IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACERTA PHARMA B.V., ASTRAZENECA UK LIMITED, ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA AB, Plaintiffs, v. CIPLA LIMITED and CIPLA USA, INC., Defendants.	C.A. No. 24-cv-587-GBW

ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants Cipla Limited and Cipla USA, Inc. ("Cipla USA") (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs Acerta Pharma B.V. ("Acerta"), AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca AB (collectively, "AstraZeneca") (collectively, "Plaintiffs") as follows:

COMPLAINT

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., which arises out of the submission by Cipla of Abbreviated New Drug New Drug Application ("ANDA") No. 219228 ("Cipla's Tablet 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 CALQUENCE® (acalabrutinib maleate) 100 mg base equivalent oral tablets prior to the expiration of U.S. Patent No. 10,272,083 ("the '083 patent") and U.S. Patent No. 11,059,829 ("the '829 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

ANSWER: Cipla admits that the Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. §§ 100, et seq. Cipla further admits that the Complaint alleges that this action arises out of Cipla's filing of Abbreviated New Drug Application ("ANDA") No.

219228 ("Cipla's Tablet ANDA"). Cipla admits that Cipla filed Cipla's Tablet ANDA with the United States Food and Drug Administration (the "FDA"), and that Cipla's Tablet ANDA seeks approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or import of the product described in Cipla's Tablet ANDA ("Cipla's Tablet ANDA Product") prior to the expiration dates listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for U.S. Patent No. 10,272,083 (the "'083 patent") and U.S. Patent No. 11,059,829 (the "'829 patent") (collectively, the "Patents-in-Suit"). Cipla denies the remaining allegations in paragraph 1 of the complaint.

PARTIES

2. Plaintiff Acerta Pharma B.V. is a private limited liability company organized and exiting under the laws of the Netherlands, having its principal place of business at Kloosterstraat 9, 5349 AB Oss, The Netherlands.

ANSWER: On information and belief, Cipla admits that Acerta Pharma B.V. maintains an address at Kloosterstraat 9, 5349 AB Oss, The Netherlands. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations of paragraph 2 and therefore denies them.

3. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, having its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom. AstraZeneca UK Limited is the holder of New Drug Application No. 216387 for the manufacture and sale of CALQUENCE® (acalabrutinib maleate) 100 mg base equivalent oral tablets ("CALQUENCE® Tablets") which has been approved by the FDA.

ANSWER: Cipla admits that the Orange Book lists AstraZeneca UK Limited as the New Drug Application ("NDA") holder for NDA No. 216387 for CALQUENCE® Tablets. Cipla further admits that CALQUENCE Tablets have been approved by the FDA. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the state of Delaware, having its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, Delaware, 19850.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

5. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

8. On information and belief, Cipla USA, Inc. is an indirect, wholly-owned subsidiary of Cipla Limited and is controlled and/or dominated by Cipla Limited.

ANSWER: Cipla admits that Cipla USA is an indirect, wholly owned subsidiary of Cipla Limited. Cipla denies the remaining allegations of paragraph 8.

9. By letter dated April 24, 2024 ("Cipla's Tablet Notice Letter"), Cipla informed Plaintiffs that Cipla USA, Inc. is "U.S. Agent for Cipla Limited." On information and belief, Cipla Limited and Cipla USA, Inc. acted in concert to prepare and submit Cipla's Tablet ANDA to the FDA.

ANSWER: Cipla admits that Cipla USA, Inc. is Cipla Limited's U.S. agent with respect to Cipla's Tablet ANDA. Cipla denies the remaining allegations of paragraph 9.

10. On information and belief, Cipla Limited and Cipla USA, Inc. know and intend that upon approval of Cipla's Tablet ANDA, Cipla Limited will manufacture Cipla's Tablet ANDA Products and Cipla Limited and Cipla USA, Inc. will directly or indirectly market, sell, and distribute Cipla's Tablet ANDA Products throughout the United States, including in Delaware.

ANSWER: Cipla admits that Cipla Limited prepared and submitted Cipla's Tablet ANDA, seeking approval from the FDA to market and sell Cipla's Tablet ANDA Product in the United States. Cipla denies the remaining allegations in paragraph 10 of the Complaint.

11. On information and belief, following any FDA approval of Cipla's Tablet ANDA, Cipla Limited and Cipla USA, Inc. will act in concert to distribute and sell Cipla's Tablet ANDA Products throughout the United States, including within Delaware.

ANSWER: Cipla admits that Cipla Limited prepared and submitted Cipla's Tablet ANDA seeking approval from the FDA to market and sell Cipla's Tablet ANDA Product in the United States. Cipla denies the remaining allegations in paragraph 11 of the Complaint.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as fully set forth herein.

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

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest subject matter jurisdiction over the Patents-in-Suit for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 13.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla does not contest personal jurisdiction in this Court for the limited purposes of this litigation. Cipla denies the remaining allegations of paragraph 14.

15. Cipla Limited is subject to personal jurisdiction in Delaware because, among other things, Cipla Limited, itself and through its wholly-owned subsidiary Cipla USA, Inc., has purposefully availed itself of the benefits and protections of Delaware'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, Inc, 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 systematic and continuous business contacts within the State of Delaware. In addition, Cipla Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Cipla USA, Inc. and therefore the activities of Cipla USA, Inc. in this jurisdiction are attributed to Cipla Limited.

ANSWER: Paragraph 15 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 for the limited purposes of this litigation, and admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations of paragraph 15.

16. Cipla USA, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Cipla USA, Inc. 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 systematic and continuous business contact within the State of Delaware.

ANSWER: Paragraph 16 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 USA, Inc. for the limited purposes of this litigation. Cipla further admits that Cipla USA,

Inc. is a corporation organized and existing under the laws of the State of Delaware, and that Cipla USA, Inc. is in the business of marketing, importing, and selling pharmaceutical drug products, including generic drug products, in the United States. Cipla denies the remaining allegations of paragraph 16.

17. In addition, this Court has personal jurisdiction over Cipla because, among other things, on information and belief: (1) Cipla filed Cipla's Tablet ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's Tablet ANDA Product in the United States, including in Delaware; and (2) upon approval of Cipla's tablet ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla's Tablet ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Cipla's Tablet ANDA Product in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's Tablet ANDA, Cipla's Tablet ANDA Products will, among other things, be marketed distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

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 or Cipla USA, Inc. for the limited purposes of this litigation. Cipla further admits that Cipla Limited prepared and submitted Cipla's Tablet ANDA seeking approval from the FDA to market and sell Cipla's Tablet ANDA Product in the United States. Cipla denies the remaining allegations of paragraph 17.

18. In addition, this Court has personal jurisdiction over Cipla because Cipla Limited and Cipla USA, Inc. regularly (1) engage in patent litigation concerning Cipla's ANDA products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Onyx Therapeutics, Inc. v. Cipla Limited & Cipla USA, Inc.*, 1:16-cv-00988 (D. Del. Feb. 15, 2019).

ANSWER: Paragraph 18 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 or Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited and/or Cipla USA, Inc. were named Defendants in *Onyx Therapeutics,*

Inc. v. Cipla Limited & Cipla USA, Inc., 1:16-cv-00988 (D. Del. Feb. 15, 2019). Cipla further admits that Cipla USA, Inc. asserted counterclaims in *Onyx Therapeutics, Inc. v. Cipla Limited & Cipla USA Inc.*, 1:16-cv-00988 (D. Del. Feb. 15, 2019). Cipla denies the remaining allegations of paragraph 18.

19. For the above reasons, it would not be unfair or unreasonable for Cipla to litigate this action in this District, and the Court has personal jurisdiction over it here.

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 or Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla denies the remaining allegations of paragraph 19.

VENUE

20. Plaintiffs incorporate each of the preceding paragraphs 1–19 as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as fully set forth herein.

21. Venue is proper in this District under 28 U.S.C. § 1391 with respect to Cipla Limited, at least because, on information and belief, Cipla Limited is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla Limited is a foreign corporation. Cipla denies the remaining allegations of paragraph 21.

22. Venue is proper in this district as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware and thus "resides" in this judicial district. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258, 262 (2017).

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware. Cipla denies the remaining allegations of paragraph 22.

FACTUAL BACKGROUND

23. CALQUENCE® Tablets, which contains acalabrutinib maleate as their active ingredient, are indicated for the treatment of adult patients with mantle cell lymphoma ("MCL") who have received at least one prior therapy, and as a first-line treatment for chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL").

ANSWER: Admitted.

24. On information and belief, Cipla's Tablet ANDA Product is a generic version of CALQUENCE® Tablets.

ANSWER: Admitted.

25. In Cipla's Tablet Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '083 patent and the '829 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's Tablet ANDA Product prior to the expiration of those patents. According to Cipla's Tablet Notice Letter, Cipla's Tablet ANDA contains a Paragraph IV Certification asserting that the '083 patent and the '829 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's Tablet ANDA Products, and/or that those patents are invalid and/or unenforceable.

ANSWER: Cipla admits that, in its Tablet Notice Letter, Cipla notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '083 patent and the '829 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's Tablet ANDA Product prior to the expiration of those patents. Cipla further admits that Cipla's Tablet ANDA contains a Paragraph IV Certification asserting that the '083 patent and the '829 patent are invalid, unenforceable, and/or will not be infringed by the

manufacture, use or sale of Cipla's Tablet ANDA Product. Cipla denies the remaining allegations of paragraph 25.

26. The purpose of Cipla's submission of Cipla's Tablet ANDA was 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 Tablet ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Cipla admits that the purpose of Cipla's submission of Cipla's Tablet ANDA was 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 Tablet ANDA Product prior to the expiration of the '083 patent and the '829 patent. Cipla denies the remaining allegations of paragraph 26.

27. In Cipla's Tablet Notice Letter, Cipla stated that the subject of Cipla's Tablet ANDA is for an acalabrutinib maleate tablet, 100 mg base equivalent.

ANSWER: Admitted.

28. This action is being commenced before the expiration forty-five days from the date of receipt of Cipla's Tablet Notice Letter.

ANSWER: Admitted.

COUNT I – INFRINGEMENT OF THE '083 PATENT UNDER 35 U.S.C. § 271(e)(2)

29. Plaintiffs incorporate each of the preceding paragraphs 1–28 as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as if fully set forth herein.

30. The '083 patent, entitled, "Methods of Treating Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia Using a BTK Inhibitor" (attached as Exhibit A), was duly and legally issued on April 30, 2019.

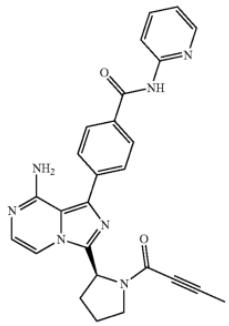
ANSWER: Cipla admits that what purports to be a copy of the '083 patent is attached as Exhibit A to the Complaint. Cipla admits that the '083 patent is entitled "Methods of Treating

Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia using a BTK Inhibitor" and lists April 30, 2019 as an issue date. Cipla denies the remaining allegations in paragraph 30.

31. Acerta Pharma B.V. is the owner and assignee of the '083 patent. AstraZeneca has all rights, title and interest in the '083 patent.

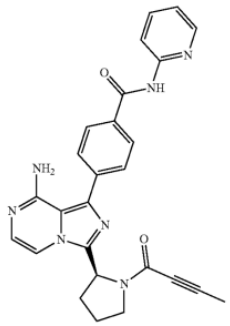
ANSWER: Cipla admits that the U.S. Patent and Trademark Office lists Acerta Pharma B.V. as the assignee of the '083 Patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 31 and therefore denies them.

32. The '083 patent claims, *inter alia*, a method of treating chronic lymphocytic leukemia (CLL), small lymphocytic leukemia (SLL), or mantle cell lymphoma (MCL) in a human subject suffering therefrom comprising the step of orally administering, to the human subject, a dose of 100 mg twice daily of a Bruton's tyrosine kinase (BTK) inhibitor, wherein the BTK inhibitor is a compound of Formula (II)

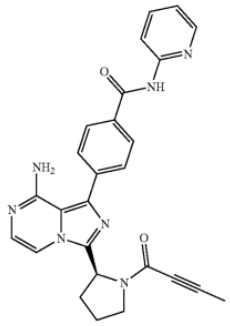


or a pharmaceutically acceptable salt, hydrate, or solvate thereof, as recited in claim 1 and claim 8 of the '083 patent.

ANSWER: Cipla admits that claim 1 of the '083 patent recites "[a] method of treating chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) in a human subject suffering therefrom, comprising the step of orally administering, to the human subject, a dose of 100 mg twice daily of a Bruton's tyrosine kinase (BTK) inhibitor, where in the BTK inhibitor is compound of Formula (II):



or a pharmaceutically acceptable salt, solvate, or hydrate thereof." Cipla admits claim 8 of the '083 patent recites "[a] method of treating mantle cell lymphoma (MCL) in a human subject suffering therefrom comprising the step of orally administering, to the human subject, a dose of 100 mg twice daily of a BTK inhibitor, where the BTK inhibitor is a compound of Formula (II):



or a pharmaceutically acceptable salt thereof." Cipla denies the remaining allegations of paragraph 32.

33. CALQUENCE® Tablets, as well as methods of using CALQUENCE ® Tablets, are covered by one or more of the claims of the '083 patent, including claims 1 and 8 of the '083 patent, and the '083 patent has been listed in connection with CALQUENCE ® Tablets in the FDA's Orange Book.

ANSWER: Cipla admits that the '083 patent is listed in connection with CALQUENCE in the FDA's Orange Book. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 33 and therefore denies them.

34. Cipla's submission of Cipla's Tablet ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's

Tablet ANDA Product prior to the expiration of the '083 patent was an act of infringement of the '083 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

35. In Cipla's Tablet Notice Letter, Cipla did not contest the infringement of at least claim 8 of the '083 patent on any basis other than the alleged invalidity of that claim.

ANSWER: Denied.

36. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's Tablet ANDA Product would infringe at least claim 8 of the '083 patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

37. On information and belief, Cipla has not challenged U.S. Patent No. 7,459,554, which is listed in connection with CALQUENCE® Tablets in the FDA's Orange Book and expires on November 24, 2026. On information and belief, Cipla has not challenged U.S. Patent No. 9,290,504, U.S. Patent No. 9,758,524, and U.S. Patent No. 10,239,883, which are listed in connection with CALQUENCE® Tablets in the FDA's Orange Book and expire on July 11, 2032. On information and belief, following the expiration of those patents, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's Tablet ANDA Product immediately and imminently upon FDA Approval of Cipla's Tablet ANDA.

ANSWER: Cipla admits that U.S. Patent No. 7,459,554 (the "'554 patent") is listed in connection with CALQUENCE Tablets in the FDA's Orange Book, and that the Orange Book lists the expiration date of the '554 patent as November 24, 2026. Cipla admits U.S. Patent No. 9,290,504 (the "'504 patent"), U.S. Patent No. 9,758,524 (the "'524 patent"), and U.S. Patent No. 10,239,883 (the "'883 patent") are listed in connection with CALQUENCE Tablets in the FDA's Orange Book, and that the Orange Book lists the expiration date of the '504 patent, the '524 patent, and the '883 patent as July 11, 2032. Cipla has certified to the FDA that Cipla's Tablet ANDA Product will not be made available for sale until after the expiration of the '554 patent, the '504 patent, the '524 patent, and the '883 patent. Cipla denies the remaining allegations in paragraph 37.

38. On information and belief, the use of Cipla's Tablet ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 8 of the '083 patent.

ANSWER: Denied.

39. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '083 patent when Cipla's Tablet ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

40. On information and belief, Cipla knows that Cipla's Tablet ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '083 patent and that Cipla's Tablet ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '083 patent after approval of Cipla's Tablet ANDA.

ANSWER: Denied.

41. The foregoing actions by Cipla constitute and/or will constitute infringement of the '083 patent, active inducement of infringement of the '083 patent, and contribution to the infringement by others of the '083 patent.

ANSWER: Denied.

42. On information and belief, Cipla has acted with full knowledge of the '083 patent and without a reasonable basis for believing that it would not be liable for infringing the '083 patent, actively inducing infringement of the '083 patent, and contributing to the infringement by others of the '083 patent.

ANSWER: Denied.

43. Unless Cipla is enjoined from infringing the '083 patent, actively inducing infringement of the '083 patent, and contributing to the infringement by others of the '083 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '083 PATENT

44. Plaintiffs incorporate each of the preceding paragraphs 1–43 as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as if fully set forth herein.

45. 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 or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding Cipla's infringement, active inducement of infringement, and contribution to the infringement by others of the '083 patent.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations in paragraph 45.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's Tablet ANDA Product with its proposed labeling, or any other Cipla acalabrutinib maleate tablet drug product that is covered by or whose use is covered by the '083 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '083 patent, and that claims of the '083 patent are valid.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations in paragraph 46.

COUNT III – INFRINGEMENT OF THE '829 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as if fully set forth herein.

48. The '829 patent, entitled, "Crystal Forms of (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridine-2-yl)benzamide" (attached as Exhibit B), was duly and legally issued on July 13, 2021.

ANSWER: Cipla admits that what purports to be a copy of the '829 Patent is attached as Exhibit B to the Complaint. Cipla admits that the '829 patent is entitled "Crystal Forms of (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridine-2-yl)benzamide maleate" and lists July 13, 2021 as an issue date. Cipla denies the remaining allegations in paragraph 48.

49. Acerta Pharma B.V.is the owner and assignee of the ’829 patent. AstraZeneca has all rights, title, and interest in the ’829 patent.

ANSWER: Cipla admits that the U.S. Patent and Trademark Office assignment database lists Acerta Pharma B.V. as the assignee of the ’829 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 49 and therefore denies them.

50. The ’829 patent claims, *inter alia*, a crystal form of (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridine-2-yl)benzamide maleate characterized by an X-ray powder diffraction pattern comprising certain peaks as recited in claim 1 of the ’829 patent.

ANSWER: Cipla admits that claim 1 of the ’829 patent recites “[a] crystal form of (S)-4-(8-amino-3-(1-(but-2-ynoyl)pyrrolidine-2-yl)imidazo[1,5-alpyrazin-1-yl)-N-9pyridin-2-yl)benzamide maleate, or hydrate thereof, characterized by a reflection X-ray powder diffraction pattern comprising at least five peaks selected from the group consisting of 5.3°±0.2° 2θ, 9.8°±0.2° 2θ, 10.6°±0.2° 2θ, 11.6°±0.2° 2θ, 13.5°±0.2° 2θ, 13.8°±0.2° 2θ, 13.9°±0.2° 2θ, 14.3°±0.2° 2θ, 15.3°±0.2° 2θ, 15.6°±0.2° 2θ, 15.8°±0.2° 2θ, 15.9°±0.2° 2θ, 16.6°±0.2° 2θ, 17.4°±0.2° 2θ, 17.5°±0.2° 2θ, 18.7°±0.2° 2θ, 19.3°±0.2° 2θ, 19.6°±0.2° 2θ, 19.8°±0.2° 2θ, 20.0°±0.2° 2θ, 20.9°±0.2° 2θ, 21.3°±0.2° 2θ, 22.1°±0.2° 2θ, 22.3°±0.2° 2θ, 22.7°±0.2° 2θ, 23.2°±0.2° 2θ, 23.4°±0.2° 2θ, 23.7°±0.2° 2θ, 23.9°±0.2° 2θ, 24.5°±0.2° 2θ, 24.8°±0.2° 2θ, 25.2°±0.2° 2θ, 25.6°±0.2° 2θ, 26.1°±0.2° 2θ, 26.4°±0.2° 2θ, 26.7°±0.2° 2θ, 26.9°±0.2° 2θ, 27.1°±0.2° 2θ, 27.6°±0.2° 2θ, 28.8°±0.2° 2θ, 29.5°±0.2° 2θ, 30.0°±0.2° 2θ, 30.3°±0.2° 2θ, 30.9°±0.2° 2θ, 31.5°±0.2° 2θ, 31.9°±0.2° 2θ, 32.5°±0.2° 2θ, 34.0°±0.2° 2θ, and 35.1°±0.2° 2θ.” Cipla denies the remaining allegations of paragraph 50.

51. CALQUENCE® Tablets, as well as methods of using CALQUENCE® Tablets, are covered by one or more claims of the ’829 patent, including claim 1 of the ’829 patent, and the ’829 patent has been listed in connection with CALQUENCE® Tablets in the FDA’s Orange Book.

ANSWER: Cipla admits that the '829 patent is listed in connection with CALQUENCE in the FDA's Orange Book. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 51 and therefore denies them.

52. Cipla's submission of Cipla's Tablet ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's Tablet ANDA Product prior to the expiration of the '829 patent was an act of infringement of the '829 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

53. In Cipla's Tablet Notice Letter, Cipla did not contest the infringement of the '829 patent on any basis other than the alleged invalidity of that patent.

ANSWER: Denied.

54. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's Tablet ANDA Product would infringe at least claim 1 of the '829 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

55. On information and belief, Cipla has not challenged U.S. Patent No. 7,459,554, which is listed in connection with CALQUENCE® Tablets in the FDA's Orange Book and expires on November 24, 2026. On information and belief, Cipla has not challenged U.S. Patent No. 9,290,504, U.S. Patent No. 9,758,524, and U.S. Patent No. 10,239,883, which are listed in connection with CALQUENCE® Tablets in the FDA's Orange Book and expire on July 11, 2032. On information and belief, following the expiration of those patents, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's Tablet ANDA Product immediately and imminently upon FDA approval of Cipla's Tablet ANDA.

ANSWER: Cipla admits that the '554 patent is listed in connection with CALQUENCE in the FDA's Orange Book, and that the Orange Book lists the expiration date of the '554 patent as November 24, 2026. Cipla admits that the '504 patent, the '524 patent, and the '883 patent are listed in connection with CALQUENCE in the FDA's Orange Book, and that the Orange Book lists the expiration date of the '504 patent, the '524 patent, and the '883 patent as July 11, 3032. Cipla has certified to the FDA that it is not seeking approval of Cipla's Tablet ANDA Product

before the expiration of the ’554 patent, the ’504 patent, the ’524 patent, and the ’883 patent. Cipla denies the remaining allegations in paragraph 55.

56. On information and belief, the use of Cipla’s Tablet ANDA Product in accordance with and as directed by Cipla’s proposed labeling for that product would infringe at least claim 1 of the ’829 patent.

ANSWER: Denied.

57. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the ’829 patent when Cipla’s Tablet ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

58. On information and belief, Cipla knows that Cipla’s Tablet ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’829 patent and that Cipla’s Tablet ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the ’829 patent after approval of Cipla’s Tablet ANDA.

ANSWER: Denied.

59. The foregoing actions by Cipla constitute and/or will constitute infringement of the ’829 patent, active inducement of infringement of the ’829 patent, and contribution to the infringement by others of the ’829 patent.

ANSWER: Denied.

60. On information and belief, Cipla has acted with full knowledge of the ’829 patent and without a reasonable basis for believing that it would not be liable for infringing the ’829 patent, actively inducing infringement of the ’829 patent, and contributing to the infringement by others of the ’829 patent.

ANSWER: Denied.

61. Unless Cipla is enjoined from infringing the ’829 patent, actively inducing infringement of the ’829 patent, and contributing to the infringement by others of the ’829 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '829 PATENT

62. Plaintiffs incorporate each of the preceding paragraphs 1–61 as if fully set forth herein.

ANSWER: Cipla repeats and realleges its responses to the foregoing allegations of the Complaint as if fully set forth herein.

63. 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 or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding Cipla's infringement, active inducement of infringement, and contribution to the infringement by others of the '829 patent.

ANSWER: Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Cipla denies the allegations of paragraph 63.

64. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's Tablet ANDA Product with its proposed labeling, or any other Cipla acalabrutinib maleate tablet drug product that is covered by or whose use is covered by the '829 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '829 patent, and that claims of the '829 patent are valid.

ANSWER: Paragraph 64 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 64.

PRAYER FOR RELIEF

Cipla denies that Plaintiffs are entitled to the relief sought in paragraphs A through I on pages 14 and 15 of the Complaint.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 64 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 '083 Patent)

Each claim of the '083 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
(Non-infringement of the '083 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '083 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's Tablet ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '083 patent, either literally or under the doctrine of equivalents.

Third Defense
(Invalidity of the '829 Patent)

Each claim of the '829 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
(Non-infringement of the '829 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '829 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's Tablet ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '829 patent, either literally or under the doctrine of equivalents.

Fifth Defense
(Waiver)

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

Sixth Defense
(Estoppel)

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

Seventh Defense
(Failure to State a Claim)

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

Eighth 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 Acerta Pharma B.V. ("Acerta"), AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, and AstraZeneca AB (collectively, "AstraZeneca") (all 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. 10,272,083 (the

"'083 patent") and U.S. Patent No. 11,059,829 (the "'829 patent") (collectively, the "Patents-in-Suit") are invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application ("ANDA") No. 219228 ("Cipla's Tablet 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-400 013, 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, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant Acerta Pharma B.V. is a private limited liability company organized and existing under the laws of the Netherlands, with a principal place of business at Kloosterstraat 9, 5349 AB Oss, The Netherlands.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, having its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, having its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, Delaware 19850.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

7. Upon information and belief, Counterclaim Defendant AstraZeneca UK Limited is the holder of New Drug Application ("NDA") No. 216387 for CALQUENCE® (acalabrutinib maleate tablets).

8. Upon information and belief, Counterclaim Defendants currently market acalabrutinib maleate 100 mg base equivalent tablets under the trade name CALQUENCE® pursuant to the U.S. Food and Drug Administration's ("FDA") approval of NDA No. 216387.

Jurisdiction and Venue

9. This Court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, 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*.

10. 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.

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

12. On or about May 16, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the Patents-in-Suit. 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 judgments regarding Cipla and Cipla's Tablet ANDA Product's non-infringement and invalidity of the Patents-in-Suit.

The Patents-in-Suit

13. Based on allegations in the Complaint, the '083 patent, entitled "Methods of Treating Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia Using a BTK Inhibitor," was issued on April 30, 2019. The face of the '083 patent lists Acerta Pharma B.V. as the assignee.

14. Based on allegations in the Complaint, the '829 patent, entitled "Crystal Forms of (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridine-2-yl)benzamide Maleate" was issued on July 13, 2021. The face of the '829 patent lists Acerta Pharma B.V. as the assignee.

15. The Patents-in-Suit are listed in the electronic version of the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in association with CALQUENCE® (acalabrutinib maleate tablets).

16. On April 4, 2024, Cipla sent Counterclaim Defendants, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, notification of paragraph IV certification for the Patents-in-Suit with respect to Cipla's filing of ANDA No. 219228 ("Cipla's Tablet Notice Letter").

17. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv), Cipla's Tablet Notice Letter included, among other things, Cipla's detailed factual and legal basis for the paragraph IV certification regarding the Patents-in-Suit as it pertains to Cipla's Tablet ANDA Product and an Offer of Confidential Access to Cipla's Tablet ANDA Product.

18. On May 16, 2024, Counterclaim Defendants brought this present action alleging infringement of the Patents-in-Suit.

First Counterclaim
(Declaratory Judgment of Non-infringement of the '083 Patent)

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

20. Counterclaim Defendants have accused Cipla of infringing the '083 patent.

21. Cipla denies infringement of the '083 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's Tablet 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 claim of the '083 patent.

22. 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 '083 patent.

23. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's Tablet ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '083 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the '083 Patent)

24. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 23 of the Counterclaims as if fully set forth herein.

25. The claims of the '083 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.

26. For at least the reasons stated in Cipla's Tablet Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '083 patent are not infringed by Cipla's Tablet ANDA Product and/or are invalid.

27. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's Tablet ANDA Product is infringing the claims of the '083 patent and will continue to try to interfere with Cipla's business with respect to Cipla's Tablet ANDA Product.

28. 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 '083 patent.

29. Cipla is entitled to a judicial declaration that all claims of the '083 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 Non-infringement of the '829 Patent)

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

31. Counterclaim Defendants have accused Cipla of infringing the '829 patent.

32. Cipla denies infringement of the '829 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's Tablet 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 claim of the ’829 patent.

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 ’829 patent.

34. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla’s Tablet ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the ’829 patent.

Fourth Counterclaim
(Declaratory Judgment of Invalidity of the ’829 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 ’829 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 Tablet Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’829 patent are not infringed by Cipla’s Tablet ANDA Product and/or are invalid.

38. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla’s Tablet ANDA Product is infringing the claims of the ’829 patent and will continue to try to interfere with Cipla’s business with respect to Cipla’s Tablet 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 '829 patent.

40. Cipla is entitled to a judicial declaration that all claims of the '829 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 Tablet ANDA Product does not and will not directly or indirectly infringe any claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patents-in-Suit are invalid and 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 Patents-in-Suit 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 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: July 22, 2024

K&L GATES LLP

/s/ Steven L. Caponi

Steven L. Caponi (No. 3484)
Matthew B. Goeller (No. 6283)
Megan E. Hunt (No. 6569)
600 King Street, Suite 901
Wilmington, DE 19801
Phone: (302) 416-7000
steven.caponi@klgates.com
matthew.goeller@klgates.com
megan.hunt@klgates.com

OF COUNSEL:

Anil H. Patel (*pro hac vice forthcoming*)
1000 Main Street, Suite 2550
Houston, TX 77002
Phone: (713) 815-7300
anil.patel@klgates.com

Peter Giunta (*pro hac vice forthcoming*)
599 Lexington Avenue
New York, NY 10022
Phone: (212) 536-3900
peter.giunta@klgates.com

Harold Storey (*pro hac vice forthcoming*)
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
Phone: (206) 623-7580
harold.storey@klgates.com

Attorneys for Defendants Cipla Ltd. and Cipla USA Inc.