UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

ACTELION PHARMACEUTICALS US, INC., ACTELION PHARMACEUTICALS LTD and NIPPON SHINYAKU CO., LTD. Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	Civil Action No. 1:23-cv-00389-GBW

DEFENDANTS CIPLA LIMITED AND CIPLA USA, INC.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Cipla Limited and Cipla USA, Inc. (collectively "Cipla" or "Defendants"), by their counsel, hereby answer the allegations set forth in Actelion Pharmaceuticals US, Inc. ("Actelion Inc."), Actelion Pharmaceuticals Ltd ("Actelion Ltd"), (together "Actelion"), and Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") (collectively "Plaintiffs") Complaint for patent infringement against Cipla, as follows:

THE PARTIES[1]

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: Cipla lacks sufficient information or knowledge to form a belief as to the truth of the allegations of 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.

[1] For convenience, certain section headings used by Plaintiffs in their Complaint are repeated herein.

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

4. Upon information and belief, Defendant Cipla Ltd. is an entity organized and existing under the laws of India, with a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

ANSWER: Cipla admits that Cipla Ltd. is an Indian corporation with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

5. Upon information and belief, Cipla 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.

ANSWER: Cipla admits that Cipla Ltd. develops and manufactures generic pharmaceutical products. Cipla denies any remaining allegations in this paragraph.

6. Upon information and belief, Cipla Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey 07059.

ANSWER: Cipla admits that Cipla USA, Inc. is a Delaware corporation with a place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

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

ANSWER: Cipla admits that Cipla USA, Inc. is engaged in the distribution and sale of generic pharmaceutical products in the United States. Cipla denies any remaining allegations in this paragraph.

8. Upon information and belief, Cipla Inc. is registered with the Delaware Department of State Division of Corporations as a business operating in Delaware under Business ID No. 5207954.

ANSWER: Admitted.

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

ANSWER: Cipla admits that Cipla USA, Inc. is an indirect wholly-owned-subsidiary of Cipla Ltd.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla USA, Inc. is the U.S. agent for Cipla Ltd.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla Ltd. and Cipla USA, Inc. each perform certain tasks with respect to Cipla's ANDAs and Cipla's generic pharmaceutical products. Cipla denies any remaining allegations in this paragraph.

NATURE OF 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Plaintiffs purport to bring this action under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Cipla denies any remaining allegations in this paragraph.

13. This action relates to Defendant Cipla Ltd.'s submission of Cipla Ltd.'s Abbreviated New Drug Application ("ANDA") No. 216607, 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, 1.8 mg/vial ("Cipla's ANDA Product"), before expiration of the patents-in-suit.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that Cipla Ltd. filed an Abbreviated New Drug Application ("ANDA") No. 216607, 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, 1.8 mg/vial ("Cipla's ANDA Product"). Cipla denies any remaining allegations in this paragraph.

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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, to the extent that a response is required, and for the limited purposes of this case only, Cipla does not contest subject matter jurisdiction or venue in this action. Cipla denies any remaining allegations in this paragraph.

15. The Court has personal jurisdiction over Cipla Ltd., and venue is proper as to Cipla Ltd., because, *inter alia*, Cipla Ltd.: (1) directs and/or controls Cipla 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 Cipla's ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla Ltd. is subject to personal jurisdiction in this District or that venue is proper in this district, but Cipla does not contest jurisdiction or venue in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

16. This Court also has personal jurisdiction over Cipla 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., Acerta Pharma BV et al. v. Cipla Ltd. et al.*, C.A. No. 22-0162-RGA; *UCB Inc. et al. v. Cipla Ltd. et al.*, C.A. No. 21-1229-CFC; *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. et al.*, C.A. No. 19-1494-CFC; *H. Lundbeck A/S et al. v. Cipla Ltd. et al.*, C.A. No. 18-0753-LPS; *Pharmacyclics LLC et al. v. Cipla Ltd. et al.*, C.A. No. 18-0247-GMS; *Alcon Rsch., Ltd. v. Cipla Ltd. et al.*, C.A. No. 17-1244-GMS.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla Ltd. is subject to personal jurisdiction in this District, but Cipla does not contest jurisdiction in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

17. Cipla Ltd. 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.*, *Cipla Ltd. v. Boehringer Ingelheim Pharms. Inc. et al.*, C.A. No. 22-0300-MN; *Cipla Ltd. et al. v. AstraZeneca AB et al.*, C.A. No. 19-0733-MN.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that it initiated litigation in this Judicial District in *Cipla Ltd. v. Boehringer Ingelheim Pharms. Inc. et al.*, C.A. No. 22-0300-MN and *Cipla Ltd. et al. v. AstraZeneca AB et al.*, C.A. No. 19-0733-MN. Cipla denies any remaining allegations in this paragraph.

18. Alternatively, this Court may exercise jurisdiction over Cipla Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Cipla Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Cipla 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 Cipla Ltd. satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla Ltd. is subject to personal jurisdiction in this District, but Cipla does not contest jurisdiction in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

19. This Court has personal jurisdiction over Cipla Inc., and venue is proper as to Cipla Inc., because, *inter alia*, Cipla 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. 5207954; (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 Cipla's ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla USA, Inc. is subject to personal jurisdiction in this District or that venue is proper in this district, but Cipla does not contest jurisdiction or venue in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

20. This Court also has personal jurisdiction over Cipla 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.*, *Acerta Pharma BV et al. v. Cipla Ltd. et al.*, C.A. No. 22-0162-RGA; *UCB Inc. et al. v. Cipla Ltd. et al.*, C.A. No. 21-1229-CFC; *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. et al.*, C.A. No. 19-1494-CFC; *Genentech, Inc. et al. v. Cipla Ltd. et al.*, C.A. No. 19-0219-RGA; *H. Lundbeck A/S et al. v. Cipla Ltd. et al.*, C.A. No. 18-0753-LPS; *Onyx Therapeutics, Inc. v. Cipla Ltd. et al.*, C.A. No. 18-0598-LPS.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla USA, Inc. is subject to personal jurisdiction in this District, but Cipla does not contest jurisdiction in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

21. Cipla Inc. 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.*, *Cipla Limited et al. v. AstraZeneca AB et al.*, C.A. No. 19-0733-MN.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla admits that it initiated litigation in this Judicial District in *Cipla Ltd. et al. v. AstraZeneca AB et al.*, C.A. No. 19-0733-MN. Cipla denies any remaining allegations in this paragraph.

22. This Court also has personal jurisdiction over Cipla because, *inter alia*, Cipla Ltd. and Cipla 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that it is subject to personal jurisdiction in this District, but Cipla does not contest jurisdiction in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

23. Venue is proper in this Court for Cipla Ltd. pursuant to 28 U.S.C. §§ 1391(c) and 1400(b) because Cipla Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Cipla 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that Cipla Ltd. is subject to personal jurisdiction in this District or that venue is proper in this district, but Cipla does not contest

jurisdiction or venue in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Cipla denies that venue is proper in this district, but Cipla does not contest venue in this District for the limited purpose of this case only. Cipla denies any remaining allegations in this paragraph.

25. Upon information and belief, the actions of Cipla of, *inter alia*, causing Cipla's ANDA No. 216607 to be filed and maintaining distribution channels, including in the State of Delaware, establish that if granted approval, Cipla will commercially manufacture, use, offer to sell, sell, and/or import Cipla's ANDA Product throughout the United States, including in Delaware.

ANSWER: Denied.

UPTRAVI® AND THE PATENTS-IN-SUIT

26. 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.

ANSWER: Cipla admits that NDA 214275 was approved on July 29, 2021. Cipla further admits that 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. Cipla lacks sufficient information or knowledge to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

27. 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.

ANSWER: Cipla admits the UPTRAVI® labeling states that UPTRAVI® 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. Cipla lacks sufficient information or knowledge to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

28. Nippon Shinyaku is the assignee of the '122 patent and the '280 patent. Actelion Ltd is an exclusive licensee of the '122 patent and the '280 patent. Actelion Inc. markets and sells UPTRAVI® in the United States. Actelion Inc. and Actelion Ltd are wholly-owned subsidiaries of Johnson & Johnson.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required Cipla lacks sufficient information or knowledge to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

29. 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)-NIsopropylamino] Butyloxy}-N-(Methylsulfonyl)Actemide." A copy of the '122 patent is attached as Exhibit A.

ANSWER: Cipla admits that the face of the '122 patent indicates that it is titled "Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-NIsopropylamino] Butyloxy}-N-(Methylsulfonyl)Actemide" and that it purports to have been issued on July 29, 2014. Cipla further admits that what purports to be a copy of the '122 Patent is attached as Exhibit A to the Complaint. Cipla is without sufficient knowledge or information to admit or deny the remaining allegations of this paragraph and therefore denies them.

30. 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.

ANSWER: Cipla admits that the face of the '280 patent indicates that it is titled "Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-NIsopropylamino] Butyloxy}-N-(Methylsulfonyl)Actemide" and that it purports to have been issued on March 15, 2016. Cipla

further admits that what purports to be a copy of the '280 Patent is attached as Exhibit B to the Complaint. Cipla is without sufficient knowledge or information to admit or deny the remaining allegations of this paragraph and therefore denies them.

31. 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.

ANSWER: Admitted.

CIPLA'S ANDA AND NOTICE LETTER

32. Upon information and belief, Cipla Ltd. submitted ANDA No. 216607 to the FDA, including a certification with respect to the patents-in-suit 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 Cipla's ANDA Product prior to expiration of the patents-in-suit.

ANSWER: Cipla admits that Cipla submitted ANDA No. 216607 seeking approval to engage in the commercial manufacture, importation, use, offer for sale, or sale within the United States, and/or importation into the United States, of Cipla's ANDA Product. Cipla denies any remaining allegations of this paragraph.

33. Upon information and belief, Cipla Ltd. sent Plaintiffs a Paragraph IV Certification Notice Letter dated March 9, 2023 stating that Cipla Ltd. filed ANDA No. 216607 seeking approval from the FDA to commercially manufacture, use, market, or sell generic Selexipag for Injection, 1.8 mg/vial, in the United States (including, on information and belief, in the State of Delaware), prior to the expiration of the patents-in-suit.

ANSWER: Admitted.

34. On March 21, 2023, Plaintiffs requested that Cipla 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 patents-in-suit. Plaintiffs repeated the request on at least March 29, 2023, during a meet and confer, and on March 30, 2023. Cipla did not agree to provide pertinent information about its ANDA Product, including its ANDA, on reasonable terms. This has impaired Plaintiffs' ability to evaluate the veracity of the statements made by Cipla Ltd. in its Paragraph IV Certification Notice Letter as well as Cipla's infringement of the patents-in-suit.

ANSWER: Denied.

35. Plaintiffs commenced this action within 45 days of the date of receipt of the Cipla Ltd. Paragraph IV Certification Notice Letter, which was dated March 9, 2023.

ANSWER: Admitted.

CIPLA'S [ALLEGED] INFRINGEMENT OF THE PATENTS-IN-SUIT

36. Plaintiffs re-allege paragraphs 1-35 as if fully set forth herein.

ANSWER: Cipla incorporates by reference its responses to paragraphs 1-35 as if fully set forth herein.

37. Cipla Ltd. and Cipla Inc. are jointly and severally liable for any infringement of the patents-in-suit because, on information and belief, Cipla Ltd. and Cipla Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 216607 and the Paragraph IV Certification to the FDA.

ANSWER: Denied.

38. By seeking approval of ANDA No. 216607 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Cipla's ANDA Product prior to the expiration of the patents-in-suit, Cipla has infringed one or more claims of each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: Denied.

40. Upon information and belief, Cipla 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 Cipla's ANDA Product upon receipt of final FDA approval of ANDA No. 216607.

ANSWER: Denied.

41. If Cipla manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Cipla's ANDA Product prior to the expiration of the patents-in-

suit, Cipla will infringe one or more claims of each of the patents-in-suit under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

ANSWER: Denied.

42. Cipla Ltd.'s Paragraph IV Certification Notice Letter does not dispute that the '122 patent is valid.

ANSWER: Denied.

43. Cipla Ltd.'s Paragraph IV Certification Notice Letter does not dispute that the '280 patent is valid.

ANSWER: Denied.

44. Cipla had actual and constructive notice of the patents-in-suit prior to the filing of Cipla's ANDA No. 216607 seeking approval of Cipla's ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no answer is required.

To the extent an answer is required Cipla admits that it was aware of the patents-in-suit prior to the filing of Cipla's ANDA.

45. 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 Cipla's ANDA No. 216607 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiffs are or become entitled.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to any of the relief sought in their Prayer for

Relief, including the relief sought in Paragraphs A through F thereof, and/or any other relief. Cipla lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraphs A through F of Plaintiffs' Prayer for Relief, and on that basis, denies them.

AFFIRMATIVE DEFENSES

Cipa reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure and any other defense at law or at equity that may now exist or in the future be available based on discovery and further factual investigation in this case, whether or not expressly stated herein. Without prejudice to the denials set forth in its Answer and without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations not expressly admitted in Plaintiffs' Complaint, Cipla states the following defenses:

FIRST AFFIRMATIVE DEFENSE

The allegations set forth in Plaintiffs' Complaint fail to state a claim for which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the Patents-in-Suit are invalid and/or unenforceable for failure to satisfy or comply with the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE

Cipla has not infringed, is not infringing, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. Cipla has not

contributed to, is not contributing to, and will not contribute to any infringement of any valid and enforceable claim of the Patents-in-Suit. Cipla has not induced, is not inducing, and will not induce infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH AFFIRMATIVE 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 AFFIRMATIVE DEFENSE

Cipla has not intentionally, willfully, or deliberately infringed any valid claim of the Patents-in-Suit.

SIXTH AFFIRMATIVE DEFENSE

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

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' infringement claims against Cipla regarding the Patents-in-Suit are barred and the Patents-in-Suit are unenforceable against Cipla under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF ADDITIONAL DEFENSES

Cipla hereby reserves the right to assert additional defenses and/or counterclaims if such defenses or counterclaims are discovered during the course of this litigation.

COUNTERCLAIMS

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer, *supra*, and without prejudice to Cipla's right to plead additional counterclaims as the facts of the matter warrant, the Defendants/Plaintiffs-In-

Counterclaim, Cipla Limited ("Cipla") and Cipla USA, Inc. ("Cipla USA") (collectively "Cipla" or "Counterclaim-Plaintiffs"), for its Counterclaims against Plaintiffs Actelion Pharmaceuticals US, Inc. ("Actelion Inc."), Actelion Pharmaceuticals Ltd ("Actelion Ltd"), (together "Actelion"), and Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") (collectively "Counterclaim-Defendants"), hereby allege as follows:

THE PARTIES

1. Counterclaim-Plaintiff Cipla Limited is a corporation organized and existing under the laws of India, having its corporate office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

2. Counterclaim-Plaintiff Cipla USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. Cipla USA is an indirect subsidiary of Cipla Limited.

3. On information and belief, 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.

4. On information and belief, Actelion Ltd is a Swiss corporation, having its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

5. On information and belief, Nippon Shinyaku is a Japanese corporation having its principal place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

JURISDICTION AND VENUE

6. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100, *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, 1338, 2201, and 2202.

7. Personal jurisdiction over the Plaintiffs/Counterclaim-Defendants exists because the Plaintiffs/Counterclaim-Defendants have submitted to the personal jurisdiction of the Court.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

The Patents-in-Suit

9. On April 6, 2023, Plaintiffs/Counterclaim-Defendants filed a Complaint alleging, inter alia, infringement of United States Patent Nos. 8,791,122 ("the '122 patent") and 9,284,280 ("the '280 patent") (collectively the "Patents-in-Suit").

10. Prior to the filing of this action, upon information and belief, Plaintiffs/Counterclaim-Defendants listed and/or caused to be listed the '122 and '280 patents in the publication of the Federal Food and Drug Administration ("FDA") entitled "Approved Drug Products for Therapeutic Equivalents Evaluations" (commonly known as the "Orange Book") for NDA No. 214275.

11. The '122 Patent is entitled, "Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropyl-Amino]Butyloxy}-N-(Methyl-Sulfonyl)Acetamide," and indicates on the face of that patent that it issued on July 29, 2014.

12. The '280 Patent is entitled, "Use of Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropyl-Amino]Butyloxy}-N-(Methyl-Sulfonyl)Acetamide," and indicates on the face of that patent that it issued on March 15, 2016.

13. Upon information and belief, Nippon Shinyaku has licensed each of the Patents-in-Suit to Actelion Ltd.

Cipla's Notice Letter and Par's Suit

14. Cipla has filed with the FDA an Abbreviated New Drug Application ("ANDA") bearing No. 216607, seeking to obtain approval to engage in the commercial manufacture, use, sale, or importation of a proposed generic selexipag for injection, 1.8 mg/vial product ("Cipla's ANDA Product").

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(iv), Cipla's ANDA No. 216607 contains a "Paragraph IV" certification stating that each of the '122 and '280 patents are invalid or will not be infringed by the manufacturing, use, sale, offer to sell, or importation into the United States of the proposed drug product which is the subject of Cipla's ANDA No. 216607.

16. Pursuant to the applicable statutes, rules, and regulations, Cipla notified Plaintiffs/Counterclaim-Defendants that it had submitted to the FDA ANDA No. 216607 for Cipla's ANDA Product by letter dated March 9, 2023 ("Cipla's Notice Letter").

17. Pursuant to 21 U.S.C. § 355(c)(3)(C), Plaintiffs/Counterclaim-Defendants had 45 days from receipt of Cipla's Notice Letter to file the Complaint.

18. Plaintiffs/Counterclaim-Defendants filed their Complaint within the 45-day period following receipt of Cipla's Notice Letter ("the 45-day period").

19. Pursuant to 21 U.S.C. § 355(c)(3)(C), Plaintiffs/Counterclaim-Defendants' act of filing the Complaint within the 45-day period prohibits the FDA from approving Cipla's ANDA Product for a period of thirty months following Plaintiffs/Counterclaim-Defendants' receipt of Cipla's Notice Letter ("the thirty-month stay").

20. During the pendency of the thirty-month stay, Cipla is prohibited from selling Cipla's ANDA Product in the United States.

21. By virtue of Plaintiffs/Counterclaim-Defendants having listed the '122 and '280

patents in the Orange Book, by virtue of Cipla's submission of a "Paragraph IV" certification regarding these patents and providing Plaintiffs/Counterclaim-Defendants with notice and the basis for such certification, and by virtue of the Complaint filed herein, an actual case and controversy exists between Cipla and Plaintiffs/Counterclaim-Defendants as to the infringement and validity of the '122 and '280 patents.

22. Cipla does not infringe any valid and enforceable claim of the Patents-in-Suit, either directly or indirectly.

23. An actual and justiciable controversy exists between Plaintiffs/Counterclaim-Defendants and Cipla relating to, inter alia, the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Noninfringement – U.S. Patent No. 8,791,122)

24. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

25. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '122 patent.

26. Cipla's manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product upon FDA approval to do so pursuant to ANDA No. 216607 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 Patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Cipla's Notice Letter.

27. Cipla does not and has not committed any acts in violation of 35 U.S.C. § 271.

28. Cipla is entitled to a declaratory judgment that their manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product pursuant to ANDA No. 216607 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '122 Patent, either literally or under the doctrine of equivalents.

COUNT II

(Declaratory Judgment of Noninfringement – U.S. Patent No. 9,284,280)

29. Cipla repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

30. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '280 patent.

31. Cipla's manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product upon FDA approval to do so pursuant to ANDA No. 216607 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '280 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Cipla's Notice Letter.

32. Cipla does not and has not committed any acts in violation of 35 U.S.C. § 271.

33. Cipla is entitled to a declaratory judgment that their manufacture, use, offer for sale, sale, and/or importation into the United States of Cipla's ANDA Product pursuant to ANDA No. 216607 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '280 Patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Cipla respectfully requests that the Court enter judgment for Cipla, and against Plaintiffs/Counterclaim-Defendants, and decree:

A. That the Complaint be dismissed with prejudice and that each and every prayer for relief contained therein be denied;

B. That the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Cipla's ANDA No. 216607 has not infringed, does not infringe, would not infringe, would not contributorily infringe and would not induce the infringement of any valid and enforceable claim of the '122 and '280 patents, either literally or under the doctrine of equivalents;

C. That this case is exceptional and awarding Cipla reasonable attorneys' fees, costs, and expenses in this action, pursuant to 35 U.S.C. § 285 and/or other applicable laws;

D. Cipla be awarded its fees, costs, and expenses in this action;

E. That the effective date of any FDA approval of Cipla's ANDA Product shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii); and

F. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: June 12, 2023

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