IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., FOLDRX PHARMACEUTICALS, LLC, PF PRISM IMB B.V. AND WYETH LLC, Plaintiffs, v. CIPLA LIMITED, Defendant.	C.A. No. 23-909-GBW

DEFENDANT CIPLA LIMITEDS' ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant Cipla Limited ("Cipla"), by its undersigned attorneys, hereby answers the Complaint (D.I. 1) ("Complaint) brought by Plaintiffs Pfizer Inc., FoldRx Pharmaceuticals, LLC, PF PRISM IMB B.V., and Wyeth LLC ("Plaintiffs") concerning U.S. Patent No. 9,770,441 ("the '441 patent").

GENERAL DENIAL

Cipla denies all allegations in Plaintiffs' Complaint except those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Cipla's own acts, and upon information and belief as to other matters, Cipla responds and alleges as follows:

NATURE OF THE CASE

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for 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 Cipla's 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 a generic version of Vyndamax® (tafamidis) 61 mg capsules prior to the expiration of U.S. Patent No. 9,770,441 ("the '441 patent") (attached as Exhibit A).

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent that a response is required, Cipla admits that the above-captioned action purports to be an action for patent infringement arising under the Food and Drug Laws and the U.S. Patent Laws. Cipla denies any remaining allegations contained in Paragraph 1.

2. Cipla notified Pfizer by letter dated July 7, 2023 ("Cipla's Notice Letter") that it has submitted to the FDA ANDA No. 218409 ("Cipla's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic tafamidis 61 mg capsules ("Cipla's ANDA Product") prior to the expiration of the '441 patent.

ANSWER: Cipla admits that it served on Pfizer a notice letter ("Cipla's Notice Letter") dated July 7, 2023. Cipla further admits that it filed ANDA No. 218409 with FDA for purposes of the matters stated therein. Cipla denies any remaining allegations contained in Paragraph 2.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3, and therefore denies them.

4. Plaintiff FoldRx Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 66 Hudson Boulevard East, New York, NY 10001. FoldRx Pharmaceuticals, LLC is the holder of New Drug Application ("NDA") No. 212161 for the manufacture and sale of tafamidis 61 mg capsules, which has been approved by the FDA. FoldRx Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4, and therefore denies them.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Cepelle aan den IJessel, the Netherlands.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5, and therefore denies them.

6. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6, and therefore denies them.

7. Upon information and belief, defendant Cipla is a corporation organized and existing under the laws of India, with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

ANSWER: Admitted.

8. Upon information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's ANDA Product throughout the United States, including in Delaware.

ANSWER: Cipla admits that it filed ANDA No. 218409 with FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis, 61 mg. Cipla denies any remaining allegations in Paragraph 8.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits only that, insofar as this action is properly brought, this Court has subject matter to adjudicate this claim. Cipla denies any remaining allegations contained in Paragraph 9.

10. Cipla is subject to personal jurisdiction in Delaware because, among other things, Cipla has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Cipla, itself and through its agents develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore

transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in continuous and systematic business contacts within the State of Delaware.

ANSWER: Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction or venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 10.

11. Upon information and belief, if Cipla's ANDA is approved, Cipla will directly or indirectly manufacture, market, sell, and/or distribute Cipla's ANDA Product within the United States, including in Delaware, consistent with Cipla's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Cipla regularly does business in Delaware, and its practices with other generic products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Cipla's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Cipla's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of the activities would have a substantial effect within Delaware and would constitute infringement of the '441 patent in the event that Cipla's ANDA Product is approved before the '441 patent expires.

ANSWER: Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction or venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 11.

12. Upon information and belief, Cipla derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Cipla and/or for which Cipla is the named applicant on approved ANDAs. Upon information and belief, various products for which Cipla is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction or venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 12.

13. Alternatively, the Court may exercise personal jurisdiction over Cipla pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Cipla would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Cipla has sufficient contacts with the United States as a whole, including but not limited to filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that the Court's exercise of jurisdiction over Cipla satisfies due process.

ANSWER: Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction or venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 13.

14. Venue is proper in this district as to Cipla pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Cipla does not contest personal jurisdiction or venue in this case for the purposes of this action only. Cipla denies any remaining allegations contained in Paragraph 14.

FACTUAL BACKGROUND

15. Plaintiff FoldRx Pharmaceuticals, LLC is the holder of New Drug Application No. 212161 for Vyndamax®, which has been approved by the FDA.

ANSWER: Upon information and belief, Cipla admits that according to information provided by the FDA on its website, "FoldRx Pharmaceuticals, LLC" is listed as the holder for NDA No. 212161 for tafamidis, marketed under the trade name Vyndamax®. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 15, and therefore denies them.

16. Vyndamax® is approved for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

ANSWER: Admitted.

17. Vyndamax® contains tafamidis as its active ingredient.

ANSWER: Admitted.

18. Cipla's ANDA Product is a generic version of Vyndamax®.

ANSWER: Cipla admits that it filed ANDA No. 218409 with FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis, 61 mg. Cipla denies any remaining allegations in paragraph 18.

19. Cipla's Notice Letter purported to include an "Offer of Confidential Access" to Plaintiffs to portions Cipla's ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

ANSWER: Cipla admits that Plaintiffs rejected the terms and conditions in Cipla's Offer of Confidential Access and that Plaintiffs failed to accept Cipla's reasonable restrictions. Cipla denies any remaining allegations contained in Paragraph 19.

20. On July 26, 2023, counsel for Plaintiffs sent a letter to counsel for Cipla attempting to negotiate access to Cipla's internal documents, data, and/or samples relevant to infringement based on reasonable confidentiality terms. Counsel for Cipla did not accept Plaintiffs' proposal.

ANSWER: Cipla admits that Plaintiffs responded to Cipla's reasonably restrictive Offer of Confidential Access and that Cipla denied Plaintiffs' unreasonably lax proposal. Cipla denies any remaining allegations contained in Paragraph 20.

21. Plaintiffs are filing this Complaint within forty-five days of receipt of Cipla's Notice Letter.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21, and therefore denies them.

CLAIMS FOR RELIEF

COUNT I – INFRINGEMENT OF THE '441 PATENT

22. Plaintiffs incorporate each of the preceding paragraphs 1–21 as if fully set forth herein.

ANSWER: Cipla restates and incorporates its responses to Paragraphs 1-21 as if fully set forth herein.

23. The '441 patent, titled "CRYSTALLINE SOLID FORMS OF 6-CARBOXY-2(3,5-DICHLOROPHENYL)-BENZOXAZOLE", was duly and legally issued on September 26, 2017.

ANSWER: Cipla admits that, on its fact, the '441 patent titled "Crystalline Solid Forms of 6-Carboxy-2(3,5-dichlorophenyl)-benzoxazole," issued on September 26, 2017. Cipla denies any remaining allegations contained in Paragraph 23.

24. The inventors named on the '441 patent are Kevin Paul Girard, Andrew J. Jensen, and Kris Nicole Jones.

ANSWER: Cipla admits that, on its face, the '441 patent names Kevin Paul Girard, Andrew J. Jensen, and Kris Nicole Jones as inventors. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 24, and therefore denies them.

25. Pfizer Inc. is the assignee of the '441 patent.

ANSWER: Cipla admits that, on its face, the '441 patent lists Pfizer Inc. as the assignee. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 25, and therefore denies them.

26. Plaintiffs together own all substantial rights in the '441 patent.

ANSWER: Cipla lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26, and therefore denies them.

27. Vyndamax® and its use are covered by one or more of claims 1–16 of the '441 patent, and the '441 patent has been listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Vyndamax®.

ANSWER: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that according to information provided by FDA on its website, the '441 patent is listed in the Orange Book for NDA No. 212161 for Vyndamax®. Cipla denies any remaining allegations in Paragraph 27.

28. For example, claim 1 of the '441 patent recites:

> A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
> a solid state NMR spectrum comprising 13C chemical shifts (ppm) at 120.8±0.2 and 127.7±0.2,powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
> a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

ANSWER: Cipla admits that, on its face, the '441 patent recites claim 1 as set forth in Paragraph 28. Cipla denies any remaining allegations in Paragraph 28.

29. In Cipla's Notice Letter, Cipla notified Plaintiffs of the submission of Cipla's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Cipla's ANDA Product prior to the expiration of the '441 patent.

ANSWER: Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Cipla states that it submitted Cipla's Notice Letter in accord with its obligations under the laws and regulations of the United States and FDA, e.g., 21 C.F.R. § 314.95.

30. In Cipla's Notice Letter, Cipla also notified Plaintiffs that, as part of its ANDA, Cipla had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '441 patent. Cipla submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '441 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

ANSWER: Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that the claims of the '441 patent are invalid, unenforceable, and/or or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product. Cipla denies any remaining allegations in Paragraph 30.

31. Upon information and belief, Cipla's ANDA Product and the use of Cipla's ANDA Product (including in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product) are covered by one or more of claims 1–16 of the '441 patent.

ANSWER: Denied.

32. For example, claim 1 of the '441 patent recites:

> A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)- benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
> a solid state NMR spectrum comprising 13C chemical shifts (ppm) at 120.8±0.2 and 127.7±0.2,
> a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
> a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

ANSWER: Cipla admits that, on its face, the '441 patent recites claim 1 as set forth in Paragraph 32. Cipla denies any remaining allegations in Paragraph 32.

33. In Cipla's Notice Letter, Cipla states that its ANDA Product contains tafamidis, i.e., 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

ANSWER: Admitted.

34. Upon information and belief, the proposed labeling for Cipla's ANDA Product directs and encourages a method of treating a transthyretin amyloid disease, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy using Cipla's ANDA Product.

ANSWER: Denied.

35. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product before the expiration of the '441 patent was an act of infringement of the '441 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits that it seeks approval from FDA to sell Cipla's ANDA Product in the United States before the expiration of the '441 patent. Cipla denies any remaining allegations in Paragraph 35, and specifically denies that the submission of its ANDA is an act of infringement.

36. Upon information and belief, Cipla will engage, directly or indirectly, in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon approval of Cipla's ANDA.

ANSWER: Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Cipla denies the allegations contained in Paragraph 36.

37. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product would infringe one or more of claims 1–16 of the '441 patent.

ANSWER: Denied.

38. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more of claims 1–16 of the '441 patent.

ANSWER: Denied.

39. Upon information and belief, Cipla plans and intends to, and will, actively induce infringement of the '441 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Cipla's activities will be done with knowledge of the '441 patent and specific intent to infringe that patent.

ANSWER: Denied.

40. Upon information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '441 patent, that Cipla's ANDA Product is not a staple article or commodity of commerce, and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to infringement of the '441 patent immediately and imminently upon approval of Cipla's ANDA.

ANSWER: Denied.

41. Notwithstanding Cipla's knowledge of the claims of the '441 patent, Cipla has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Cipla's ANDA Product with their product labeling following FDA approval of Cipla's ANDA prior to the expiration of the '441 patent.

ANSWER: Cipla admits that it intends to sell Cipla's ANDA Product in the United States upon FDA approval and prior to the expiration of the '441 patent. Cipla denies any remaining allegations in Paragraph 41.

42. The foregoing actions by Cipla constitute and/or will constitute infringement of the '441 patent; active inducement of infringement of the '441 patent; and contribution to the infringement by others of the '441 patent.

ANSWER: Denied.

43. Upon information and belief, Cipla has acted with full knowledge of the '441 patent and without a reasonable basis for believing that it would not be liable for infringement of the '441 patent; active inducement of infringement of the '441 patent; and/or contribution to the infringement by others of the '441 patent.

ANSWER: Denied.

44. Plaintiffs will be substantially and irreparably damaged by infringement of the '441 patent.

ANSWER: Denied.

45. Unless Cipla is enjoined from infringing the '441 patent, actively inducing infringement of the '441 patent, and contributing to the infringement by other of the '441 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '441 PATENT

46. Plaintiffs incorporate by reference each of the preceding paragraphs 1–45 as if fully set forth herein.

ANSWER: Cipla restates and incorporates its responses to Paragraphs 1-45 as if fully set forth herein.

47. The Court may declare the rights and legal relations of the parties pursuant to

28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Cipla on the other regarding Cipla's infringement, active inducement of infringement, and contribution to the infringement by others of the '441 patent, and/or the validity of the '441 patent.

ANSWER: Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits the above-captioned action purports to be an action for patent infringement arising under the Food and Drug Laws and the U.S. Patent Laws. Cipla denied any remaining allegations contained in Paragraph 47.

48. An actual case or controversy exists between Plaintiffs and Cipla with respect to Cipla's liability for infringement of the '441 patent.

ANSWER: Paragraph 48 contains legal conclusions to which no response is required. To the extent a response is required, Cipla admits only that, insofar as this action is properly brought, this Court has subject matter jurisdiction to adjudicate this action. Cipla denies any remaining allegations contained in Paragraph 48.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Cipla's ANDA Product will infringe, induce infringement, and actively contribute to the infringement of the '441 patent.

ANSWER: Denied.

PRAYER FOR RELIEF

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

ADDITIONAL AND OTHER DEFENSES

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

FIRST DEFENSE

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

SECOND DEFENSE

Cipla has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '441 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '441 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

THIRD DEFENSE

Each claim of the '441 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FOURTH DEFENSE

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

FIFTH DEFENSE

Cipla has not intentionally, willfully, or deliberately infringed any valid claim of the '441 patent.

SIXTH DEFENSE

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

SEVENTH DEFENSE

Plaintiffs' infringement claims against Cipla regarding the '441 patent are barred and the '441 patent is unenforceable against Cipla under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF DEFENSES

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

DEFENDANT'S RESPONSE TO PRAYER FOR RELIEF

Cipla respectfully requests that the Court enter judgment in its favor and against Plaintiffs as follows:

A. Dismissing the Complaint with prejudice, denying each and every request for relief in Items (a) through (g) of Plaintiffs' Prayer for Relief, and that Plaintiffs take nothing thereby;

B. Finding that each and every claim of the '441 patent is invalid;

C. Finding that each and every claim of the '441 patent was not, is not, and will not be infringed by Cipla;

D. Declaring that Plaintiffs are not entitled to any injunctive remedy for the '441 patent;

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

F. Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding to Cipla its reasonable attorneys fees; and

G. Awarding to Cipla such further relief as this Court may deem just, proper, or equitable.

Dated: September 25, 2023

SMITH, KATZENSTEIN & JENKINS, LLP

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(*Pro hac vice* applications forthcoming)