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*Attorneys for Plaintiffs
Actelion Pharmaceuticals US, Inc.,
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Nippon Shinyaku Co., Ltd.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ACTELION PHARMACEUTICALS US,
INC., ACTELION PHARMACEUTICALS
LTD and NIPPON SHINYAKU CO., LTD.,

Plaintiffs,

v.

VGYAAN PHARMACEUTICALS LLC
and RK PHARMA, INC.,

Defendants.

Civil Action No. _____

**COMPLAINT
FOR PATENT INFRINGEMENT**

(Filed Electronically)

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 VGYAAN Pharmaceuticals LLC (“VGYAAN”) and RK Pharma, Inc. (collectively, “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 VGYAAN is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558.

5. Upon information and belief, Defendant RK Pharma, Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, New York 10965.

6. Upon information and belief, VGYAAN is a wholly-owned subsidiary of RK Pharma, Inc.

7. Upon information and belief, RK Pharma, Inc., through its wholly-owned subsidiary, VGYAAN, maintains regular places of business in New Jersey, including at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558 and at c/o RK Pharma, Inc., One Tower Center Boulevard, 23rd Floor, East Brunswick, New Jersey 08816.

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

9. Upon information and belief, VGYAAN is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600406976.

10. Upon information and belief, VGYAAN is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005560.

11. Upon information and belief, RK Pharma, Inc., 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.

12. Upon information and belief, RK Pharma, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101052900.

NATURE OF THE ACTION

13. This is a civil action for infringement of United States Patent No. 7,205,302 ("the '302 patent"). 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.

14. This action relates to VGYAAN's submission of Abbreviated New Drug Application ("ANDA") No. 214055, 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 ("the ANDA Products"), before expiration of the '302 patent.

JURISDICTION AND VENUE

15. 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 is an actual controversy within the Court's jurisdiction.

16. This Court has personal jurisdiction over VGYAAN, and venue is proper as to VGYAAN, because, *inter alia*, VGYAAN: (1) is organized and exists under the laws of the State of New Jersey; (2) has its principal place of business in New Jersey; (3) has employees in the places of business that it maintains in New Jersey; (4) has purposefully availed itself of the privilege of doing business in New Jersey, including by, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Service to do business in New Jersey under Business ID No. 0600406976 and securing a New Jersey manufacturer's and wholesale drug distributor's license under Registration No. 5005560; (5) maintains pervasive, continuous, and systematic contacts with New Jersey; (6) upon information and belief, develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in New Jersey; (7) upon information and belief, derives substantial revenue from the sale of its products in the State of New Jersey; (8) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, alter ego, and/or partner, market, sell, or distribute the ANDA Products throughout the United States, including in the State of New Jersey; and (9) has committed acts of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

17. This Court also has personal jurisdiction over VGYAAN, and venue is proper as to VGYAAN, because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction and venue in this Judicial District. *See, e.g., Actelion Pharms. Ltd et al. v. MSN Pharms. Inc. et al.*, No. 20-03859 (RMB) (KMW).

18. This Court has personal jurisdiction over RK Pharma, Inc., and venue is proper as to RK Pharma, Inc., because, *inter alia*, RK Pharma, Inc.: (1) directs and/or controls VGYAAN, which is an entity organized and existing under the laws of New Jersey and has a principal place of business in New Jersey; (2) maintains regular places of business in New Jersey through VGYAAN; (3) has purposefully availed itself of the privilege of doing business in New Jersey, including by, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Service to do business in New Jersey under Business ID No. 0101052900 and/or through its subsidiaries, agents, and/or alter egos; (4) maintains pervasive, continuous, and systematic contact with New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical products in New Jersey, directly and/or indirectly through its subsidiaries, agents, and/or alter egos; (5) upon information and belief, derives substantial revenue from the sale of its products in the State of New Jersey; (6) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, including VGYAAN, market, sell, or distribute the ANDA Products throughout the United States, including in the State of New Jersey; and (7) has committed acts of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

19. This Court also has personal jurisdiction over RK Pharma, Inc., and venue is proper as to RK Pharma, Inc., because, *inter alia*, it has availed itself of the legal protections of the State

of New Jersey by previously consenting to personal jurisdiction and venue, as well as by asserting counterclaims in this Judicial District. *See, e.g., Am. Regent, Inc. v. Somerset Therapeutics, LLC et al.*, No. 24-01022 (BRM) (CLW) (consolidated); *Jazz Pharms. Ireland Ltd. et al. v. Sandoz, Inc. et al.*, No. 24-09110 (RK) (RLS) (consolidated).

20. This Court also has personal jurisdiction over Defendants because, upon information and belief, Defendants have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, which have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

21. Upon information and belief, Defendants are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to the ANDA Products, for which Defendants have sought approval from the FDA.

22. Upon information and belief, Defendants are acting in concert with respect to each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to the ANDA Products.

23. Venue is proper in this Court as to VGYAAN under 28 U.S.C. §§ 1391(b), (c), and/or (d) and 1400(b) because, *inter alia*, VGYAAN is organized and exists under the laws of the State of New Jersey, has a principal place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth above, and for other reasons that will be presented to the Court if such venue is challenged.

24. Venue is proper in this Court as to RK Pharma, Inc. under 28 U.S.C. §§ 1391(b), (c), and/or (d) and 1400(b) because, *inter alia*, RK Pharma, Inc. submitted or caused to be submitted a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) (“Paragraph IV Certification”) with respect to the ’302 patent from its affiliate VGYAAN’s New Jersey place of business, and therefore, has committed and will commit further acts of infringement in this Judicial District, and maintains regular places of business in New Jersey through VGYAAN for the purposes of venue. Venue is proper for the additional reasons set forth above, and for other reasons that will be presented to the Court if such venue is challenged.

25. Upon information and belief, the actions of Defendants of, *inter alia*, causing ANDA No. 214055 to be filed and maintaining distribution channels, including in the State of New Jersey, establish that if granted approval, Defendants will commercially manufacture, use, offer to sell, sell, and/or import the ANDA Products throughout the United States, including in New Jersey.

UPTRAVI® AND THE PATENT-IN-SUIT

26. 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.

27. 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.

28. Nippon Shinyaku is the assignee of the '302 patent. Actelion Ltd is an exclusive licensee of the '302 patent. Actelion Inc. markets and sells UPTRAVI® in the United States. Actelion Inc. and Actelion Ltd are wholly-owned subsidiaries of Johnson & Johnson.

29. The '302 patent was duly and legally issued on April 17, 2007, and is titled "Heterocyclic Compound Derivatives and Medicines." A copy of the '302 patent is attached as Exhibit A.

30. Pursuant to 21 U.S.C. § 355(b)(1), the '302 patent is 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.

ACTS GIVING RISE TO THE ACTION

31. Upon information and belief, VGYAAN submitted ANDA No. 214055 to the FDA, seeking FDA approval for the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Products.

32. Upon information and belief, Defendants sent a letter dated July 24, 2025 ("Defendants' Notice Letter") with respect to the '302 patent to Plaintiffs, stating that VGYAAN filed ANDA No. 214055, seeking approval from the FDA to commercially manufacture, use, or sell the ANDA Products in the United States (including, upon information and belief, in the State of New Jersey) prior to the expiration of the '302 patent.

33. Defendants' Notice Letter represented that ANDA No. 214055 included a Paragraph IV Certification with respect to the '302 patent.

34. Upon information and belief, prior to July 24, 2025, VGYAAN submitted a certification with respect to the '302 patent under § 505(j)(2)(A)(vii)(III) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph III Certification").

35. Upon information and belief, prior to July 24, 2025, Defendants converted the Paragraph III Certification to the Paragraph IV Certification with respect to the '302 patent.

36. Upon information and belief, at some time prior to July 24, 2025, Defendants were aware of the Consent Judgment (D.I. 137) in *Actelion Pharms. Ltd et al. v. MSN Pharms. Inc. et al.*, No. 20-03859 (RMB) (SAK) (D.N.J.), in which Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc. admitted that the claims of the '302 patent are valid and enforceable.

37. Upon information and belief, at some time prior to July 24, 2025, Defendants were aware of the Consent Judgment (D.I. 12) in *Actelion Pharms. US, Inc. et al. v. Alembic Pharms. Ltd. et al.*, No. 23-00383 (GBW) (D. Del.), in which Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. admitted that the claims of the '302 patent are valid and enforceable.

38. Separate and apart from certain contentions regarding patent validity, Defendants' Notice Letter with respect to the '302 patent does not identify any factual basis for, or any opinion of, noninfringement of Claims 1-5 and 10-15 of the '302 patent.

39. Upon information and belief, the ANDA Products for which Defendants seek FDA approval in ANDA No. 214055 are selexipag tablets 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg.

40. The chemical name of the compound selexipag is one of the chemical names recited in, *inter alia*, Claim 14 of the '302 patent.

41. On August 6, 2025, Plaintiffs requested that VGYAAN produce its ANDA and Drug Master File(s), among other information, in connection with the Offer of Confidential Access that accompanied Defendants' Notice Letter. Plaintiffs subsequently reiterated their request to VGYAAN on at least August 11, 2025, August 14, 2025, and August 20, 2025 without receiving any response. To date, VGYAAN has not provided Plaintiffs with any of the requested information,

which has interfered with Plaintiffs' ability to fully evaluate the allegations raised in Defendants' Notice Letter with respect to the '302 patent.

42. Plaintiffs commenced this action within 45 days of the date of Plaintiffs' receipt of Defendants' Notice Letter with respect to the '302 patent, which was dated July 24, 2025.

INFRINGEMENT

43. Plaintiffs re-allege paragraphs 1-42 as if fully set forth herein.

44. VGYAAN and RK Pharma, Inc. are jointly and severally liable for any infringement of the '302 patent because, upon information and belief, VGYAAN and RK Pharma, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214055 and the Paragraph IV Certification for the '302 patent to the FDA.

45. In Defendants' Notice Letter, Defendants represented that "[t]he active ingredient present in [the ANDA Products] is 2-{4-[(5,6-diphenylpyrazin-2-yl)(isopropyl)amino]butoxy}-N-(methylsulfonyl) acetamide, commonly known as selexipag," "the dosage strengths are 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg of selexipag," and "the dosage form is a tablet for oral use."

46. Defendants' Notice Letter does not dispute that one or more claims of the '302 patent would be infringed by the ANDA Products.

47. By seeking approval of ANDA No. 214055 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Products prior to the expiration of the '302 patent, Defendants have infringed one or more claims of the '302 patent under 35 U.S.C. § 271(e)(2)(A).

48. Defendants had actual and constructive notice of the '302 patent prior to the filing of ANDA No. 214055 seeking approval of the ANDA Products.

49. Upon information and belief, Defendants were aware that the submission of ANDA No. 214055 that included the Paragraph IV Certification with respect to the '302 patent to the FDA constituted an act of infringement of the '302 patent.

50. Upon information and belief, Defendants' commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Products meets or embodies all elements of one or more claims of the '302 patent.

51. Upon information and belief, Defendants intend 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 the ANDA Products upon receipt of final FDA approval of ANDA No. 214055.

52. If Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, the ANDA Products prior to the expiration of the '302 patent, Defendants will infringe one or more claims of the '302 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) either literally or under the doctrine of equivalents.

53. Upon information and belief, Defendants were aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Products before the expiration of the '302 patent would constitute an act of infringement of the '302 patent.

54. 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 ANDA No. 214055 be a date that is

not earlier than the expiration date of the '302 patent, or any later expiration of any patent term extension or exclusivity for the '302 patent to which Plaintiffs are or become entitled.

55. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell the ANDA Products within the United States, import the ANDA Products into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '302 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

56. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of a judgment, in favor of Plaintiffs and against Defendants, that Defendants have infringed the '302 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214055 that included the Paragraph IV Certification with respect to the '302 patent;

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 Defendants, their respective directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Defendants, from infringing the '302 patent by the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the 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. 214055 be a date that is not earlier than the expiration date of the '302 patent, or any later expiration of any patent term extension or exclusivity for the '302 patent to which Plaintiffs are or become entitled;

D. An award of monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States, any product that infringes, induces, or contributes to the infringement of the '302 patent within the United States prior to the expiration of the '302 patent, including any later expiration of any patent term extension or exclusivity for the '302 patent 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.

Dated: September 3, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action in any court, or of any pending arbitration or administrative proceeding, except the following:

1. *Actelion Pharms. Ltd et al. v. MSN Pharms. Inc. et al.*, 1:20-cv-03859-RMB-SAK (D.N.J.);
2. *Actelion Pharms. US, Inc. et al. v. Alembic Pharms. Ltd. et al.*, 1:22-cv-01450-GBW (consolidated) (D. Del.);
3. *Actelion Pharms. US, Inc. et al. v. Alembic Pharms. Ltd. et al.*, 1:23-cv-00383-GBW (D. Del.);
4. *Actelion Pharms. US, Inc. et al. v. MSN Lab'ys Private Ltd. et al.* 1:23-cv-00731-GBW-CJB (D. Del.); and
5. *Actelion Pharms. US, Inc. et al. v. Lannett Co., Inc.*, 1:24-cv-01162-GBW (D. Del.).

Dated: September 3, 2025

s/ Keith J. Miller
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