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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LIMITED, Defendants.	Civil Action No. 1:24–CV-10213 **ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS** ***Document Electronically Filed***

Defendants Cipla Limited and Cipla USA Inc. (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by

Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland Ltd. (collectively, "Plaintiffs") as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Xifaxan® (rifaximin tablets, 550 mg) prior to the expiration of U.S. Patent Nos. 11,564,912 (the "'912 patent"), 11,779,571 (the "'571 patent") and U.S. Patent No. 8,193,196 (the "'196 patent") (collectively, the "Xifaxan® patents" or "patents-in-suit").

ANSWER: Cipla admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, Title 35, United States Code, and 28 U.S.C. §§ 2201 and 2202. Cipla admits that Cipla Limited prepared and submitted Cipla's Abbreviated New Drug Application ("ANDA") No. 219570 ("Cipla's ANDA") to the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA ("Cipla's ANDA Product") prior to the expiration of U.S. Patent Nos. 11,564,912 (the "'912 patent"), 11,779,571 (the "'571 patent") and U.S. Patent No. 8,193,196 (the "'196 patent") (collectively, the "Xifaxan® patents" or "patents-in-suit"). Cipla denies the remaining allegations in paragraph 1.

2. By letter dated September 18, 2024 ("Notice Letter"), Defendants notified Salix that they had submitted to FDA ANDA No. 219570 ("Cipla ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, and/or sale of generic rifaximin 550 mg tablets ("Cipla's ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Xifaxan® patents. The Notice Letter stated that Defendants have received a Paragraph IV acceptance acknowledgement receipt letter from FDA.

ANSWER: Cipla admits that Cipla notified Plaintiffs by letter dated September 18, 2024 ("Notice Letter") that Cipla had submitted Cipla's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA Product,

prior to the expiration of the '912 patent, the '571 patent, and the '196 patent. Cipla admits that Cipla's Notice Letter indicated that Cipla had received a Paragraph IV acceptance acknowledgement receipt letter from the FDA. Cipla denies any remaining allegations of paragraph 2.

PARTIES

3. Plaintiff Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

ANSWER: On information and belief, Cipla admits that Salix Pharmaceuticals, Inc. maintains an address at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

4. Plaintiff Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

ANSWER: On information and belief, Cipla admits that Salix Pharmaceuticals, Ltd. maintains an address at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

5. Plaintiff Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del '99, 5, 40133 Bologna, Italy.

ANSWER: On information and belief, Cipla admits that Alfasigma S.p.A. maintains an address at Via Ragazzi del '99, 5, 40133 Bologna, Italy. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

6. Plaintiff Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

ANSWER: On information and belief, Cipla admits that Bausch Health Ireland Ltd. maintains an address at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

7. On information and belief, defendant Cipla USA is a corporation organized and existing under the laws of Delaware with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

ANSWER: Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla admits that Cipla USA, Inc. distributes pharmaceutical drug products, including generic drug products, for sale in the U.S. market. Cipla denies the remaining allegations in paragraph 7.

8. On information and belief, Cipla Limited is a company organized and existing under the laws of the Republic of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Cipla USA.

ANSWER: Cipla admits that Cipla Limited is a company organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Cipla admits that Cipla Limited manufactures and sells pharmaceutical drug products, including generic drug product. Cipla denies any remaining allegations of paragraph 8.

9. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Limited.

ANSWER: Cipla admits that Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla denies any remaining allegations of paragraph 9.

10. On information and belief, Cipla USA and Cipla Limited acted in concert to prepare the Cipla ANDA. On information and belief, both Cipla USA and Cipla Limited assisted with the preparation of the Cipla ANDA.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Limited and Cipla USA, Inc. seek regulatory approval of pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 10.

11. On information and belief, Cipla USA and Cipla Limited acted in concert to submit the Cipla ANDA to FDA. On information and belief, Cipla Limited directed Cipla USA to submit the Cipla ANDA from Cipla USA's principal place of business in New Jersey.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Limited and Cipla USA, Inc. seek regulatory approval of pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 11.

12. On information and belief, if the Cipla ANDA were approved, Cipla USA and Cipla Limited would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, Cipla USA and Cipla Limited are agents of each other, and/or operate in concert as integrated parts of the same business group, including regarding the ANDA Product, and enter into intercompany agreements with each other. On information and belief, Cipla USA and Cipla Limited participated in, assisted, and cooperated with each other in the acts complained of herein.

ANSWER: Cipla admits that Cipla Limited and Cipla USA, Inc. prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies the remaining allegations in paragraph 12.

13. On information and belief, following any FDA approval of the Cipla ANDA, Cipla USA and Cipla Limited will act in concert to distribute and sell the ANDA Product throughout the United States, including within New Jersey.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 13 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies any remaining allegations in paragraph 13.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Cipla does not contest subject matter jurisdiction.

15. Cipla USA is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA is qualified to do business in New Jersey and has its principal place of business in New Jersey. On information and belief, Cipla USA develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey and therefore transacts business within New Jersey related to Salix's claims, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla admits that Cipla USA, Inc. has its principal place of business in New Jersey. Cipla denies the remaining allegations of paragraph 15.

16. On information and belief, the Court has personal jurisdiction over Cipla USA because Cipla USA regularly engages in patent litigation concerning FDA approved branded drug products in this District and purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla admits that Cipla USA, Inc. was a named Defendant and filed counterclaims in *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11), *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5), *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22), and *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15). Cipla denies the remaining allegations of paragraph 16.

17. Cipla Limited is subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited itself, and through its wholly owned subsidiary Cipla USA, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should

reasonably anticipate being haled into court here. On information and belief, Cipla Limited itself, and through its wholly owned subsidiary Cipla USA, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within the New Jersey, and/or has engaged in systematic and continuous business contacts within the New Jersey. In addition, Cipla Limited is subject to personal jurisdiction in New Jersey because, on information and belief, it controls Cipla USA, and therefore Cipla USA's activities in this jurisdiction are attributed to Cipla Limited.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited in this Court for the limited purpose of this litigation. Cipla admits that Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla further admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic pharmaceutical drug products. Cipla denies the remaining allegations of paragraph 17.

18. On information and belief, Cipla Limited consented to jurisdiction, did not contest jurisdiction, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd.*, No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11); *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

ANSWER: Cipla admits that Cipla Limited filed counterclaims and/or did not contest jurisdiction in New Jersey for the limited purposes of the following litigations: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd.*, No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-

cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11); *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15). Cipla Limited does not contest personal jurisdiction in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 18.

19. In the alternative, this Court has personal jurisdiction over Cipla Limited under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Salix's claims arise under federal law; (b) Cipla Limited is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Cipla Limited has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla Limited satisfies due process, and is consistent with the Constitution and laws of the United States.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 19.

20. On information and belief, if the Cipla ANDA were approved, Defendants would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in New Jersey, and they have placed other generic pharmaceutical products into the stream of commerce for distribution throughout the United States, including in New Jersey. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the patents-in-suit in the event that the ANDA Product is approved before the patents-in-suit expire.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla pharmaceutical products, including generic pharmaceutical products, are sold in the United States, including New Jersey. Cipla further responds that Cipla will decide whether to market its product in the United States, including New Jersey, upon FDA approval. Cipla denies the remaining allegations of paragraph 20.

21. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue is proper in this District as to Cipla USA because, amongst other things, on information and belief, Cipla USA (a) has its principal place of business in New Jersey and is subject to personal jurisdiction in this District; (b) has acted in concert with Cipla Limited to seek approval from FDA to market and sell the ANDA Product in this District; (c) prepared and submitted the Cipla ANDA from its principal place of business in New Jersey; (d) conducts business, alone and/or in concert with Cipla Limited, from its place of business located in this District; (e) has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities concerning the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (f) will directly benefit from the approval of the Cipla ANDA.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest venue over Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc.'s principal place of business is in Warren, New Jersey. Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product. Cipla will decide whether to market and sell Cipla's ANDA Product in the United States, including New Jersey, upon FDA approval. Cipla denies the remaining allegations of paragraph 21.

22. On information and belief, Cipla USA is in the business of preparing and submitting ANDAs on behalf of its related entities, including Cipla Limited, from its principal place of business in New Jersey.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA Inc.'s

principal place of business is in Warren, New Jersey. Cipla further responds that Cipla Limited and Cipla USA, Inc. prepared and submitted Cipla's ANDA to the FDA. Cipla denies the remaining allegations of paragraph 22.

23. On information and belief, Cipla USA is regularly compensated for its services of preparing and submitting ANDAs on behalf of its related entities, including Cipla Limited.

ANSWER: Paragraph 23 contains legal conclusion and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla denies the remaining allegations of paragraph 23.

24. On information and belief, Cipla Limited consented to Cipla USA acting on its behalf when it engaged Cipla USA to prepare and submit the Cipla ANDA on Cipla Limited's behalf.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no response is required. To the extent that an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 24.

25. On information and belief, Cipla USA acted and continues to act on Cipla Limited's behalf. On information and belief, Cipla Limited owns the Cipla ANDA and thus controlled and directed Cipla USA's acts related to the preparation and submittal of the Cipla ANDA.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no response is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 25.

26. On information and belief, Cipla USA is Cipla Limited's agent regarding the Cipla ANDA, and in that capacity, Cipla USA prepared and submitted the Cipla ANDA on Cipla Limited's behalf from its principal place of business in New Jersey.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no response is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 26.

27. On information and belief, Cipla USA consented to venue, did not contest venue, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

ANSWER: Cipla admits that Cipla USA, Inc. asserted counterclaims and/or did not contest venue in New Jersey for the limited purposes of the following litigations: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Cubist Pharmaceuticals. LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15). Cipla denies the remaining allegations of paragraph 27.

28. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue is proper in this district as to Cipla Limited because, amongst other things, Cipla Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest venue over Cipla

Limited in this Court for the limited purposes of this litigation. Cipla further admits that Cipla Limited is a company organized and existing under the laws of the Republic of India. Cipla denies the remaining allegations of paragraph 28.

29. Cipla Limited owns the Cipla ANDA and will directly benefit from the approval of Cipla's ANDA.

ANSWER: Cipla admits that Cipla Limited owns Cipla's ANDA. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations of paragraph 29 because those allegations are based on speculation about future events, and therefore Cipla denies them.

30. On information and belief, Cipla USA is Cipla Limited's agent, and in that capacity, Cipla USA prepared and submitted the Cipla ANDA on Cipla Limited's behalf from its principal place of business in New Jersey.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla further admits that Cipla USA's principal place of business is in Warren, New Jersey. Cipla denies the remaining allegations of paragraph 30.

31. On information and belief, Cipla Limited consented to Cipla USA acting on its behalf when it engaged Cipla USA to prepare and submit the Cipla ANDA on Cipla Limited's behalf.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 31.

32. On information and belief, Cipla USA consented to act on behalf of Cipla Limited when it submitted the Cipla ANDA.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 32.

33. On information and belief, Cipla Limited controlled and directed Cipla USA's acts related to the preparation and submittal of the Cipla ANDA.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla responds that Cipla USA, Inc. is the authorized U.S. agent for Cipla Limited as required for non-U.S. applicants by the FDA. Cipla denies the remaining allegations of paragraph 33.

34. On information and belief, by virtue of its agency relationship with Cipla USA, Cipla Limited has a regular and established place of business in New Jersey.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla denies the allegations of paragraph 34.

35. On information and belief, Cipla Limited consented to venue, did not contest venue, and asserted claims and/or counterclaims in New Jersey in one or more prior litigations, including the following: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF. 11); *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd.*, No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8); *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5); *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22); *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11); *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15).

ANSWER: Cipla admits that Cipla asserted counterclaims and/or did not contest venue in New Jersey for the limited purposes of the following litigations: *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla USA, Inc. and Cipla Ltd.*, No. 2:24-cv-05856 (D.N.J. Jul. 3, 2024) (ECF.

11), *Teva Branded Pharm. Prod. R&D, Inc., et al. v. Cipla Ltd.*, No. 2:20-cv-14890 (D.N.J. Oct. 27, 2020) (ECF. 8), *Par Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-01150 (D.N.J. Mar. 23, 2023) (ECF. 5), *Fennec Pharm., Inc., et al. v. Cipla Ltd. & Cipla USA, Inc.*, No. 2:23-cv-00123 (D.N.J. Mar. 27, 2023) (ECF. 22), *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J. Aug. 26, 2019) (ECF. 11), and *Cubist Pharmaceuticals LLC v. Cipla USA, Inc. & Cipla Ltd.*, No. 3:19-cv-12920 (D.N.J. Jul. 2, 2019) (ECF. 15). Cipla denies the remaining allegations of paragraph 35.

THE XIFAXAN® NDA

36. Salix Pharmaceuticals, Inc. holds the approved New Drug Application ("NDA") Nos. 021361 and 022554 (a supplement to NDA No. 021361 that was granted a new NDA number for Xifaxan® (rifaximin) 550 mg tablets).

ANSWER: Upon information and belief, admitted.

37. FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004 and approved NDA No. 022554 for Xifaxan® 550 mg tablets on March 24, 2010. Xifaxan® 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy recurrence in adults and the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults.

ANSWER: Upon information and belief, Cipla admits that the Orange Book lists an approval date of May 25, 2004 for NDA No. 021361 for Xifaxan® 200 mg tablets. Cipla further admits that the Orange Book lists an approval date of March 24, 2010 for Xifaxan® 550 mg tablets. Cipla admits that the Xifaxan® prescribing information recites the following indications: "reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults" and "treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults." The remainder of paragraph 37 contains legal conclusions to which no answer is required. To the extent that an answer is required, Cipla denies the remaining allegations of paragraph 37.

THE PATENTS-IN-SUIT

38. On October 10, 2023, the '571 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '571 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Exhibit A to the Complaint purports to be a copy of the '571 patent. Cipla admits that the '571 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)" and lists October 10, 2023 as the issue date. Cipla admits that the '571 patent identifies Salix Pharmaceuticals, Inc. as the assignee on its face. Cipla denies the remaining allegations of paragraph 38.

39. On January 31, 2023, the '912 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '912 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Exhibit B to the Complaint purports to be a copy of the '912 patent. Cipla admits that the '912 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)" and lists January 31, 2023 as the issue date. Cipla admits that the '912 patent identifies Salix Pharmaceuticals, Inc. as the assignee on its face. Cipla denies the remaining allegations of paragraph 39.

40. On June 5, 2012, the '196 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wassermann, S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '196 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Exhibit C to the Complaint purports to be a copy of the '196 patent. Cipla admits that the '196 patent is titled

"Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations" and lists June 5, 2012 as the issue date. Cipla admits that the '196 patent identifies Alfa Wasserman S.p.A as the assignee on its face. Cipla lacks sufficient knowledge or information to admit or deny whether AlfaSigma, S.p.A is the successor to Alfa Wasserman, S.p.A. by operation of law, and therefore denies it. Cipla denies the remaining allegations of paragraph 40.

41. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 patent, the '912 patent, and the '196 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that the Orange Book lists the '571 patent, the '912 patent, and the '196 patent in connection with Xifaxan® 550 mg tablets. Cipla denies the remaining allegations of Paragraph 41.

42. Pursuant to agreements entered into between Bausch Health Ireland Ltd., Salix Pharmaceuticals, Inc., and Alfasigma S.p.A., Bausch Health Ireland Ltd. and Salix Pharmaceuticals, Inc. have substantial rights in the '196 patent, including, but not limited to, an exclusive license to those patents in the United States and the right to sue for infringement of those patents in the United States. Pursuant to those agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla states that Cipla lacks sufficient knowledge or information to admit or deny the allegations of paragraph 42, and therefore denies them.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

43. On information and belief, Defendants submitted the Cipla ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the

commercial manufacture, use, and sale of Cipla's ANDA Product as a generic version of Xifaxan® 550 mg tablets.

ANSWER: Cipla admits that Cipla submitted Cipla's ANDA to the FDA pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to manufacture, use, and/or sale of Cipla's ANDA Product in the United States. Cipla denies the remaining allegations of paragraph 43.

44. On information and belief, the Cipla ANDA seeks FDA approval of Cipla's ANDA Product for the indication of the treatment of IBS-D in adults.

ANSWER: Admitted.

45. The Notice Letter stated that the Cipla ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding several Xifaxan® patents, including the '571 patent, the '912 patent, and the '196 patent, and that, in Defendants' opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

ANSWER: Cipla admits that Cipla's Notice Letter stated that Cipla's ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding, *inter alia*, the '571 patent, the '912 patent, and the '196 patent and that, in Cipla's opinion, the patents were invalid, unenforceable, and/or would not be infringed by Cipla's ANDA Product.

46. The Notice Letter does not allege non-infringement of the claims of the '571 patent and the '912 patent.

ANSWER: Denied.

47. By not identifying non-infringement defenses for the claims of the '571 patent and '912 patent in the Notice Letter, Defendants admit the ANDA Product meets all limitations of those claims.

ANSWER: Denied.

48. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the '571 patent or the '912 patent.

ANSWER: Denied.

49. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '571 patent and the '912 patent in the Notice Letter, Defendants admit the claims of the '571 patent and the '912 patent are valid under 35 U.S.C. §§ 101, 102, and 112, and are enforceable.

ANSWER: Denied.

50. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 103, or unenforceability of any claims of the '196 patent.

ANSWER: Denied.

51. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 103, or unenforceability defenses for the '196 patent in the Notice Letter, Defendants admit the claims of the '196 patent are valid under 35 U.S.C. §§ 101, 102, and 103, and are enforceable.

ANSWER: Denied.

52. On information and belief, Defendants' statements of the factual and legal bases for its assertions regarding non-infringement and invalidity of the Xifaxan® patents are devoid of an objective good faith basis in either facts or the law. This case is exceptional.

ANSWER: Denied.

53. An actual, real, immediate, and justiciable controversy exists between Salix and Defendants regarding the infringement, validity, and enforceability of the Xifaxan® patents.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that a controversy exists between Salix and Cipla regarding the non-infringement, invalidity, and unenforceability of the Xifaxan® patents.

54. Salix is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Admitted.

COUNT I
(Infringement of the '571 Patent)

55. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

ANSWER: In response to paragraph 55, Cipla repeats and realleges its responses to the allegations of paragraphs 1–54 of the Complaint as if fully set forth herein.

56. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Cipla ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '571 patent, Defendants committed an act of infringement of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

57. The '571 patent claims, inter alia, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits claim 1 of the '571 patent recites: "A method of treating bloating associated with diarrhea-predominant irritable bowel syndrome (dIBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating bloating associated with dIBS in the female subject." Cipla denies any remaining allegations in paragraph 57.

58. Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '571 patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '571 patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

ANSWER: Denied.

59. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of IBS-D in patients, which uses would constitute direct infringement of one or more claims of the '571 patent.

ANSWER: Denied.

60. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

ANSWER: Denied.

61. On information and belief, Defendants' induced infringement of the '571 patent would be willful, intentional, deliberate, and in conscious disregard of Salix's rights under the patent.

ANSWER: Denied.

62. On information and belief, Defendants would actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '571 patent.

ANSWER: Denied.

63. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product prior to the '571 patent's expiry would induce the direct infringement of one or more claims of the '571 patent.

ANSWER: Denied.

64. On information and belief, Defendants' acts would be performed with knowledge of the '571 patent and with intent to encourage infringement prior to the '571 patent's expiry.

ANSWER: Denied.

65. Defendants were aware of the '571 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '571 patent in the Notice Letter.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla's Notice Letter references the '571 patent, and that Cipla was aware of the '571 patent and its listing in the Orange Book when it sent its Notice Letter. Cipla denies the remaining allegations of paragraph 65.

66. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

ANSWER: Denied.

COUNT II
(Infringement of the '912 Patent)

67. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

ANSWER: In response to paragraph 67, Cipla repeats and realleges its responses to the allegations of paragraphs 1–66 of the Complaint as if fully set forth herein.

68. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '912 patent, Defendants committed an act of infringement of the '912 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

69. The '912 patent claims, inter alia, methods of treating irritable bowel syndrome with rifaximin.

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits claim 1 of the '912 patent recites: "A method of treating one or more symptoms of irritable bowel syndrome (IBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating one or more symptoms of IBS in the female subject." Cipla denies any remaining allegations in paragraph 69.

70. Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '912 patent, including any applicable exclusivities or extensions, would infringe one or more claims of the '912 patent under 35 U.S.C. § 271(b) either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the '912 patent.

ANSWER: Denied.

72. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

ANSWER: Denied.

73. On information and belief, Defendants' induced infringement of the '912 patent would be willful, intentional, deliberate, and in conscious disregard of Salix's rights under the patent.

ANSWER: Denied.

74. On information and belief, Defendants will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '912 patent.

ANSWER: Denied.

75. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the '912 patent's expiry will induce the direct infringement of one or more claims of the '912 patent.

ANSWER: Denied.

76. On information and belief, Defendants' acts would be performed with knowledge of the '912 patent and with intent to encourage infringement prior to the '912 patent's expiry.

ANSWER: Denied.

77. Defendants were aware of the existence of the '912 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '912 patent in the Notice Letter.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla's Notice Letter references the '912 patent, and that Cipla was aware of the '912 patent and its listing in the Orange Book when it sent its Notice Letter. Cipla denies the remaining allegations of paragraph 77.

78. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

ANSWER: Denied.

COUNT III
(Infringement of the '196 Patent)

79. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

ANSWER: In response to paragraph 79, Cipla repeats and realleges its responses to the allegations of paragraphs 1–78 of the Complaint as if fully set forth herein.

80. By submitting the Cipla ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '196 patent, Defendants committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

81. The '196 patent claims, inter alia, a composition comprising a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

ANSWER: Denied.

82. On information and belief, Defendants manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product prior to the expiration of the '196 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(a)-(b) either literally or under the doctrine of equivalents.

ANSWER: Denied.

83. On information and belief, Cipla's ANDA Product, if approved by FDA, would be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients, which uses would constitute direct infringement of one or more claims of the '196 patent.

ANSWER: Denied.

84. On information and belief, these directly infringing uses would occur with Defendants' specific intent and encouragement and would be uses that Defendants know or should know will occur.

ANSWER: Denied.

85. On information and belief, Defendants would actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses would contravene Salix's rights under the '196 patent.

ANSWER: Denied.

86. On information and belief, Defendants' direct infringement of the '196 patent would be willful, intentional, deliberate and in conscious disregard of Salix's rights under the patent.

ANSWER: Denied.

87. On information and belief, Defendants know or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the '196 patent's expiry would induce the direct infringement of one or more claims of the '196 patent.

ANSWER: Denied.

88. On information and belief, Defendants' acts would be performed with knowledge of the '196 patent and with intent to encourage infringement prior to the '196 patent's expiry.

ANSWER: Denied.

89. Defendants were aware of the '196 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '196 patent in the Notice Letter.

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that Cipla's Notice Letter references the '196 patent, and that Cipla was aware of the '196 patent and its listing in the Orange Book when it sent its Notice Letter. Cipla denies the remaining allegations of paragraph 89.

90. Salix would be substantially and irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to the relief sought in paragraphs i through viii on pages 17 through 18 of the Complaint. Should Plaintiffs receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 90 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity of the '571 Patent)

Each claim of the '571 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '571 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '571 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '571 patent, either literally or under the doctrine of equivalents.

Third Defense
(Invalidity of the '912 Patent)

Each claim of the '912 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fourth Defense
(Noninfringement of the '912 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '912 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '912 patent, either literally or under the doctrine of equivalents.

Fifth Defense
(Invalidity of the '196 Patent)

Each claim of the '196 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Sixth Defense
(Noninfringement of the '196 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '196 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent, either literally or under the doctrine of equivalents.

Seventh Defense
(Waiver)

Plaintiffs have waived any defect in the manner in which Cipla served Cipla's Notice Letter and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letter.

Eighth Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Ninth Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Tenth Defense
(No Exceptional Case)

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Eleventh Defense
(No Willful Infringement)

Cipla has not willfully infringed any claim of the patents-in-suit.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland Ltd. (collectively, "Plaintiffs" or "Counterclaim Defendants") other than those expressly admitted herein, Defendants Cipla Limited and Cipla USA Inc. (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that U.S. Patent No. 11,564,912 (the "'912 patent"), U.S. Patent No. 11,779,571 (the "'571 patent"), U.S. Patent No. 8,193,196 (the "'196 patent"), and U.S. Patent No. 8,309,569 (the "'569 patent") (collectively, the "Counterclaim Patents") are invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application ("ANDA") No. 219570 ("Cipla's ANDA Product").

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del ’99, 5, 40133 Bologna, Italy.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

7. Upon information and belief, Counterclaim Defendant Salix Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 021361.

8. Upon information and belief, Counterclaim Defendants currently market rifaximin tablets, 550 mg per tablet, under the trade name XIFAXAN pursuant to the U.S. Food and Drug Administration's ("FDA") approval of NDA No. 021361.

9. Upon information and belief, one or more Counterclaim Defendants own the Counterclaim Patents.

The Counterclaim Patents

10. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 9 of the Counterclaims as if fully set forth herein.

11. The Counterclaim Patents are listed in the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for XIFAXAN, 550 mg. On information and belief, one or more Counterclaim Defendants owns the '912 patent, the '571 patent, the '196 patent, and the '569 patent.

12. Based on the allegations in the Complaint, the '196 patent, entitled "Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations," was issued on June 5, 2012. The face of the '196 patent lists Alfa Wassermann, S.p.A. as the assignee. Based on the allegations in the Complaint, AlfaSigma S.p.A. is the successor to Alfa Wassermann S.p.A. by operation of law.

13. On information and belief, the '569 patent, entitled "Methods for treating diarrhea-associated irritable bowel syndrome," was issued on November 13, 2012. The United States Patent and Trademark Office ("USPTO") assignments database indicates Salix Pharmaceuticals, Inc. is

the assignee of the ’569 patent. A true and correct copy of the ’569 patent is attached hereto as Exhibit A.

14. Based on the allegations in the Complaint, the ’912 patent, entitled “Methods for treating irritable bowel syndrome (IBS),” was issued on January 31, 2023. The face of the ’912 patent lists Salix Pharmaceuticals, Inc. as the assignee.

15. Based on the allegations in the Complaint, the ’571 patent, entitled “Methods for treating irritable bowel syndrome (IBS),” was issued on October 10, 2023. The face of the ’571 patent lists Salix Pharmaceuticals, Inc. as the assignee.

16. On September 18, 2024, Cipla sent Cipla’s Notice Letter to Salix Pharmaceuticals, Inc., AlfaSigma S.p.A., and Bausch Health Ireland Ltd., which included, among other things, notification of paragraph IV certification for the ’196 patent, the ’569 patent, the ’912 patent, and the ’571 patent, stating that each of the Counterclaim Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Cipla’s ANDA Product.

17. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla’s Notice Letter included, among other things, Cipla’s detailed factual and legal basis for the paragraph IV certification regarding the Counterclaim Patents as they pertain to Cipla’s ANDA Product and an Offer of Confidential Access to Cipla’s ANDA Product.

18. On November 1, 2024, Counterclaim Defendants initiated this present action alleging infringement of the Asserted Patents.

Jurisdiction and Venue

19. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 18 of the Counterclaims as if fully set forth herein.

20. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), 1367, and 35 U.S.C. § 271(e)(5) based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Cipla in this judicial district.

21. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

22. On November 1, 2024, Counterclaim Defendants filed this civil action in this judicial district against Cipla alleging infringement of the Asserted Patents. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the Counterclaim Patents and/or the invalidity of the Counterclaim Patents.

23. Salix listed each of the Counterclaim Patents in the Orange Book in connection with NDA No. 021361 for XIFAXAN, 550 mg tablets.

24. Cipla has submitted Cipla's ANDA to the FDA seeking approval to manufacture, use, import, offer for sale, and sell Cipla's ANDA Product prior to the expiration of the Counterclaim Patents.

25. Under the Hatch-Waxman Act, Cipla was required to submit patent certifications to each of the Orange Book patents listed for XIFAXAN, 550 mg tablets.

26. Cipla's ANDA contains a paragraph IV certification that, among other things, the '196 patent, the '569 patent, the '912 patent, and the '571 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Cipla's ANDA Product.

27. Counterclaim Defendants did not sue Cipla for patent infringement of the '569 patent, within 45 days of receiving notice of Cipla's paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (j)(5)(C).

28. Because the Counterclaim Defendants did not sue Cipla for infringement of the '569 patent, within 45 days of receiving notice of Cipla's paragraph IV certification, 35 U.S.C. § 271(e)(5) provides that Cipla can seek a declaratory judgment that the '569 patent is invalid and/or will not be infringed by Cipla's ANDA Product.

First Counterclaim
(Declaratory Judgment of Noninfringement of the '571 Patent)

29. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 28 of the Counterclaims as if fully set forth herein.

30. Counterclaim Defendants have accused Cipla of infringing the '571 patent.

31. Cipla denies infringement of the '571 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '571 patent.

32. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '571 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

33. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '571 patent.

34. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '571 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the '571 Patent)

35. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 34 of the Counterclaims as if fully set forth herein.

36. The claims of the '571 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

37. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '571 patent are not infringed by Cipla's ANDA Product and/or are invalid.

38. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '571 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

39. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '571 patent.

40. Cipla is entitled to a judicial declaration that all claims of the '571 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Third Counterclaim
(Declaratory Judgment of Noninfringement of the '912 Patent)

41. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 40 of the Counterclaims as if fully set forth herein.

42. Counterclaim Defendants have accused Cipla of infringing the '912 patent.

43. Cipla denies infringement of the '912 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '912 patent.

44. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '912 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

45. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '912 patent.

46. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '912 patent.

Fourth Counterclaim
(Declaratory Judgment of Invalidity of the '912 Patent)

47. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 46 of the Counterclaims as if fully set forth herein.

48. The claims of the '912 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

49. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '912 patent are not infringed by Cipla's ANDA Product and/or are invalid.

50. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '912 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

51. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '912 patent.

52. Cipla is entitled to a judicial declaration that all claims of the '912 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fifth Counterclaim
(Declaratory Judgment of Noninfringement of the '196 Patent)

53. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 52 of the Counterclaims as if fully set forth herein.

54. Counterclaim Defendants have accused Cipla of infringing the '196 patent. Cipla denies infringement of the '196 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '196 patent.

55. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '196 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

56. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '196 patent.

57. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '196 patent.

Sixth Counterclaim
(Declaratory Judgment of Invalidity of the '196 Patent)

58. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 57 of the Counterclaims as if fully set forth herein.

59. The claims of the '196 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not

limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

60. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '196 patent are not infringed by Cipla's ANDA Product and/or are invalid.

61. Upon information and belief, Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '196 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

62. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '196 patent.

63. Cipla is entitled to a judicial declaration that all claims of the '196 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Seventh Counterclaim
(Declaratory Judgment of Noninfringement of the '569 Patent)

64. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 63 of the Counterclaims as if fully set forth herein.

65. Counterclaim Defendants caused the '569 patent to be listed in the Orange Book in connection with XIFAXAN, 550 mg tablets.

66. Cipla alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '569 patent.

67. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid claim of the '569 patent.

68. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '569 patent.

Eighth Counterclaim
(Declaratory Judgment of Invalidity of the '569 Patent)

69. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 68 of the Counterclaims as if fully set forth herein.

70. Counterclaim Defendants caused the '569 patent to be listed in the Orange Book in connection with XIFAXAN, 550 mg tablets.

71. The claims of the '569 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

72. For at least the reasons stated in Cipla's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '569 patent are not infringed by Cipla's ANDA Product and/or are invalid.

73. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '569 patent.

74. Cipla is entitled to a judicial declaration that all claims of the '569 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not and will not directly or indirectly infringe any claim of the Counterclaim Patents, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Counterclaim Patents are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the Counterclaim Patents against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: January 16, 2025

Respectfully submitted,

K&L GATES LLP

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Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Ltd. and Cipla USA, Inc.

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action involves a request for injunctive relief and therefore is not appropriate for compulsory arbitration.

Dated: January 16, 2025

s/ *Loly G. Tor*

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Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Ltd. and Cipla USA, Inc.

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

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LIMITED, Defendants.	Civil Action No. 1:24–CV-10213 **CERTIFICATE OF SERVICE** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate Defenses, and Counterclaims to the Complaint, and this certificate of service to be served upon all counsel of record by CM/ECF and e-mail.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: January 16, 2025

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