IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACERTA PHARMA B.V., ASTRAZENCA UK LIMITED, ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA AB, *Plaintiffs,* v. CIPLA LIMITED and CIPLA USA, INC. *Defendants.*	Civil Action No. _____

COMPLAINT

Plaintiffs Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, and AstraZeneca AB (collectively "AstraZeneca" or "Plaintiffs") file this Complaint for patent infringement against Cipla Limited and Cipla USA, Inc. (collectively, "Cipla"), and by their attorneys, hereby allege as follows:

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."

PARTIES

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

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.

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.

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.

6. On information and belief, defendant Cipla Limited is a company organized and existing under the laws of the Republic 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.

7. On information and belief, defendant 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 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.

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.

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.

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.

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.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if 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.

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.

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.

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 contacts within the State of Delaware.

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.

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).

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.

VENUE

20. Plaintiffs incorporate each of the preceding paragraphs 1–19 as if 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.

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).

FACTUAL BACKGROUND

23. CALQUENCE® Tablets, which contain 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").

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

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.

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.

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.

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

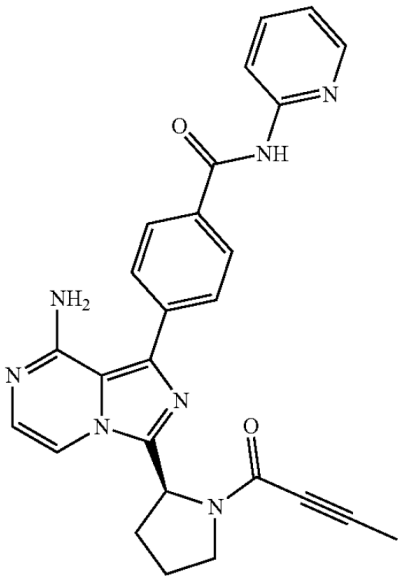
COUNT I – INFRINGEMENT OF THE '083 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

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.

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.

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.

33. CALQUENCE® Tablets, as well as methods of using CALQUENCE® Tablets, are covered by one or more 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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 the asserted claims of the ’083 patent are valid.

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.

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-(pyridin-2-yl)benzamide" (attached as Exhibit B), was duly and legally issued on July 13, 2021.

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.

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-(pyridin-2-yl)benzamide maleate characterized by an X-ray powder diffraction pattern comprising certain peaks as recited in claim 1 of the '829 patent.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 the asserted claims of the ’829 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the following relief:

a) A judgment that Cipla has infringed, will infringe, and will induce and contribute to infringement of each of the Patents-in-Suit;

b) A judgment that the asserted claims of the Patents-in-Suit are valid and enforceable;

c) A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's Tablet ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. § 271(e)(4)(B) and § 283 enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's Tablet ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's Tablet ANDA Product, or any product or

compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Cipla engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Cipla's Tablet ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

g) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

h) An award of Plaintiffs' costs and expenses in this action; and

i) Such further and other relief as this Court may deem just and proper.

Dated: May 16, 2024

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