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.	Case No. 1:25-cv-15227 **Electronically Filed**

ANSWER OF DEFENDANTS VGYAAN PHARMACEUTICALS LLC AND RK PHARMA, INC.

Defendants VGYAAN Pharmaceuticals LLC ("VGYAAN") and RK Pharma, Inc. ("RK") (collectively "Defendants") by and through its undersigned attorneys, provide the following answers and affirmative defenses to the Complaint of Plaintiffs Actelion Pharmaceuticals US, Inc., Actelion Pharmaceuticals Ltd ("Actelion") and Nippon Shinyaku Co., Ltd. (collectively "Plaintiffs"). This pleading is based upon Defendants knowledge as to its own activities, an upon information and belief as to the activities of others. Pursuant to Fed. R. Civ. P. 8(b)(3), Defendant denies all allegations in Plaintiff's Complaint, except for those specifically admitted below.

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.

ANSWER: Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph, and therefore denies them.

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

ANSWER: Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph, and therefore denies them.

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.

ANSWER: Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in this paragraph, and therefore denies them.

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.

ANSWER: Defendants admit that 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.

ANSWER: Defendants admit that RK Pharma is an entity organized and existing under the laws 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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that VGYAAN is a wholly owned subsidiary of RK Pharma and maintains a regular place 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.

ANSWER: Defendants admit that VGYAAN develops, manufactures, distributes, sells, offer to sell, and/or imports generic versions of branded pharmaceutical products throughout the United States. Defendants deny all remaining allegations of paragraph 8.

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.

ANSWER: Defendants admit that VGYAAN is registered under Business ID No.0600406976 with New Jersey's Division of Revenue and Enterprise Services. Defendants deny all remaining allegations in paragraph 9.

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.

ANSWER: Defendants admit that VGYAAN is registered with New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002312. Defendants deny all remaining allegations of paragraph 10.

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.

ANSWER: Defendants admit that RK Pharma, either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, markets, distributes, sells, and/or imports generic versions of branded pharmaceutical products in the United States. Defendants deny all remaining allegations of paragraph 11.

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.

ANSWER: Defendants admit that RK Pharma is registered under Business ID No. 0101052900 with New Jersey's Division of Revenue and Enterprise Services. Defendants deny all remaining allegations in paragraph 12.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint states that this is a civil action for infringement of United States Patent No. 7,205,302 ("the '302 patent") that arises under the patent laws of the United States and the Declaratory Judgment Act. Defendants deny that Plaintiffs are entitled to any relief, including but not limited to the pled injunction or monetary relief. Defendants deny all remaining allegations in paragraph 13.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations of paragraph 14.

JURISTICTION 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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that this Court has subject matter jurisdiction solely for the limited purposes of this particular action.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for the limited purposes of this particular action.

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).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that they did not contest personal jurisdiction solely for the limited purpose of the particular identified action.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for the limited purposes of this particular action.

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).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that it did not contest personal jurisdiction solely for the limited purposes of the particular identified actions.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny the allegations of paragraph 20.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that VGYAAN is a subsidiary of RK Pharma. Defendants deny the remaining allegations of paragraph 21.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admit that VGYAAN is a subsidiary of RK Pharma. Defendants deny the remaining allegations of paragraph 22.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny that venue is appropriate under 28 U.S.C. §§ 1391 and/or 1400 but does not contest venue solely for the limited purposes of this particular action.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest venue solely for the limited purposes of this particular action. Defendants deny all remaining allegations of paragraph 24.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants admits that Defendants acted as an agent in submitting ANDA No. 214055 for the purposes of the matters described therein. Defendants do not contest personal jurisdiction for this action only. Defendants deny all remaining allegations of paragraph 25.

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.

ANSWER: Defendants admit that the FDA's website indicates that Actelion Inc. holds NDA No. 207947 which has an approval date of December 21, 2015. Defendants admit that the brand name for selexipag is Uptravi®, and that it is marketed in strengths of 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg. Defendants deny all remaining allegations of paragraph 26.

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.

ANSWER: Admitted.

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.

ANSWER: Defendant is without sufficient knowledge and information to form a belief as to the truth of the allegations, and therefore denies them.

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.

ANSWER: Defendants admit that a purported copy of the '302 patent is attached to the Complaint as Exhibit A. Defendants admits that, on its face, the '302 patent is titled "Heterocyclic Compound Derivatives and Medicines" and bears an issuance date of April 17, 2007. Defendants deny that the patent was duly and legally issued. Defendants deny all remaining allegations of paragraph 29.

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.

ANSWER: Defendants admit that the FDA's website indicates that the '302 patent is listed in the Orange Book in connection with UPTRAVI®. Defendants deny all remaining allegations of paragraph 30.

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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that 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 and that the Defendants' Notice Letter speaks for itself.

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

ANSWER: Admitted.

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").

ANSWER: Admitted.

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.

ANSWER: Defendants admit that they converted their Paragraph III certification on the '302 patent to a Paragraph IV certification on July 24, 2025. Otherwise denied.

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.

ANSWER: Defendants admit that Plaintiffs were parties to prior litigations involving the '302 patent. Otherwise denied.

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.

ANSWER: Defendants admit that Plaintiffs were parties to prior litigations involving the '302 patent. Otherwise denied.

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.

ANSWER: Defendants admit that Defendants' Notice Letter speaks for itself as to the contents therein.. Defendants deny all remaining allegations of paragraph 38.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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.

ANSWER: Defendants admit that Plaintiffs communicated with Defendants' counsel after receipt of Defendants' Notice Letter and those communications speak for themselves. Otherwise denied.

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.

ANSWER: Admitted.

RESPONSE TO ALLEGED INFRINGEMENT

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

ANSWER: Defendants incorporate each of the preceding paragraphs 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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny any liability, either jointly or severally.

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."

ANSWER: Admitted.

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

ANSWER: Defendants admit that Defendants' Notice Letter speaks for itself as to the contents therein. Defendants deny all remaining allegations of paragraph 46, and specifically deny that they infringe any valid and enforceable claim of the '302 patent.

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(c)(2)(A).

ANSWER: Defendants admit that the submission of ANDA No. 214055 with a Paragraph IV Certification to the '302 patent was a technical act of infringement sufficient to confer jurisdiction to bring an action. Otherwise denied.

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.

ANSWER: Admitted.

49. 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.

ANSWER: Defendants admit that the submission of ANDA No. 214055 with a Paragraph IV Certification to the '302 patent was a technical act of infringement sufficient to confer jurisdiction to bring an action. Otherwise denied.

50. 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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny infringement of any valid and enforceable claim 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.

ANSWER: Defendants admit that they are seeking FDA approval of ANDA No. 214055. Otherwise denied.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny infringement of any valid and enforceable claim of the '302 patent.

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.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny infringement of any valid and enforceable claim of the '302 patent.

54. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271©(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 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.

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any judgment or relief against Defendants, and therefore, specifically denies Paragraph (A)-(F) of the Complaint's prayer for relief. Each averment or allegation contained in Plaintiffs' Complaint that is not specifically admitted herein is hereby denied. Defendants request that judgment be entered in their favor, dismissing Plaintiffs' Complaint with prejudice, awarding Defendants' attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting further relief as the Court may deem just and proper.

ADDITIONAL AND OTHER DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of Plaintiffs' Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Defendants aver and assert the following Additional Defenses to the Complaint. Defendants expressly reserve the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs fail to state a claim upon which relief can be granted.

SECOND DEFENSE

Defendants have not, do not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '302 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '302 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

THIRD DEFENSE

Each claim of the '302 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FOURTH DEFENSE

Plaintiffs are not entitled to injunctive relief because any injury to Plaintiffs is not immediate or irreparable, because any such injunction would be against the public interest, and because Plaintiffs have an adequate remedy at law.

FIFTH DEFENSE

Defendants have not intentionally, willfully, or deliberately infringed any valid claim of the '302 patent.

SIXTH DEFENSE

Plaintiffs' case is not exceptional under 35 U.S.C. § 285.

SEVENTH DEFENSE

Plaintiffs' infringement claims against Defendants regarding the '302 patent are barred and the '302 patent is unenforceable against Defendants under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF DEFENSES

Defendants reserve the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

DEFENDANTS' COUNTERCLAIMS

THE PARTIES

1. Defendant/Counterclaim-Plaintiff VGYAAN ("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.

2. Defendant/Counterclaim-Plaintiff RK Pharma, Inc. ("RK Pharma") is an entity organized and existing under the laws of Delaware, with a principal place of business at 401 N. Middletown Road, Building 215/215A, Pearl River, New York 10965.

3. On information and belief, and based on paragraphs 1-3 of the Counterclaim-Defendants' Complaint, Counterclaim-Defendant Actelion Pharmaceuticals US, Inc. ("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, Counterclaim-Defendant Actelion Pharmaceuticals Ltd ("Actelion Ltd") is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland, and Counterclaim-Defendant Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") is a Japanese corporation having a primary place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, and 1338(a), based on an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*.

5. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have voluntarily subjected themselves to the Court's jurisdiction by filing the Complaint.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

7. Upon information and belief, Actelion Inc. is the current holder of NDA No. 207947.

8. The United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book," lists United States

Patent No. 7,205,302 ("the '302 patent" or "Patent-in-Suit"), *inter alia*, as covering UPTRAVI® as manufactured under NDA No. 207947.

9. VGYAAN filed ANDA No. 214055 with the FDA seeking approval to engage in the commercial manufacture, use, or sale of selexipag tablets containing 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg selexipag ("VGYAAN's ANDA product").

10. On its face, the '302 patent, entitled "Heterocyclic Compound Derivatives and Medicines" indicates it was issued on April 17, 2007.

11. Counterclaim-Defendant Nippon Shinyaku purports to be the assignee of the '302 patent.

12. The '302 patent is currently listed in connection with UPTRAVI® in the Orange Book.

COUNTERCLAIM I
(Declaration of Invalidity and/or Unenforceability of the '302 Patent)

13. Counterclaim-Plaintiffs incorporate by reference the allegations set forth in paragraphs 1-12 of the Counterclaims as if fully set forth herein.

14. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

15. A real and present controversy exists regarding infringement of the '302 patent where Counterclaim-Defendants have previously stated that Counterclaim-Plaintiffs infringe the '302 patent, had threatened to sue, and have now sued Counterclaim-Plaintiffs for infringement.

16. Actual and justiciable controversies exist between Counterclaim-Defendants and Counterclaim-Plaintiffs regarding the validity and enforceability of the '302 patent.

17. This counterclaim is for a declaration that each and every claim of the '302 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, double patenting, and/or other judicially-created bases for invalidation or enforceability, for example, due to prosecution laches. Without limitation, the '302 patent is invalid because each claim limitation of the claims of the '302 patent were known in the prior art or would have been obvious to a person of ordinary skill in light of the relevant prior art and such person of ordinary skill would have had a reasonable expectation of success in combining such well-known elements, each claim of the '302 patent lacks adequate description in the specification to inform the full scope of the claims, the specification fails to enable the full scope of each claim, and/or the claims are indefinite.

18. Counterclaim-Plaintiffs are entitled to a declaration that the claims of the '302 patent are invalid or unenforceable.

19. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Counterclaim-Plaintiffs request a declaration from the Court that each assertable claim of the '302 patent is invalid or unenforceable.

DEFENDANTS' RESPONSE TO PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully pray for judgement as follows:

a) Dismissing the Complaint with prejudice;

b) Denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;

c) Awarding Defendants their reasonable attorney's fees under 35 U.S.C. § 285;

d) Awarding Defendants their costs; and

e) Awarding Defendants such other and further relief as the Court deems just and equitable.

DATED: October 31, 2025

/s/ Frank D. Rodriguez

Frank D. Rodriguez
WINDELS MARX LANE &
MITTENDORF LLP
1 Giralda Farms
Madison, NJ 07940
(973) 966-3200
Fax (973) 966-3250
frodriguez@windelsmarx.com

Attorney for Defendants VGYAAN Pharmaceuticals LLC and RK Pharma, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that a true and accurate copy of the foregoing Answer of Defendants VGYAAN Pharmaceuticals LLC and RK Pharma, Inc. was caused to be filed with the Court's electronic filing system and served upon all counsel of record for Plaintiffs via the Court's electronic filing system on the 31st day of October, 2025.

/s/ Frank D. Rodriguez
Frank D. Rodriguez