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.	)	
LANNETT COMPANY, INC.	)	
Defendant.	)	

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 Defendant Lannett Company, Inc. ("Lannett" or "Defendant"), 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, Lannett is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 1150 Northbrook Drive, Suite 155, Trevose, Pennsylvania 19053.

5. Upon information and belief, Lannett 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, Lannett is registered with the Delaware Department of State Division of Corporations as a business operating in Delaware under Business ID No. 2280565.

NATURE OF THE ACTION

7. 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.

8. This action relates to Defendant Lannett's submission of Lannett's Abbreviated New Drug Application ("ANDA") No. 219117, 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 tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg ("Lannett's ANDA Products"), before expiration of the patents-in-suit.

JURISDICTION AND VENUE

9. 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.

10. This Court has personal jurisdiction over Lannett, and venue is proper as to Lannett, because, *inter alia*, Lannett: (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. 2280565; (3) develops, manufactures, and/or imports generic versions of branded pharmaceutical 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, market, sell, or distribute Lannett's ANDA Products.

11. This Court also has personal jurisdiction over Lannett 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.*, *Genus Lifesciences Inc. v. Lannett Co., Inc.*, C.A. No. 20-770-LPS (D. Del.); *Braintree Lab'ys, Inc. v. Lannett Co., Inc.*, C.A. No. 17-293-GMS (D. Del.).

12. Lannett also has availed itself of the benefits and protections of Delaware law by initiating litigation in this Judicial District and invoking this Court's jurisdiction. *See, e.g.*, *Lannett Co., Inc. v. KV Pharms. et al.*, C.A. No. 8-338-JJF-CJS (D. Del.).

13. This Court also has personal jurisdiction over Lannett because, *inter alia*, Lannett has 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.

14. Venue is proper in this Court as to Lannett under 28 U.S.C. §§ 1391(b) or 1400(b) because Lannett 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.

15. Upon information and belief, the actions of Lannett of, *inter alia*, causing Lannett's ANDA No. 219117 to be filed and maintaining distribution channels, including in the State of Delaware, establish that if granted approval, Lannett will commercially manufacture, use, offer to sell, sell, and/or import Lannett's ANDA Products throughout the United States, including in Delaware.

UPTRAVI® AND THE PATENTS-IN-SUIT

16. Actelion Inc. holds approved New Drug Application ("NDA") No. 207947, under which the FDA granted approval on December 21, 2015 for oral tablets, marketed in the United States under the brand name UPTRAVI®. The UPTRAVI® labeling states that selexipag tablets are available in the following strengths: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg.

17. UPTRAVI® (selexipag), approved in NDA No. 207947, 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.

18. 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.

19. 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)Acetamide." A copy of the '122 patent is attached as Exhibit A.

20. 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.

21. 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 tablets.

LANNETT'S ANDA AND NOTICE LETTER

22. Upon information and belief, Lannett submitted ANDA No. 219117 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 Lannett's ANDA Products prior to expiration of the '122 and '280 patents.

23. Upon information and belief, Lannett sent Plaintiffs a Paragraph IV Certification Notice Letter dated September 6, 2024 stating that Lannett filed ANDA No. 219117 seeking

approval from the FDA to commercially manufacture, use, market, or sell generic selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg, in the United States (including, upon information and belief, in the State of Delaware), prior to the expiration of the '122 and '280 patents.

24. Plaintiffs requested that Lannett produce, among other things, representative samples of its active pharmaceutical ingredient, and representative samples for the exhibit batches of its ANDA Products in connection with evaluating infringement of the '122 and '280 patents. To date, Lannett has not provided Plaintiffs with any samples or the Drug Master File(s) referenced in its ANDA.

25. Plaintiffs commenced this action within 45 days of the date of receipt of Lannett's Paragraph IV Certification Notice Letter.

LANNETT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

26. Plaintiffs re-allege paragraphs 1-25 as if fully set forth herein.

27. By seeking approval of ANDA No. 219117 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lannett's ANDA Products prior to the expiration of the '122 and '280 patents, Lannett has infringed one or more claims of each of the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, Lannett's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Lannett's ANDA Products meets or embodies all elements of one or more claims of each of the '122 and '280 patents.

29. Upon information and belief, Lannett 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 Lannett's ANDA Products upon receipt of final FDA approval of ANDA No. 219117.

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

31. Lannett's Paragraph IV Certification Notice Letter does not dispute that the '122 patent is valid.

32. Lannett's Paragraph IV Certification Notice Letter does not dispute that the '280 patent is valid.

33. Lannett had actual and constructive notice of the '122 and '280 patents prior to the filing of Lannett's ANDA No. 219117 seeking approval of Lannett's ANDA Products.

34. 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 Lannett's ANDA No. 219117 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.

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

36. Plaintiffs will be irreparably harmed by Lannett'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 Lannett, that Lannett has infringed the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 219117;

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 Lannett, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Lannett, 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 Lannett's ANDA Products;

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. 219117 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 Lannett 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
Mi Zhou
Sarah E. Spencer
PAUL HASTINGS LLP
200 Park Avenue
New York, NY 10166
(212) 318-6000

Dated: October 17, 2024