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Counsel for Plaintiffs BeiGene USA, Inc. and BeiGene Switzerland GmbH

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

BEIGENE USA, INC. and BEIGENE SWITZERLAND GMBH

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs BeiGene USA, Inc. ("BeiGene USA") and BeiGene Switzerland GmbH ("BeiGene Switzerland," and together with BeiGene USA, "BeiGene" or "Plaintiffs"), by their attorneys, file this Complaint for patent infringement against Sandoz Inc. ("Sandoz" or "Defendant") and hereby allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of BRUKINSA® (zanubrutinib) capsules, 80 mg, prior to the expiration of U.S. Patent No. 10,927,117 ("the '117 patent") and U.S. Patent No. 11,591,340 ("the '340 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Sandoz notified Plaintiffs by letter dated January 24, 2024 ("Sandoz's Notice Letter") that it had submitted to the FDA ANDA No. 218957 ("Sandoz's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic zanubrutinib capsules, 80 mg, ("Sandoz's ANDA Product") prior to the expiration of the Patents-in-Suit.

The Parties

3. Plaintiff BeiGene USA is a corporation organized and existing under the laws of Delaware and having a place of business at 55 Cambridge Parkway, Suite 700W, Cambridge, Massachusetts 02142. BeiGene USA is the holder of New Drug Application ("NDA") No. 213217

for the manufacture and sale of zanubrutinib capsules, 80 mg, which has been approved by the FDA.

4. Plaintiff BeiGene Switzerland is a limited liability company organized under the laws of Switzerland, having its registered seat in Basel, Switzerland, and having a place of business at Aeschengraben 27, 4051 Basel, Switzerland.

5. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware and having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. Upon information and belief, Sandoz is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

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

Jurisdiction

7. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

9. 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.

10. Upon information and belief, Sandoz has a principal place of business in New Jersey, and is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic versions of branded pharmaceutical products

throughout the United States, including in New Jersey, through its own actions and/or through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

11. Upon information and belief, Sandoz is registered to do business in New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

12. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA; continues to engage in seeking FDA approval of Sandoz's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of Sandoz's ANDA.

13. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, prepared and submitted Sandoz's ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications").

14. Upon information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including in New Jersey, consistently with Sandoz's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sandoz regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Sandoz's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon

information and belief, Sandoz's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that Sandoz's ANDA Product is approved before the Patents-in-Suit expire.

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

16. Sandoz is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sandoz is a corporation with a principal place of business in New Jersey, is registered to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

17. This Court also has personal jurisdiction over Sandoz because, among other things, upon 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 New Jersey; and (2) upon approval of

Sandoz's ANDA, Sandoz will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey. Upon information and belief, upon approval of Sandoz's ANDA, Sandoz's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

18. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufactures BRUKINSA® drug products for sale and use throughout the United States, including in New Jersey. As a result, the consequences of Sandoz's actions were, and will be, suffered in New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time Sandoz sent notice of the Paragraph IV certifications, it was reasonably foreseeable that Sandoz would be sued within 45 days in New Jersey, where Sandoz is located. Upon information and belief, Sandoz's actions will injure Plaintiffs by displacing at least some, if not all, of Plaintiffs' sales of BRUKINSA® drug products in New Jersey, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of BRUKINSA® drug products in New Jersey.

19. Sandoz is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical 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.*, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 23-cv-1214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-3044, ECF No. 23 (D.N.J. Aug. 1, 2022).

20. 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 Sandoz.

Venue

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

22. Venue is proper in this District under 28 U.S.C. § 1391, at least because, upon information and belief, Sandoz resides in this District and a substantial part of the events and injury giving rise to Plaintiffs' claims has and continues to occur in this District.

23. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b), at least because, upon information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. Upon information and belief, among other things, (1) Sandoz prepared and/or submitted Sandoz's ANDA with Paragraph IV certifications in New Jersey, where Sandoz is located; 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 New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey.

24. Venue is proper in this District as to Sandoz because Sandoz (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, and (2) does not contest that venue is proper in this District. *See, e.g.*, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 23-cv-1214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-3044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Factual Background

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

26. BRUKINSA®, which contains zanubrutinib, is approved for the treatment of chronic lymphocytic leukemia, small lymphocytic lymphoma, Waldenström's macroglobulinemia, mantle cell lymphoma where the patient has received at least one prior therapy, and relapsed or refractory marginal zone lymphoma where the patient has received at least one anti-CD20-based regimen.

27. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is zanubrutinib capsules, 80 mg. In Sandoz's Notice Letter, Sandoz states that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Sandoz's ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. Upon information and belief, Sandoz's ANDA Product is a generic version of BRUKINSA®.

28. In Sandoz's Notice Letter, Sandoz stated that it had submitted Paragraph IV certifications to FDA alleging that the Patents-in-Suit were invalid, unenforceable, and/or not infringed, and that Sandoz is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

29. The purpose of Sandoz's submission of Sandoz's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (the "FDCA") 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.

30. Upon information and belief, Sandoz's ANDA Product is not publicly available, nor is ANDA No. 218957 accessible to the public.

31. In Sandoz's Notice Letter, Sandoz included an Offer of Confidential Access to a redacted version of Sandoz's ANDA, and Sandoz's offer was subject to various unreasonably restrictive conditions.

32. 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 unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. Sandoz further refused to produce samples of Sandoz's ANDA Product and other internal documents and material relevant to infringement.

33. This action is being commenced within 45 days from the date Plaintiffs received Sandoz's Notice Letter.

Count I – Infringement of the '117 Patent

34. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

35. The '117 patent, entitled "Crystalline Form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide, Preparation, and Uses Thereof" (attached as Exhibit A), was duly and legally issued on February 23, 2021.

36. The inventors named on the '117 patent are Zhiwei Wang, Yunhang Guo, and Gongyin Shi.

37. BeiGene Switzerland GmbH is the owner and assignee of the '117 patent.

38. BRUKINSA® is covered by one or more claims of the '117 patent, which has been listed in connection with BRUKINSA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

39. In Sandoz's Notice Letter, Sandoz notified Plaintiffs of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval

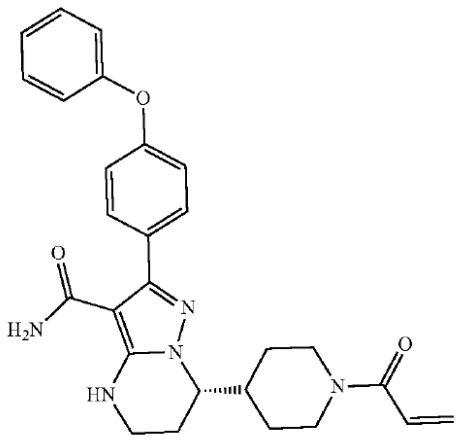
under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '117 patent.

40. In Sandoz's Notice Letter, Sandoz also notified Plaintiffs that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '117 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '117 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

41. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains zanubrutinib.

42. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '117 patent, either literally or under the doctrine of equivalents.

43. As an example, claim 1 of the '117 patent recites:

> A crystalline form of Compound 1,
>
> Compound 1
>
> 
>
>
> wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2° and 21.4±0.2°.

44. Upon information and belief, Sandoz's ANDA Product contains a crystalline form of Compound 1, as recited in Claim 1.

45. As a further example, claim 6 of the '117 patent recites a pharmaceutical composition comprising a therapeutically effective amount of the crystalline form of claim 1, and a pharmaceutically acceptable excipient thereof.

46. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical composition comprising a therapeutically effective amount of the crystalline form of the compound recited in claim 1.

47. Upon information and belief, Sandoz's ANDA Product contains a pharmaceutically acceptable excipient.

48. Upon information and belief, Sandoz's ANDA Product infringes claims 1 through 6 of the '117 patent, literally or under the doctrine of equivalents.

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 before the expiration of the '117 patent was an act of infringement of the '117 patent under 35 U.S.C. § 271(e)(2)(A).

50. Upon information and belief, 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 approval of its ANDA.

51. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '117 patent.

52. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '117 patent.

53. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '117 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '117 patent and specific intent to infringe that patent.

54. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '117 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '117 patent immediately and imminently upon approval of Sandoz's ANDA.

55. Notwithstanding Sandoz's knowledge of the claims of the '117 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '117 patent.

56. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '117 patent; active inducement of infringement of the '117 patent; and/or contribution to the infringement by others of the '117 patent.

57. Upon information and belief, Sandoz has acted with full knowledge of the '117 patent and without a reasonable basis for believing that it would not be liable for infringement of the '117

patent; active inducement of infringement of the '117 patent; and/or contribution to the infringement by others of the '117 patent.

58. BeiGene will be substantially and irreparably damaged by infringement of the '117 patent.

59. Unless Sandoz is enjoined from infringing the '117 patent, actively inducing infringement of the '117 patent, and contributing to the infringement by others of the '117 patent, BeiGene will suffer irreparable injury. BeiGene has no adequate remedy at law.

Count II - Declaratory Judgment of Infringement of the '117 Patent

60. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

61. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between BeiGene on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '117 patent, and/or the validity of the '117 patent.

62. The Court should declare that the commercial manufacture, use, sale, offer for sale and/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 '117 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '117 patent, and that the claims of the '117 patent are not invalid.

Count III – Infringement of the '340 Patent

63. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

64. The ’340 patent, entitled “Crystalline Form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide, Preparation, and Uses Thereof” (attached as Exhibit B), was duly and legally issued on February 28, 2023.

65. The inventors named on the ’340 patent are Zhiwei Wang, Yunhang Guo, Gongyin Shi, and Lai Wang.

66. BeiGene Switzerland GmbH is the owner and assignee of the ’340 patent.

67. Methods of using BRUKINSA® are covered by one or more claims of the ’340 patent, which has been listed in connection with BRUKINSA® in the FDA’s Orange Book.

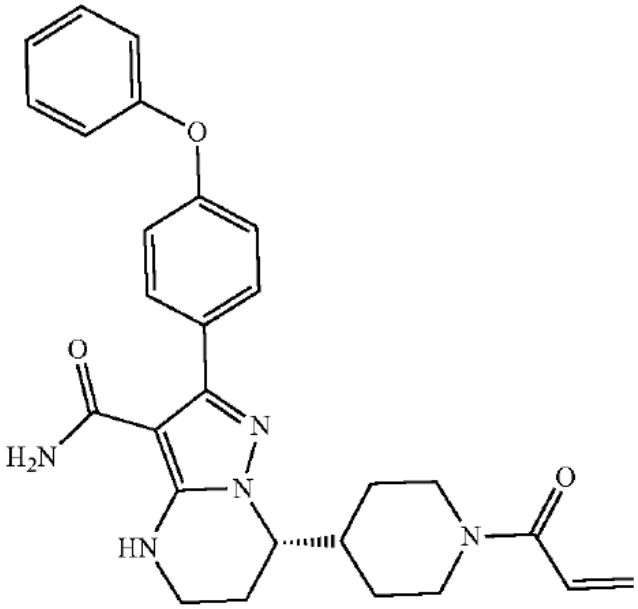
68. In Sandoz’s Notice Letter, Sandoz notified BeiGene of the submission of Sandoz’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’340 patent.

69. In Sandoz’s Notice Letter, Sandoz also notified BeiGene that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the ’340 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’340 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product.

70. According to Sandoz’s Notice Letter, Sandoz’s ANDA Product contains zanubrutinib.

71. Upon 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 one or more claims of the ’340 patent.

72. As an example, claim 1 of the ’340 patent recites:

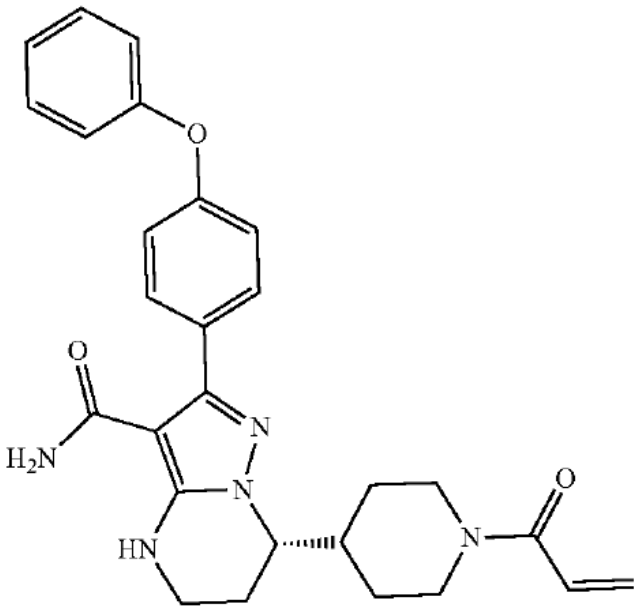
> A method for treating mantle cell lymphoma in a subject, comprising administering to the subject in need thereof a crystalline form of Compound 1,
>
> Compound 1
>
> 
>
>
> wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

73. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating mantle cell lymphoma in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 1.

74. As a further example, Claim 8 of the '340 patent recites:

> A method for treating Waldenström's macroglobulinemia in a subject, comprising administering to the subject in need thereof a crystalline form of Compound 1,

Compound 1



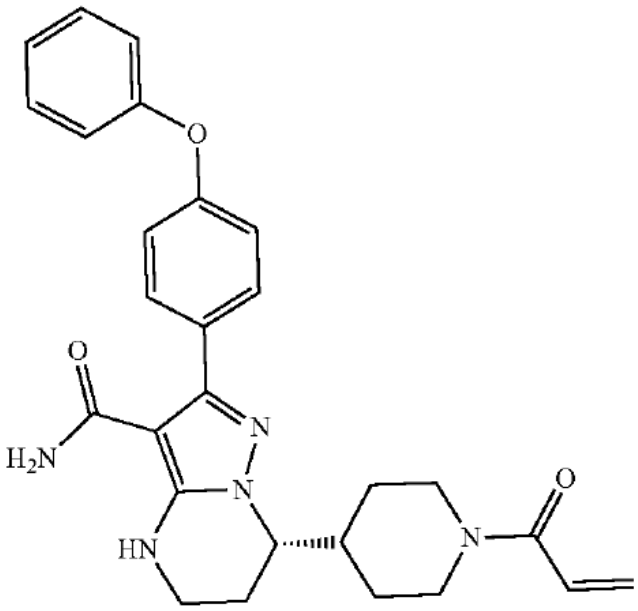
wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

75. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating Waldenström's macroglobulinemia in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 8.

76. Claim 14 of the '340 patent recites:

A method for treating marginal zone lymphoma in a subject, comprising administering to the subject in need thereof a crystalline form of Compound 1,

Compound 1



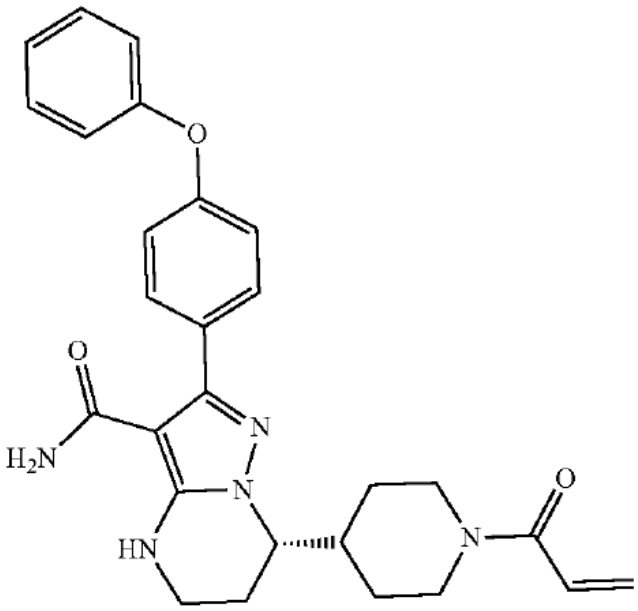
wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

77. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating marginal zone lymphoma in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 14.

78. Claim 21 of the '340 patent recites:

A method for treating chronic lymphocytic leukemia or small lymphocytic lymphoma in a subject, comprising administering to the subject in need thereof a crystalline form of Compound 1,

Compound 1



wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

79. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating chronic lymphocytic leukemia or small lymphocytic lymphoma in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 21.

80. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed product labeling would infringe claims 1 through 27 of the '340 patent.

81. 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 before the expiration of the '340 patent was an act of infringement of the '340 patent under 35 U.S.C. § 271(e)(2)(A).

82. Upon information and belief, 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 approval of its ANDA.

83. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe one or more claims of the '340 patent.

84. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '340 patent.

85. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '340 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '340 patent and specific intent to infringe that patent.

86. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '340 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '340 patent immediately and imminently upon approval of Sandoz's ANDA.

87. Notwithstanding Sandoz's knowledge of the claims of the '340 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '340 patent.

88. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '340 patent; active inducement of infringement of the '340 patent; and/or contribution to the infringement by others of the '340 patent.

89. Upon information and belief, Sandoz has acted with full knowledge of the '340 patent and without a reasonable basis for believing that it would not be liable for infringement of the '340 patent; active inducement of infringement of the '340 patent; and/or contribution to the infringement by others of the '340 patent.

90. BeiGene will be substantially and irreparably damaged by infringement of the '340 patent.

91. Unless Sandoz is enjoined from infringing the '340 patent, actively inducing infringement of the '340 patent, and contributing to the infringement by others of the '340 patent, BeiGene will suffer irreparable injury. BeiGene has no adequate remedy at law.

Count IV - Declaratory Judgment of Infringement of the '340 Patent

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

93. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between BeiGene on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '340 patent, and/or the validity of the '340 patent.

94. The Court should declare that the commercial manufacture, use, sale, offer for sale and/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 '340 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the '340 patent, and that the claims of the '340 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, BeiGene requests the following relief:

(a) A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Sandoz's submission to the FDA of Sandoz's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sandoz's ANDA Product, or any other drug product that infringes or the use of which infringes the Patents-in-Suit, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patent, will infringe, induce the infringement and contribute to infringement by others of said patents;

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

(f) Costs and expenses in this action; and

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

Dated: March 8, 2024

By: *s/Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending litigation in any court, administrative proceeding, or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. This matter is related to the following action:

- *Beigene USA, Inc., et al. v. MSN Pharmaceuticals Inc., et al.*, No. 2:24-cv-01971, United States District Court for the District of New Jersey.

Dated: March 8, 2024

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: March 8, 2024

By: *s/Liza M. Walsh*
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