IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACERTA PHARMA B.V., ASTRAZENECA UK LIMITED, ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and MERCK SHARP & DOHME B.V., *Plaintiffs,* v. SANDOZ INC., *Defendant.*	Civil Action No. _____

COMPLAINT

Plaintiffs Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca AB (collectively "AstraZeneca"), and Merck Sharp & Dohme B.V. ("Merck") (together hereinafter "Plaintiffs") file this Complaint for patent infringement against Sandoz Inc. ("Sandoz"), 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 Sandoz of Abbreviated New Drug New Drug Application ("ANDA") No. 216405 ("Sandoz's 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) 100 mg oral capsules prior to the expiration of U.S. Patent No. 9,290,504 ("the '504 patent"); U.S. Patent No. 9,758,524 ("the '524 patent"); U.S. Patent No. 10,239,883 ("the '883 patent"); U.S. Patent No. 9,796,721 ("the

'721 patent"); U.S. Patent No. 10,167,291 ("the '291 patent"); and U.S. Patent No. 10,272,083 ("the '083 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. 210259 for the manufacture and sale of CALQUENCE® (acalabrutinib) 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. Plaintiff Merck Sharp & Dohme B.V. is a company organized and existing under the laws of The Netherlands, having its principal place of business at Waarderweg 39, 2031BN Haarlem, The Netherlands.

7. On information and belief, defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz 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, Sandoz knows and intends that upon approval of Sandoz's ANDA, Sandoz will manufacture Sandoz's ANDA Products and directly or indirectly market, sell, and distribute them throughout the United States, including in Delaware.

JURISDICTION

9. Plaintiffs incorporate each of the preceding paragraphs 1–8 as if fully set forth herein.

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

11. 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 Sandoz.

12. Sandoz 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. Sandoz 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, Sandoz 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.

13. In addition, this Court has personal jurisdiction over Sandoz because, among other things, on information and belief: (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including in Delaware; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Sandoz's 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 Sandoz's ANDA, Sandoz's 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.

14. In addition, this Court has personal jurisdiction over Sandoz because Sandoz regularly (1) engages in patent litigation concerning Sandoz's ANDA products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., In re: Copaxone 775 Patent Litig.*, C.A. No. 16-1267-GMS (D. Del. Sept. 27, 2018); *Bristol-Myers Squibb Company et al. v. Sandoz Inc.*, No. 1:17-cv-00407-LPS (D. Del. June 12, 2017); *Forest Laboratories, LLC et al. v. Apotex Corp. et al.*, C.A. No. 1:15-cv-18-GMS (D. Del. Feb. 22, 2016).

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

VENUE

16. Plaintiffs incorporate each of the preceding paragraphs 1–15 as if fully set forth herein.

17. Venue is proper in this district as to Sandoz pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Sandoz 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*, 137 S.Ct. 1514, 1515 (2017).

FACTUAL BACKGROUND

18. CALQUENCE®, which contains acalabrutinib as its active ingredient, is a kinase inhibitor 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").

19. On information and belief, Sandoz's ANDA Product is a generic version of CALQUENCE®.

20. By letter dated December 28, 2021 ("Sandoz's Notice Letter"), Sandoz notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the '504 patent, the '524 patent, the '721 patent, the '291 patent, and the '083 patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of those patents. On information and belief, Sandoz's ANDA contains a Paragraph IV Certification asserting that the '504 patent, the '524 patent, the '721 patent, the '291 patent, and the '083 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Products, and/or that the Patents-in-Suit are invalid and/or unenforceable.

21. The purpose of Sandoz's submission of Sandoz's 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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

22. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is for an acalabrutinib oral capsule, 100 mg.

23. In an exchange of correspondence, counsel for Plaintiffs and counsel for Sandoz discussed the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Sandoz's ANDA or the Drug Master File referred to in Sandoz's ANDA, and Sandoz did not provide all information that Plaintiffs requested.

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

COUNT I – INFRINGEMENT OF THE '504 PATENT UNDER 35 U.S.C. § 271(e)(2)

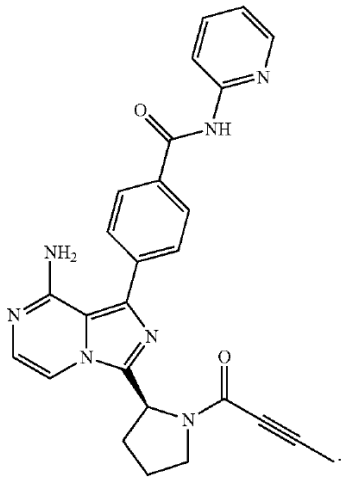
25. Plaintiffs incorporate each of the preceding paragraphs 1–24 as if fully set forth herein.

26. The '504 patent, entitled "4-Imidazopyridazin-1-yl-Benzamides and 4-Imidazotriazin-1-yl-Benzamides as BTK Inhibitors" (attached as Exhibit A), was duly and legally issued on March 22, 2016.

27. Merck is the owner and assignee of the '504 patent. AstraZeneca is exclusive licensee of the '504 patent. Merck and AstraZeneca collectively possess all rights, title, and interest in the '504 patent.

28. The ’504 patent claims, *inter alia,* an isolated compound of the structure recited in claim 1, or a pharmaceutically acceptable salt thereof.

29. The ’504 patent claims, *inter alia*, a compound which is (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide, having the structure:



as recited in claim 30 of the ’504 patent.

30. CALQUENCE® is covered by one or more claims of the ’504 patent, including claims 1 and 30 of the ’504 patent, and the ’504 patent has been listed in connection with CALQUENCE® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

31. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’504 patent was an act of infringement of the ’504 patent under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claims 1 and 30 of the '504 patent, recited above, either literally or under the doctrine of equivalents.

33. In Sandoz's Notice Letter, Sandoz did not contest the infringement of claims 1 and 30 of the '504 patent on any basis other than the alleged invalidity of those claims.

34. On information and belief, Sandoz has not challenged U.S. Patent No. 7,459,554 ("the '554 patent"), which is listed in connection with CALQUENCE® in the FDA's Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the '554 patent, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

35. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claims 1 and 30 of the '504 patent.

36. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '504 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

37. On information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '504 patent and that its ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '504 patent after approval of Sandoz's ANDA.

38. The foregoing actions by Sandoz constitute and/or will constitute infringement of the ’504 patent, active inducement of infringement of the ’504 patent, and contribution to the infringement by others of the ’504 patent.

39. On information and belief, Sandoz has acted with full knowledge of the ’504 patent and without a reasonable basis for believing that it would not be liable for infringing the ’504 patent, actively inducing infringement of the ’504 patent, and contributing to the infringement by others of the ’504 patent.

40. Unless Sandoz is enjoined from infringing the ’504 patent, actively inducing infringement of the ’504 patent, and contributing to the infringement by others of the ’504 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’504 PATENT

41. Plaintiffs incorporate each of the preceding paragraphs 1–40 as if fully set forth herein.

42. 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 Sandoz on the other regarding Sandoz’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’504 patent.

43. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the ’504 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’504 patent, and that the claims of the ’504 patent are valid.

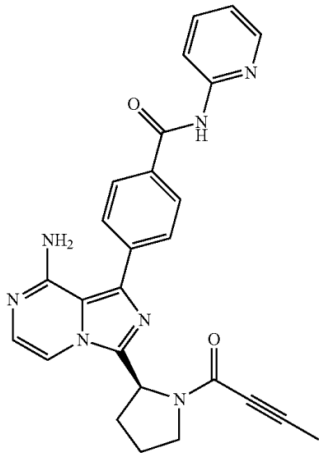
COUNT III – INFRINGEMENT OF THE ’524 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

45. The ’524 patent, entitled, “4-Imidazopyridazin-1-yl-Benzamides as BTK Inhibitors” (attached as Exhibit B), was duly and legally issued on September 12, 2017.

46. Merck is the owner and assignee of the ’524 patent. AstraZeneca is exclusive licensee of the ’524 patent. Merck and AstraZeneca collectively possess all rights, title, and interest in the ’524 patent.

47. The ’524 patent claims, *inter alia,* a method of treating Mantle Cell Lymphoma (“MCL”) in a human subject, the method comprising administering to the human subject a compound which is (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide, having the structure:



or a pharmaceutically acceptable salt thereof, in an amount effective to treat MCL in the human subject, as recited in claim 1 of the ’524 patent.

48. CALQUENCE®, as well as methods of using CALQUENCE®, are covered by one or more claims of the ’524 patent, including claim 1 of the ’524 patent, and the ’524 patent has been listed in connection with CALQUENCE® in the FDA’s Orange Book.

49. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’524 patent was an act of infringement of the ’524 patent under 35 U.S.C. § 271(e)(2)(A).

50. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product would infringe at least claim 1 of the ’524 patent, recited above, either literally or under the doctrine of equivalents.

51. In Sandoz’s Notice Letter, Sandoz did not contest the infringement of claim 1 of the ’524 patent on any basis other than the alleged invalidity of that claim.

52. On information and belief, Sandoz has not challenged the ’554 patent, which is listed in connection with CALQUENCE® in the FDA’s Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the ’554 patent, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product immediately and imminently upon FDA approval of Sandoz’s ANDA.

53. On information and belief, the use of Sandoz’s ANDA Product in accordance with and as directed by Sandoz’s proposed labeling for that product would infringe at least claim 1 of the ’524 patent.

54. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the ’524 patent when Sandoz’s ANDA is approved, and plans and intends to, and will, do so after approval.

55. On information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’524 patent and that its ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the ’524 patent after approval of Sandoz’s ANDA.

56. The foregoing actions by Sandoz constitute and/or will constitute infringement of the ’524 patent, active inducement of infringement of the ’524 patent, and contribution to the infringement by others of the ’524 patent.

57. On information and belief, Sandoz has acted with full knowledge of the ’524 patent and without a reasonable basis for believing that it would not be liable for infringing the ’524 patent, actively inducing infringement of the ’524 patent, and contributing to the infringement by others of the ’524 patent.

58. Unless Sandoz is enjoined from infringing the ’524 patent, actively inducing infringement of the ’524 patent, and contributing to the infringement by others of the ’524 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’524 PATENT

59. Plaintiffs incorporate each of the preceding paragraphs 1–58 as if fully set forth herein.

60. 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 Sandoz on the other regarding Sandoz’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’524 patent.

61. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '524 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '524 patent, and that the claims of the '524 patent are valid.

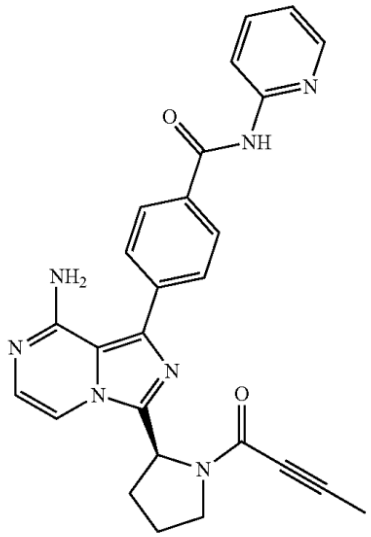
COUNT V – INFRINGEMENT OF THE '883 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

63. The '883 patent, entitled "4-Imidazopyridazin-1-yl-Benzamides as BTK Inhibitors" (attached as Exhibit C), was duly and legally issued on March 26, 2019.

64. Merck is the owner and assignee of the '883 patent. AstraZeneca is exclusive licensee of the '883 patent. Merck and AstraZeneca collectively possess all rights, title, and interest in the '883 patent.

65. The '883 patent claims, *inter alia*, a method of treating chronic lymphocytic leukemia in a human subject, the method comprising administering to the human subject a compound which is (S)-4-(8-amino-3-(1-but-2-ynoylpyrrolidin-2-yl)imidazo[1,5-a]pyrazin-1-yl)-N-(pyridin-2-yl)benzamide, having the structure:



or a pharmaceutically acceptable salt thereof, as recited in claim 1 of the ’883 patent.

66. CALQUENCE®, as well as methods of using CALQUENCE®, are covered by one or more claims of the ’883 patent, including claim 1 of the ’883 patent, and the ’883 patent has been listed in connection with CALQUENCE® in the FDA’s Orange Book.

67. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’883 patent was an act of infringement of the ’883 patent under 35 U.S.C. § 271(e)(2)(A).

68. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product would infringe at least claim 1 of the ’883 patent, recited above, either literally or under the doctrine of equivalents.

69. On information and belief, Sandoz has not challenged the ’554 patent, which is listed in connection with CALQUENCE® in the FDA’s Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the ’554 patent, Sandoz will

engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

70. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '883 patent.

71. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '883 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

72. On information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '883 patent and that its ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '883 patent after approval of Sandoz's ANDA.

73. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '883 patent, active inducement of infringement of the '883 patent, and contribution to the infringement by others of the '883 patent.

74. On information and belief, Sandoz has acted with full knowledge of the '883 patent and without a reasonable basis for believing that it would not be liable for infringing the '883 patent, actively inducing infringement of the '883 patent, and contributing to the infringement by others of the '883 patent.

75. Unless Sandoz is enjoined from infringing the '883 patent, actively inducing infringement of the '883 patent, and contributing to the infringement by others of the '883 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '883 PATENT

76. Plaintiffs incorporate each of the preceding paragraphs 1–75 as if fully set forth herein.

77. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '883 patent.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '883 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '883 patent, and that the claims of the '883 patent are valid.

COUNT VII – INFRINGEMENT OF THE '721 PATENT UNDER 35 U.S.C. § 271(e)(2)

79. Plaintiffs incorporate each of the preceding paragraphs 1–78 as if fully set forth herein.

80. The '721 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 D), was duly and legally issued on October 24, 2017.

81. Acerta Pharma B.V. is the owner and assignee of the '721 patent. AstraZeneca has all rights, title, and interest in the '721 patent.

82. The '721 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 characterized by an

X-ray powder diffraction pattern comprising peaks at 6.4° ±0.2° 2θ, 8.6° ±0.2° 2θ, 10.5° ±0.2° 2θ, 11.6° ±0.2° 2θ and 15.7° ±0.2° 2θ as recited in claim 1 of the '721 patent.

83. CALQUENCE®, as well as methods of using CALQUENCE®, are covered by one or more claims of the '721 patent, including claim 1 of the '721 patent, and the '721 patent has been listed in connection with CALQUENCE ® in the FDA's Orange Book.

84. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '721 patent was an act of infringement of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

85. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claim 1 of the '721 patent, recited above, either literally or under the doctrine of equivalents.

86. On information and belief, Sandoz has not challenged the '554 patent, which is listed in connection with CALQUENCE® in the FDA's Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the '554 patent, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

87. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '721 patent.

88. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '721 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

89. On information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '721 patent and that its ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '721 patent after approval of Sandoz's ANDA.

90. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '721 patent, active inducement of infringement of the '721 patent, and contribution to the infringement by others of the '721 patent.

91. On information and belief, Sandoz has acted with full knowledge of the '721 patent and without a reasonable basis for believing that it would not be liable for infringing the '721 patent, actively inducing infringement of the '721 patent, and contributing to the infringement by others of the '721 patent.

92. Unless Sandoz is enjoined from infringing the '721 patent, actively inducing infringement of the '721 patent, and contributing to the infringement by others of the '721 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '721 PATENT

93. Plaintiffs incorporate each of the preceding paragraphs 1–92 as if fully set forth herein.

94. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, and contribution to the infringement by others of the '721 patent.

95. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '721 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '721 patent, and that the claims of the '721 patent are valid.

COUNT IX – INFRINGEMENT OF THE '291 PATENT UNDER 35 U.S.C. § 271(e)(2)

96. Plaintiffs incorporate each of the preceding paragraphs 1–95 as if fully set forth herein.

97. The '291 patent, entitled, "Pharmaceutical Compositions Comprising 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 " (attached as Exhibit E), was duly and legally issued on January 1, 2019.

98. Acerta Pharma B.V. is the owner and assignee of the '291 patent. AstraZeneca has all rights, title, and interest in the '291 patent.

99. The '291 patent claims, *inter alia*, a solid pharmaceutical composition comprising at least one pharmaceutically acceptable excipient and 95-105 mg of 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 characterized by a reflection X-ray powder diffraction pattern comprising peaks at 6.4° ±0.2° 2θ, 8.6° ±0.2° 2θ, 10.5° ± 0.2° 2θ, 11.6° ±0.2° 2θ and 15.7° ±0.2° 2θ as recited in claim 1 of the '291 patent.

100. CALQUENCE®, as well as methods of using CALQUENCE®, are covered by one or more claims of the '291 patent, including claim 1 of the '291 patent, and the '291 patent has been listed in connection with CALQUENCE® in the FDA's Orange Book.

101. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '291 patent was an act of infringement of the '291 patent under 35 U.S.C. § 271(e)(2)(A).

102. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claim 1 of the '291 patent, recited above, either literally or under the doctrine of equivalents.

103. On information and belief, Sandoz has not challenged the '554 patent, which is listed in connection with CALQUENCE® in the FDA's Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the '554 patent, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

104. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '291 patent.

105. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '291 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

106. On information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '291 patent and that its ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '291 patent after approval of Sandoz's ANDA.

107. The foregoing actions by Sandoz constitute and/or will constitute infringement of the ’291 patent, active inducement of infringement of the ’291 patent, and contribution to the infringement by others of the ’291 patent.

108. On information and belief, Sandoz has acted with full knowledge of the ’291 patent and without a reasonable basis for believing that it would not be liable for infringing the ’291 patent, actively inducing infringement of the ’291 patent, and contributing to the infringement by others of the ’291 patent.

109. Unless Sandoz is enjoined from infringing the ’291 patent, actively inducing infringement of the ’291 patent, and contributing to the infringement by others of the ’291 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’291 PATENT

110. Plaintiffs incorporate each of the preceding paragraphs 1–109 as if fully set forth herein.

111. 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 Sandoz on the other regarding Sandoz’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’291 patent.

112. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the ’291 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’291 patent, and that the claims of the ’291 patent are valid.

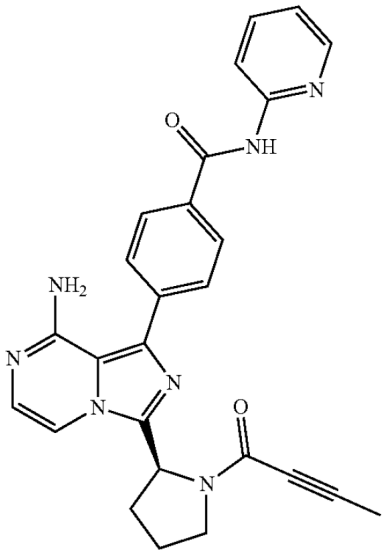
COUNT XI – INFRINGEMENT OF THE ’083 PATENT UNDER 35 U.S.C. § 271(e)(2)

113. Plaintiffs incorporate each of the preceding paragraphs 1–112 as if fully set forth herein.

114. The ’083 patent, entitled, “Methods of Treating Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia Using a BTK Inhibitor” (attached as Exhibit F), was duly and legally issued on April 30, 2019.

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

116. The ’083 patent claims, *inter alia*, 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 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 8 of the ’083 patent.

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

118. Sandoz’s submission of Sandoz’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s 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).

119. In Sandoz’s Notice Letter, Sandoz did not contest the infringement of claim 8 of the ’083 patent on any basis other than the alleged invalidity of those claims.

120. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product would infringe at least claim 8 of the ’083 patent, recited above, either literally or under the doctrine of equivalents.

121. On information and belief, Sandoz has not challenged the ’554 patent, which is listed in connection with CALQUENCE® in the FDA’s Orange Book and expires on November 24, 2026. On information and belief, following the expiration of the ’554 patent, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz’s ANDA Product immediately and imminently upon FDA approval of Sandoz’s ANDA.

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

123. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the ’083 patent when Sandoz’s ANDA is approved, and plans and intends to, and will, do so after approval.

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

125. The foregoing actions by Sandoz 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.

126. On information and belief, Sandoz 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.

127. Unless Sandoz 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 XII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’083 PATENT

128. Plaintiffs incorporate each of the preceding paragraphs 1–127 as if fully set forth herein.

129. 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 Sandoz on the other regarding Sandoz’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’083 patent.

130. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz 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 claims of the '083 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the following relief:

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

b) A judgment that 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 Sandoz to make, use, offer for sale, sell, market, distribute, or import Sandoz's 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 Sandoz, 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 Sandoz's 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 Sandoz's 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 Sandoz engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Sandoz's 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.

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Dated: February 4, 2022

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