IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACTELION PHARMACEUTICALS US, INC., ACTELION PHARMACEUTICALS LTD and NIPPON SHINYAKU CO., LTD.,	)	
Plaintiffs,	)	C.A. No.: _____
v.	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Actelion Pharmaceuticals US, Inc. ("Actelion Inc."), Actelion Pharmaceuticals Ltd ("Actelion Ltd"), (together "Actelion"), and Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Ltd. ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("Lupin Inc.") (collectively, "Lupin" or "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Actelion Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

2. Plaintiff Actelion Ltd is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

3. Plaintiff Nippon Shinyaku is a Japanese corporation having a primary place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

4. Upon information and belief, Defendant Lupin Ltd. is an entity organized and existing under the laws of India, with a principal place of business at 3rd Floor, Kalpataru Inspire, Off Western Express Highway, Santacruz (E), Mumbai 400 055, India.

5. Upon information and belief, Lupin Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

6. Upon information and belief, Lupin Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202.

7. Upon information and belief, Lupin Inc. develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

8. Upon information and belief, Lupin Inc. is registered with the Delaware Department of State Division of Corporations as a business operating in Delaware under Business ID No. 5983739.

9. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Ltd.

10. Upon information and belief, Lupin Inc. is the U.S. agent for Lupin Ltd.

11. Upon information and belief, Lupin Inc. and Lupin Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, Lupin Inc. and Lupin Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group.

NATURE OF THE ACTION

12. This is a civil action for infringement of United States Patent Nos. 8,791,122 ("the '122 patent") and 9,284,280 ("the '280 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

13. This action relates to Defendant Lupin Ltd.'s submission of Lupin Ltd.'s Abbreviated New Drug Application ("ANDA") No. 217991, 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 commercially manufacture, use, import, offer to sell, and/or sell generic Selexipag for Injection, 1800 mcg/vial ("Lupin's ANDA Product"), before expiration of the patents-in-suit.

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case involves an actual controversy within the Court's jurisdiction.

15. The Court has personal jurisdiction over Lupin Ltd., and venue is proper as to Lupin Ltd., because, *inter alia*, Lupin Ltd.: (1) directs and/or controls Lupin Inc., which is an entity organized and existing under the laws of the State of Delaware as well as registered to do business in Delaware; (2) has purposefully availed itself of the privilege of doing business in Delaware, directly or indirectly through its subsidiary, agent, and/or alter ego; (3) maintains pervasive, continuous, and systematic contacts with the State of Delaware, including marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware; (4) upon information and belief, derives

substantial revenue from the sale of its products in Delaware; and (5) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Lupin's ANDA Product.

16. This Court also has personal jurisdiction over Lupin Ltd. because, *inter alia*, it has availed itself of the legal protections of the State of Delaware by previously consenting to personal jurisdiction as well as asserting counterclaims against plaintiffs in this Judicial District. *See, e.g., Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, C.A. No. 22-01061-MN; *ZS Pharma, Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 22-01055-GBW; *Vertex Pharms. Inc. v. Lupin Ltd. et al.*, C.A. No. 22-00966-RGA; *Avion Pharms., LLC et al. v. Lupin Ltd. et al.*, C.A. No. 22-00729-CJB; *Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, C.A. No. 22-00639-MN; *Gilead Scis., Inc. v. Lupin Ltd. et al.*, C.A. No. 22-00615-MN; *Exeltis USA, Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 22-00434-RGA-MPT; *Gilead Scis., Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 21-01621-MN; *Gilead Scis. Inc. v. Lupin Ltd.*, C.A. 21-01615-MN; *Boehringer Ingelheim Pharms. Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 21-01486-CFC; *Zogenix, Inc. et al. v. Lupin Ltd.*, C.A. No. 21-1424-RGA; *Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, C.A. No. 21-01408-MN; *Supernus Pharms. Inc. v. Lupin Ltd. et al.*, C.A. No. 21-01293-MN; *Vertex Pharms. Inc. v. Lupin Ltd. et al.*, C.A. No. 21-01019-RGA-CJB; *Otsuka Pharm. Co., Ltd. v. Lupin Ltd. et al.*, C.A. No. 21-00900-RGA; *Boehringer Ingelheim Pharms. Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 21-00530-CFC; *Bayer Pharma AG, et al., v. Lupin Ltd. et al.*, C.A. No. 21-00314-RGA-JLH.

17. Alternatively, this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Lupin Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) 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, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

18. This Court has personal jurisdiction over Lupin Inc., and venue is proper as to Lupin Inc., because, *inter alia*, Lupin Inc.: (1) is a Delaware corporation; (2) has purposely availed itself of the privilege of doing business in Delaware, including, *inter alia*, registering with the Department of State Division of Corporations as a business operating in Delaware under Business ID No. 5983739; (3) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including the State of Delaware; (4) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of Delaware, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware; (5) upon information and belief, derives substantial revenue from the sale of its products in Delaware; and (6) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Lupin's ANDA Product.

19. This Court also has personal jurisdiction over Lupin Inc. because, *inter alia*, it has availed itself of the legal protections of the State of Delaware by previously consenting to personal jurisdiction as well as asserting counterclaims against plaintiffs in this Judicial District. *See, e.g., ViiV Healthcare Co. et al. v. Lupin Ltd. et al.*, C.A. No. 21-01561-MSG.

20. This Court also has personal jurisdiction over Lupin because, *inter alia*, Lupin Ltd. and Lupin Inc. have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of Delaware, that have led to foreseeable harm and injury to Plaintiffs in the State of Delaware.

21. Venue is proper in this Court for Lupin Ltd. pursuant to 28 U.S.C. §§ 1391(c) and 1400(b) because Lupin Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Lupin Ltd. is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

22. Venue is proper in this Court as to Lupin Inc. under 28 U.S.C. §§ 1391(b) or 1400(b) because Lupin Inc. is a corporation organized and existing under the laws of Delaware. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

23. Upon information and belief, the actions of Lupin of, *inter alia*, causing Lupin's ANDA No. 217991 to be filed and maintaining distribution channels, including in the State of Delaware, establish that if granted approval, Lupin will commercially manufacture, use, offer to sell, sell, and/or import Lupin's ANDA Product throughout the United States, including in Delaware.

UPTRAVI® AND THE PATENTS-IN-SUIT

24. Plaintiff Actelion Inc. holds approved New Drug Application ("NDA") No. 214275, under which the FDA granted approval on July 29, 2021 for intravenous use, marketed in the United States under the brand name UPTRAVI® (selexipag). The UPTRAVI® labeling states that selexipag for injection is 1800 mcg of selexipag as a lyophilized powder in a single-dose vial for reconstitution and dilution.

25. UPTRAVI®, approved in NDA No. 214275, is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for pulmonary arterial hypertension.

26. Nippon Shinyaku is the assignee of the patents-in-suit. Actelion Ltd is an exclusive licensee of the patents-in-suit. Actelion Inc. markets and sells UPTRAVI® in the United States. Actelion Inc. and Actelion Ltd are wholly-owned subsidiaries of Johnson & Johnson.

27. The '122 patent was duly and legally issued on July 29, 2014 (reissued September 15, 2017), and is titled "Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropylamino]Butyloxy}-N-(Methylsulfonyl)Actemide." A copy of the '122 patent is attached as Exhibit A.

28. The '280 patent was duly and legally issued on March 15, 2016, and is titled "Use of Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropyl-Amino]Butyloxy}-N-(Methyl-Sulfonyl)Acetamide." A copy of the '280 patent is attached as Exhibit B.

29. Pursuant to 21 U.S.C. § 355(b)(l), the patents-in-suit are listed in the FDA publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering UPTRAVI® brand selexipag for injection.

LUPIN'S ANDA AND NOTICE LETTER

30. Upon information and belief, Lupin Ltd. submitted ANDA No. 217991 to the FDA, including a certification with respect to the '122 and '280 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lupin's ANDA Product prior to expiration of the '122 and '280 patents.

31. Upon information and belief, Lupin Ltd. sent Plaintiffs a Paragraph IV Certification Notice Letter dated December 28, 2022 stating that Lupin Ltd. filed ANDA No. 217991 seeking approval from the FDA to commercially manufacture, use, market, or sell generic Selexipag for

Injection, 1800 mcg/vial, in the United States (including, on information and belief, in the State of Delaware), prior to the expiration of the '122 and '280 patents.

32. On January 11, 2023, Plaintiffs requested that Lupin Ltd. produce its ANDA, Drug Master File(s), representative samples of its Active Pharmaceutical Ingredient, and samples for the exhibit batches of its ANDA Product, among other information, in connection with evaluating infringement of the '122 and '280 patents. Plaintiffs repeated the request on at least January 19, 2023, January 23, 2023, January 27, 2023, and February 2, 2023. To date, Lupin Ltd. has not provided Plaintiffs with any of the requested information or samples, which has impaired Plaintiffs' ability to evaluate the veracity of the statements made by Lupin Ltd. in its Paragraph IV Certification Notice Letter as well as Lupin's infringement of the '122 and '280 patents.

33. Plaintiffs commenced this action within 45 days of the date of receipt of the Lupin Ltd. Paragraph IV Certification Notice Letter, which was dated December 28, 2022.

LUPIN'S INFRINGEMENT OF THE PATENTS-IN-SUIT

34. Plaintiffs re-allege paragraphs 1-33 as if fully set forth herein.

35. Lupin Ltd. and Lupin Inc. are jointly and severally liable for any infringement of the '122 and '280 patents because, on information and belief, Lupin Ltd. and Lupin Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 217991 and the Paragraph IV Certification to the FDA.

36. By seeking approval of ANDA No. 217991 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lupin's ANDA Product prior to the expiration of the '122 and '280 patents, Lupin has infringed one or more claims of each of the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, including Lupin's failure to produce the requested samples and information, Lupin's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lupin's ANDA Product meets or embodies all elements of one or more claims of each of the '122 and '280 patents.

38. Upon information and belief, Lupin intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lupin's ANDA Product upon receipt of final FDA approval of ANDA No. 217991.

39. If Lupin manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Lupin's ANDA Product prior to the expiration of the '122 and '280 patents, Lupin will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

40. Lupin had actual and constructive notice of the '122 and '280 patents prior to the filing of Lupin's ANDA No. 217991 seeking approval of Lupin's ANDA Product.

41. 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 of Lupin's ANDA No. 217991 be a date that is not earlier than the expiration date of the '122 and '280 patents, or any later expiration of any patent term extension or exclusivity for the '122 and '280 patents to which Plaintiffs are or become entitled.

42. Plaintiffs are entitled to a declaration that, if Lupin commercially manufactures, uses, offers for sale, or sells Lupin's ANDA Product within the United States, imports Lupin's ANDA Product into the United States, or induces or contributes to such conduct, Lupin will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g).

43. 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.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment, in favor of Plaintiffs and against Lupin, that Lupin has infringed the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 217991;

B. The issuance of a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Lupin, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Lupin, from infringing the '122 and '280 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Lupin's ANDA Product;

C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 217991 be a date that is not earlier than the expiration date of the latest to expire of the '122 and '280 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

D. An award of 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 '122 and '280 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment and post-judgment interest;

E. A declaration that this is an exceptional case and an award of reasonable attorneys' fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4)(A) and 285; and

F. Such other and further relief as the Court may deem just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

Of Counsel:

Preston K. Ratliff II
Bruce M. Wexler
Aaron P. Selikson
Sarah E. Spencer
Jessica Stauring
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

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