-suit.

2. Neurocrine filed a separate action involving the same ANDA No. 216064 in this Court for patent infringement of U.S. Patent Nos. 8,039,627 (“the ’627 patent”), 8,357,697 (“the ’697 patent”), 10,065,952 (“the ’952 patent”), 10,844,058 (“the ’058 patent”), 10,851,103 (“the ’103 patent”), 10,851,104 (“the ’104 patent”), 10,857,137 (“the ’137 patent”), 10,857,148 (“the ’148 patent”), 10,874,648 (“the ’648 patent”), 10,906,902 (“the ’902 patent”), 10,906,903 (“the ’903 patent”), 10,912,771 (“the ’771 patent”), 10,919,892 (“the ’892 patent”), 10,940,141 (“the ’141 patent”), 10,952,997 (“the ’997 patent”) and 10,993,941 (“the ’941 patent”) (collectively, “the First Suit Patents”) in *Neurocrine Biosciences, Inc. v. Lupin Limited et al*, No. 1:21-cv-01042-MN (D. Del. filed July 16, 2021) (“the First Suit”).

3. The First Suit was filed in response to a letter from Lupin dated June 3, 2021 (“Lupin’s First Notice Letter”), purporting to include a “Notice of Paragraph IV Certification Regarding [the First Suit Patents] pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 for ANDA No. 216064.” The First Suit included counts of infringement of the First Suit Patents.

4. This complaint is filed in response to a new, second letter from Lupin dated August 17, 2021 (“Lupin’s Second Notice Letter”), purporting to include a “Notice of Paragraph IV Certification Regarding [the patents-in-suit] Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 for ANDA No. 216064.” Lupin’s Second Notice Letter stated that Lupin had filed ANDA No. 216064, seeking approval to manufacture, use, import, offer to sell and/or sell Lupin’s generic products before expiration of the patents-in-suit.

THE PARTIES

5. Neurocrine is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 12780 El Camino Real, San Diego, CA 92130.

6. Neurocrine is engaged in the business of researching, developing and bringing to market innovative pharmaceutical products for the treatment of neurological, endocrine and psychiatric disorders.

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

8. Upon information and belief, Lupin Pharmaceuticals is a corporation organized under the laws of Delaware and its principal place of business is located at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

9. Upon information and belief, Lupin Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

10. Upon information and belief, Lupin S.A. is a corporation organized under the laws of Switzerland and its principal place of business is located at Landis & Gyr – Strasse 1, 6300 Zug, Switzerland.

11. Upon information and belief, Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Limited.

12. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Nanomi B.V. and Nanomi B.V. is a wholly-owned subsidiary of Lupin Limited.

13. Upon information and belief, Lupin Pharmaceuticals, Lupin Inc. and Lupin S.A. are generic pharmaceutical companies that, in coordination with each other and Lupin Limited or at the direction of Lupin Limited, develop, manufacture, market and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Lupin Limited. Upon information and belief, Lupin Limited is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Limited directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Limited purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

16. This Court has personal jurisdiction over Lupin Pharmaceuticals. Upon information and belief, Lupin Pharmaceuticals is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Pharmaceuticals directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

17. This Court has personal jurisdiction over Lupin Inc. Upon information and belief, Lupin Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

18. This Court has personal jurisdiction over Lupin S.A. Upon information and belief, Lupin S.A. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Lupin S.A. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Lupin S.A. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Lupin's generic products.

19. Upon information and belief, Lupin Limited states that it "is present in the US through manufacturing, research and development, and commercial divisions for generics, complex generics, biosimilars and branded pharmaceuticals" and that its "US revenues crossed \$1 billion" in 2017-18. <https://www.lupin.com/about-us/global-presence/> (accessed September 29, 2021).

20. Upon information and belief, Lupin Limited is the holder of FDA Drug Master File No. 35246 for valbenazine tosylate.

21. Upon information and belief, Lupin Limited, Lupin Pharmaceuticals, Lupin Inc. and Lupin S.A. hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

22. Upon information and belief, Lupin admits that it "has a strong and well-established generic presence in the United States, having entered the U.S. market in 2003 and maintaining a competitive edge in the list of top 5 generic pharmaceutical companies by prescriptions dispensed since 2010." <https://www.lupin.com/US/about-us/> (accessed September 29, 2021). Upon

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