

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH IRELAND LIMITED,
SALIX PHARMACEUTICALS, INC., and
NORGINE B.V.,

Plaintiffs,

v.

LUPIN LTD., LUPIN ATLANTIS
HOLDINGS SA, LUPIN INC., and LUPIN
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 20-19379

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health Ireland Limited, Salix Pharmaceuticals, Inc., and Norgine B.V. (collectively, “Plaintiffs”) by way of Complaint against Defendants Lupin Ltd., Lupin Atlantis Holdings SA, Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, “Lupin” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Bausch Health Ireland Limited (“Bausch”) is a company organized and existing under the laws of Ireland, having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Salix Pharmaceuticals, Inc. (“Salix”) is a corporation organized and existing under the laws of California, having its principle place of business at 400 Somerset Blvd., Bridgewater, NJ 08807. Salix is the registered holder of approved New Drug Application (“NDA”) No. 209381, which covers Plenvu®.

3. Plaintiff Norgine B.V. (“Norgine”) is a corporation organized and existing under the laws of the Netherlands, having a corporate headquarters at Antonio Vivaldistraat 150, 1083 HP Amsterdam, The Netherlands.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a corporate headquarters at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

5. Upon information and belief, Defendant Lupin Atlantis Holdings SA (“Lupin Atlantis”) is a corporation organized and existing under the laws of Switzerland, having a corporate headquarters at Landis & Gyr-Strasse 1, Zug, Switzerland 6300. Upon information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

6. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Atlantis.

7. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (“Lupin Pharm.”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharm. is a subsidiary of Lupin Ltd. (3%) and Lupin Inc. (97%).

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 10,780,112 B2 (“the ’112 patent”) and 10,792,306 B2 (“the ’306 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Lupin’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic polyethylene glycol 3350 (140 g), sodium ascorbate (48.11 g), sodium sulfate (9 g), ascorbic acid (7.54 g), sodium chloride (5.2 g), and potassium chloride (2.2 g) for oral solution (“Lupin’s ANDA Product”).

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Upon information and belief, this Court has jurisdiction over Lupin Ltd. Upon information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon 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 Lupin’s ANDA Product. Upon information and belief, Lupin Ltd. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Ltd. operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Ltd. has previously

submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Upon information and belief, this Court has jurisdiction over Lupin Atlantis. Upon information and belief, Lupin Atlantis directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. Upon information and belief, Lupin Atlantis purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Atlantis operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Atlantis has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Upon information and belief, this Court has jurisdiction over Lupin Inc. Upon information and belief, Lupin Inc. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., 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. Upon information and belief, Lupin Inc. operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this Court has jurisdiction over Lupin Pharm. Upon information and belief, Lupin Pharm. directly or indirectly manufactures, markets, and sells generic drug products, including generic drug products manufactured by Lupin Ltd., throughout

the United States and in this judicial district. Upon information and belief, Lupin Pharm. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Lupin Pharm. operates a manufacturing and research facility at 400 Campus Drive, Somerset, New Jersey 08873. Upon information and belief, Lupin Pharm. is registered to do business in New Jersey (business identification number 0101043376) and is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Numbers 5004060 and 5005159. Upon information and belief, Lupin Pharm. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Upon information and belief, Defendants have a regular and established place of business in this judicial district because, for example, they maintain a place of business in this judicial district at 400 Campus Drive, Somerset, New Jersey 08873.

15. Upon information and belief, Lupin Ltd., Lupin Atlantis, Lupin Inc., and Lupin Pharm. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. Upon information and belief, Lupin employs “vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings.” (*See* <http://www.lupinpharmaceuticals.com/about.htm>, last accessed April 1, 2019.)

16. Lupin’s ANDA No. 212934 is the subject of ongoing infringement litigations in the District of New Jersey: *Bausch Health Ireland Limited v. Lupin Inc.*, Civil Action No. 19-cv-09178-RMB-KMW and *Bausch Health Ireland Limited v. Lupin Inc.*, Civil Action No. 20-cv-11039-RMB-KMW. Lupin has consented to personal jurisdiction and venue before this Court in *Bausch Health Ireland Limited v. Lupin Inc.*, Civil Action No. 19-cv-09178-RMB-KMW. Lupin

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