Liza M. Walsh
Katelyn O'Reilly
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102-5310
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
lmalakoff@walsh.law

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Michael Xun Liu
Christie K. Corn
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
cmandernach@wc.com
mliu@wc.com
ccorn@wc.com

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.

MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LIMITED,

Defendants.

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 MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Ltd. ("MSN Labs," and together with MSN Pharmaceuticals, "MSN" or "Defendants") 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 MSN'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"), U.S. Patent No. 11,591,340 ("the '340 patent"), U.S. Patent No. 11,786,531 ("the '531 patent"), and U.S. Patent No. 11,851,437 ("the '437 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. MSN notified Plaintiffs by letter dated January 26, 2024 ("MSN's First Notice Letter") that it had submitted to the FDA ANDA No. 219095 ("MSN'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, ("MSN's ANDA Product") prior to the expiration of the '117 patent, the '340 patent, and '531 patent.

3. MSN notified Plaintiffs by letter dated February 28, 2024 ("MSN's Second Notice Letter," and together with MSN's First Notice Letter, "MSN's Notice Letters") that it had submitted to the FDA MSN's ANDA, seeking approval from the FDA to engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product prior to the expiration of the '437 patent.

The Parties

4. 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.

5. 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.

6. Upon information and belief, Defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware and having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Upon information and belief, MSN Pharmaceuticals is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

7. Upon information and belief, Defendant MSN Labs is a private limited company organized and existing under the laws of India and having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Teleangana, 500018 India. Upon information and belief, MSN Labs is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products through various operating subsidiaries and/or agents, including MSN Pharmaceuticals.

8. Upon information and belief, MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs and is dominated and controlled by MSN Labs.

9. Upon information and belief, MSN Pharmaceuticals and MSN Labs acted in concert to prepare and submit MSN's ANDA to the FDA.

10. Upon information and belief, MSN Pharmaceuticals and MSN Labs know and intend that upon approval of MSN's ANDA, MSN will manufacture, market, sell, and distribute MSN's ANDA Product throughout the United States, including in New Jersey. Upon information and belief, MSN Pharmaceuticals and MSN Labs are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to MSN's ANDA Product, and enter into agreements that are nearer than arm's length. Upon information and belief, MSN Pharmaceuticals and MSN Labs participated, assisted, and cooperated in carrying out the acts complained of herein.

11. Upon information and belief, following any FDA approval of MSN's ANDA, MSN Pharmaceuticals and MSN Labs will act in concert to distribute and sell MSN's ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

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

13. This Court has subject-matter jurisdiction 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 MSN Pharmaceuticals and MSN Labs.

15. Upon information and belief, MSN Pharmaceuticals and MSN Labs are 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 their own actions and/or through the actions of their agents and subsidiaries, from which MSN Pharmaceuticals and MSN Labs derive a substantial portion of their revenue.

16. Upon information and belief, MSN Pharmaceuticals is registered to do business in New Jersey under Entity Identification Number 0400627791 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5006107.

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

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

19. Upon information and belief, upon FDA approval of MSN's ANDA, MSN Pharmaceuticals and/or MSN Labs intend to market, offer to sell, sell, or distribute MSN's ANDA Product throughout the United States, including in New Jersey, consistently with MSN's practices for the marketing and distribution of other generic pharmaceutical products. Upon information

and belief, MSN 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, MSN's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, MSN'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 MSN's ANDA Product is approved before the Patents-in-Suit expire.

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

21. MSN Pharmaceuticals 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, MSN Pharmaceuticals 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, MSN Pharmaceuticals 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 New Jersey.

22. MSN Labs is subject to personal jurisdiction in New Jersey because, among other things, MSN Labs, itself and through its wholly owned subsidiary MSN Pharmaceuticals, has purposefully 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, MSN Labs, itself and through its subsidiary MSN Pharmaceuticals, 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 the New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within New Jersey. In addition, MSN Labs is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls and dominates MSN Pharmaceuticals, and therefore the activities of MSN Pharmaceuticals in this jurisdiction are attributed to MSN Labs.

23. This Court also has personal jurisdiction over MSN Pharmaceuticals and MSN Labs because, among other things, upon information and belief, MSN Labs and MSN Pharmaceuticals are agents of each other and/or operate in concert, and: (1) MSN filed MSN's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product in the United States, including in New Jersey; and (2) upon approval of MSN's ANDA, MSN will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import MSN's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of MSN's ANDA Product in New Jersey. Upon information and belief, upon approval of MSN's ANDA, MSN'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.

24. This Court also has personal jurisdiction over MSN Pharmaceuticals and MSN Labs because those entities have 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 MSN's actions were, and will be, suffered in New Jersey. MSN knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time MSN sent notice of the Paragraph IV certifications, it was reasonably foreseeable that MSN would be sued within 45 days in New Jersey, where MSN Pharmaceuticals is located. Upon information and belief, MSN'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.

25. This Court also has personal jurisdiction over MSN Pharmaceuticals and MSN Labs because those entities (1) engage in patent litigation concerning MSN's generic versions of branded pharmaceutical 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.*, *Bausch Health Ir. Ltd. v. MSN Lab'ys Private Ltd.*, No. 23-cv-3333, ECF No. 7 (D.N.J. July 6, 2023); *GW Rsch. Ltd. v. Teva Pharms., Inc.*, No. 23-cv-18, ECF No. 95 (D.N.J. Mar. 17, 2023).

26. For the above reasons, it would not be unfair or unreasonable for MSN Pharmaceuticals and MSN Labs to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

Venue

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

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

29. Venue is proper in this District as to MSN Pharmaceuticals under 28 U.S.C. § 1391, at least because, upon information and belief, MSN Pharmaceuticals 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.

30. Venue is proper in this District as to MSN Pharmaceuticals under 28 U.S.C. § 1400(b), at least because, upon information and belief, MSN Pharmaceuticals 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) MSN prepared and/or submitted MSN's ANDA with Paragraph IV certifications in New Jersey, where MSN Pharmaceuticals is located; and (2) upon approval of MSN's ANDA, MSN will market, distribute, offer for sale, sell, and/or import MSN's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of MSN's ANDA Product in New Jersey.

31. Venue is proper in this District as to MSN Pharmaceuticals and MSN Labs because those entities (1) engage in patent litigation concerning MSN's generic versions of branded pharmaceutical products in this District, and (2) do not contest that venue is proper in this District.

See, e.g., *Bausch Health Ir. Ltd. v. MSN Lab'ys Private Ltd.*, No. 23-cv-3333, ECF No. 7 (D.N.J. July 6, 2023); *GW Rsch. Ltd. v. Teva Pharms., Inc.*, No. 23-cv-18, ECF No. 95 (D.N.J. Mar. 17, 2023).

Factual Background

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

33. 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.

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

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

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

37. Upon information and belief, MSN's ANDA Product is not publicly available, nor is ANDA No. 219095 accessible to the public.

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

39. In an exchange of correspondence, counsel for Plaintiffs and counsel for MSN discussed the terms of MSN's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, MSN's Drug Master File or all relevant characterization data. MSN further refused to produce samples of MSN's ANDA Product and other internal documents and material relevant to infringement.

40. This action is being commenced within 45 days from the date Plaintiffs received MSN's First Notice Letter and MSN's Second Notice Letter.

Count I – Infringement of the '117 Patent

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

42. 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.

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

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

45. 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").

46. In MSN's First Notice Letter, MSN notified BeiGene of the submission of MSN'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 MSN's ANDA Product prior to the expiration of the Patents-in-Suit, including the '117 patent.

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

48. In MSN's First Notice Letter, MSN did not contest the validity of any claim of the '117 patent.

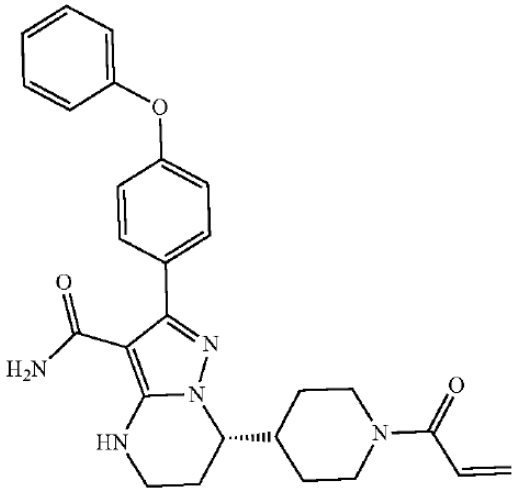
49. According to MSN's First Notice Letter, MSN's ANDA Product contains zanubrutinib.

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

51. 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±0.2º and 21.4±0.2º.

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

53. 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.

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

55. Upon information and belief, MSN's ANDA Product contains a pharmaceutically acceptable excipient.

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

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

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

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

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

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

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

63. Notwithstanding MSN's knowledge of the claims of the '117 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's

ANDA Product with its product labeling following FDA approval of MSN's ANDA prior to the expiration of the '117 patent.

64. The foregoing actions by MSN 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.

65. Upon information and belief, MSN 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.

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

67. Unless MSN 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

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

69. 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 MSN on the other regarding MSN's infringement, active inducement of infringement and contribution to the infringement by others of the '117 patent.

70. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of MSN's ANDA Product with its proposed labeling, or any other MSN 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.

Count III – Infringement of the '340 Patent

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

72. 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.

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

74. BeiGene Switzerland GmbH is the owner and assignee of the '340 patent.

75. 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.

76. In MSN's First Notice Letter, MSN notified BeiGene of the submission of MSN'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 MSN's ANDA Product prior to the expiration of the Patents-in-Suit, including the '340 patent.

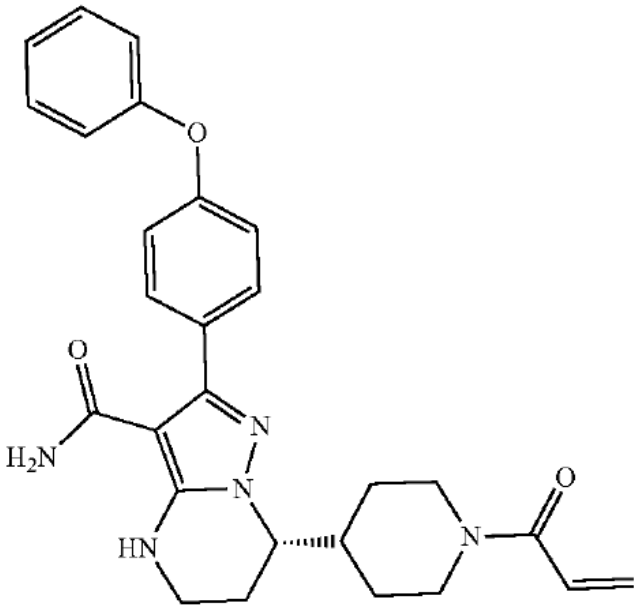
77. In MSN's First Notice Letter, MSN also notified BeiGene that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '340 patent. Upon information and belief, MSN submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '340 patent will not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

78. In MSN's First Notice Letter, MSN did not contest the validity of any claim of the '340 patent.

79. According to MSN's First Notice Letter, MSN's ANDA Product contains zanubrutinib.

80. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe one or more claims of the '340 patent.

81. As an example, claim 1 of the '340 patent recites:

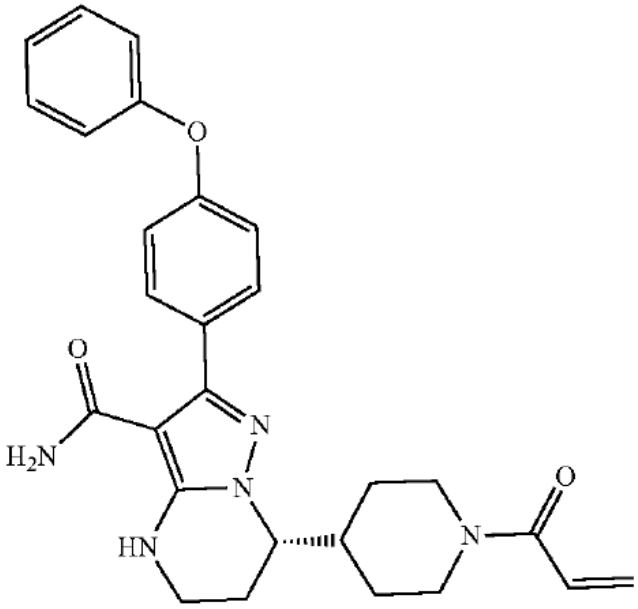
> A method for treating mantle cell lymphoma in a subject, comprising administering to the subject in need thereof a crystalline form of Compound 1,
>
> Compound 1
>
> 
>
>
> wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values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

82. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN'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.

83. 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



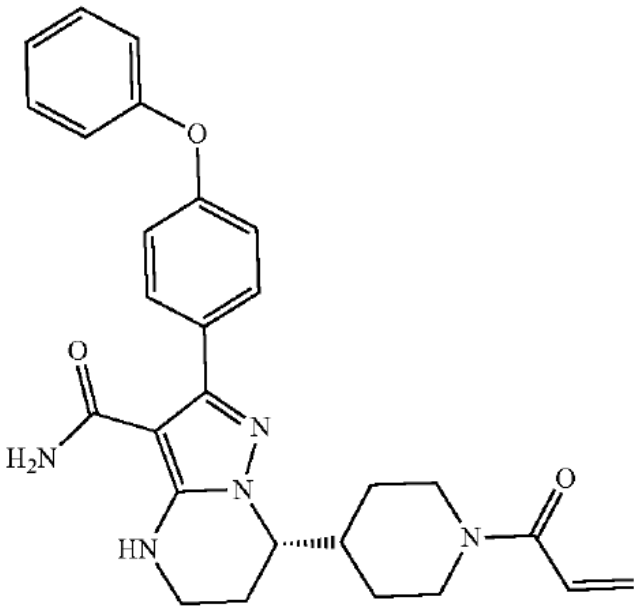
> wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

84. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN'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.

85. 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



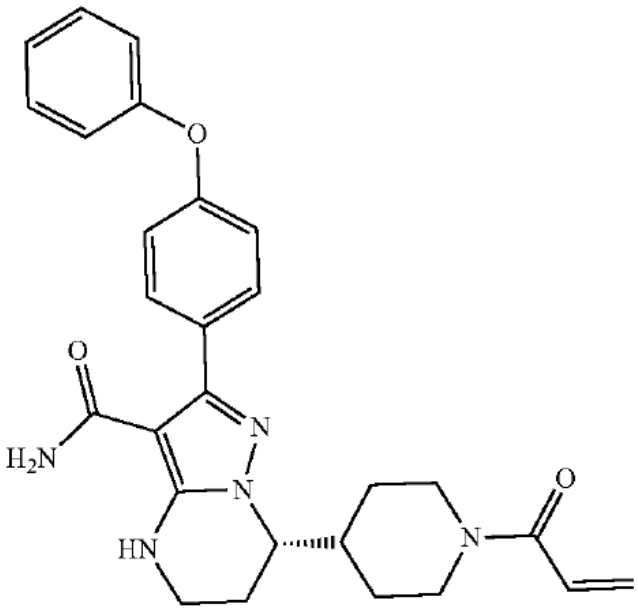
wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

86. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN'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.

87. 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.

88. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN'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.

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

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

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

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

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

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

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

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

97. The foregoing actions by MSN 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.

98. Upon information and belief, MSN 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.

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

100. Unless MSN 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

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

102. 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 MSN on the other regarding MSN's infringement, active inducement of infringement, and contribution to the infringement by others of the '340 patent.

103. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of MSN's ANDA Product with its proposed labeling, or any other MSN 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.

Count V – Infringement of the ’531 Patent

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

105. The ’531 patent, entitled “Methods of Treating B-Cell Proliferative Disorder” (attached as Exhibit C), was duly and legally issued on October 17, 2023.

106. The inventors named on the ’531 patent are Jason Paik, Tommi Salmi, and Ying Ou.

107. BeiGene Switzerland GmbH is the owner and assignee of the ’531 patent.

108. Methods of using BRUKINSA® are covered by one or more claims of the ’531 patent, which has been listed in connection with BRUKINSA® in the FDA’s Orange Book.

109. In MSN’s First Notice Letter, MSN notified BeiGene of the submission of MSN’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 MSN’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’531 patent.

110. In MSN’s First Notice Letter, MSN also notified BeiGene that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the ’531 patent. Upon information and belief, MSN submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’531 patent will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of MSN’s ANDA Product.

111. In MSN’s First Notice Letter, MSN did not contest the validity of any claim of the ’531 patent.

112. According to MSN’s First Notice Letter, MSN’s ANDA Product contains zanubrutinib.

113. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed product labeling would infringe one or more claims of the '531 patent.

114. As an example, claim 1 of the '531 patent recites:

> A method of treating or delaying progression of a B-cell proliferative disorder in a patient receiving a moderate CYP3A inducer, the method comprising,
>
> concomitantly administering to the patient zanubrutinib, or a pharmaceutically acceptable salt thereof, at a total daily dose of about 640 mg, and the moderate CYP3A inducer,
>
> wherein the B-cell proliferative disorder is chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenström macroglobulinemia (WM), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), or follicular lymphoma (FL).

115. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed product labeling would involve a method of treating or delaying progression of a B-cell proliferative disorder in a patient receiving a moderate CYP3A inducer, the method comprising the steps recited in claim 1 of the '531 patent.

116. As a further example, claim 11 of the '531 patent recites:

> A method of treating or delaying progression of a B-cell proliferative disorder in a patient, the method comprising,
>
> determining whether the patient is being treated with a moderate CYP3A inducer; and
>
> if the patient is being treated with a moderate CYP3A inducer, concomitantly administering to the patient zanubrutinib, or a pharmaceutically acceptable salt thereof, at a total daily dose of about 640 mg; and the moderate CYP3A inducer,
>
> wherein the B-cell proliferative disorder is chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenström macroglobulinemia (WM), mantle cell lymphoma

> (MCL), marginal zone lymphoma (MZL), or follicular lymphoma (FL).

117. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed product labeling would involve a method of treating or delaying progression of a B-cell proliferative disorder in a patient, the method comprising the steps recited in claim 11 of the '531 patent.

118. Claim 21 of the '531 patent recites:

> A method of treating or delaying progression of a B-cell proliferative disorder in a patient receiving a moderate CYP3A inducer, the method comprising,
>
> assessing the patient as to whether administration of the moderate CYP3A inducer can be avoided; and
>
> if the administration of the moderate CYP3A inducer cannot be avoided, concomitantly administering to the patient zanubrutinib, or a pharmaceutically acceptable salt thereof, at a total daily dose of about 640 mg, and the moderate CYP3A inducer,
>
> wherein the B-cell proliferative disorder is chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenström macroglobulinemia (WM), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), or follicular lymphoma (FL).

119. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed product labeling would involve a method of treating or delaying progression of a B-cell proliferative disorder in a patient receiving a moderate CYP3A inducer, the method comprising of the steps recited in claim 21 of the '531 patent.

120. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed product labeling would infringe claims 1 through 30 of the '531 patent.

121. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before the expiration of the '531 patent was an act of infringement of the '531 patent under 35 U.S.C. § 271(e)(2)(A).

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

123. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product would infringe one or more claims of the '531 patent.

124. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '531 patent.

125. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '531 patent when MSN's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. MSN's activities will be done with knowledge of the '531 patent and specific intent to infringe that patent.

126. Upon information and belief, MSN knows that MSN's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '531 patent, that MSN's ANDA Product is not a staple article or commodity of commerce, and that MSN's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, MSN plans and intends to, and will, contribute to infringement of the '531 patent immediately and imminently upon approval of MSN's ANDA.

127. Notwithstanding MSN's knowledge of the claims of the '531 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's ANDA Product with its product labeling following FDA approval of MSN's ANDA prior to the expiration of the '531 patent.

128. The foregoing actions by MSN constitute and/or will constitute infringement of the '531 patent; active inducement of infringement of the '531 patent; and/or contribution to the infringement by others of the '531 patent.

129. Upon information and belief, MSN has acted with full knowledge of the '531 patent and without a reasonable basis for believing that it would not be liable for infringement of the '531 patent; active inducement of infringement of the '531 patent; and/or contribution to the infringement by others of the '531 patent.

130. BeiGene will be substantially and irreparably damaged by infringement of the '531 patent.

131. Unless MSN is enjoined from infringing the '531 patent, actively inducing infringement of the '531 patent, and contributing to the infringement by others of the '531 patent, BeiGene will suffer irreparable injury. BeiGene has no adequate remedy at law.

Count VI - Declaratory Judgment of Infringement of the '531 Patent

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

133. 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 MSN on the other regarding MSN's infringement, active inducement of infringement, and contribution to the infringement by others of the '531 patent.

134. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of MSN's ANDA Product with its proposed labeling, or any other MSN drug product that is covered by or whose use is covered by the '531 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '531 patent.

Count VII – Infringement of the '437 Patent

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

136. The '437 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 D), was duly and legally issued on December 26, 2023.

137. The inventors named on the '437 patent are Zhiwei Wang, Yunhang Guo, and Gongyin Shi.

138. BeiGene Switzerland GmbH is the owner and assignee of the '437 patent.

139. BRUKINSA® is covered by one or more claims of the '437 patent, which has been listed in connection with BRUKINSA® in the FDA's Orange Book.

140. In MSN's Second Notice Letter, MSN notified BeiGene of the submission of MSN'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 MSN's ANDA Product prior to the expiration of the Patents-in-Suit, including the '437 patent.

141. In MSN's Second Notice Letter, MSN also notified BeiGene that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '437 patent. Upon information and belief, MSN submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '437 patent will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product.

142. In MSN's Second Notice Letter, MSN did not contest the validity of any claim of the '437 patent.

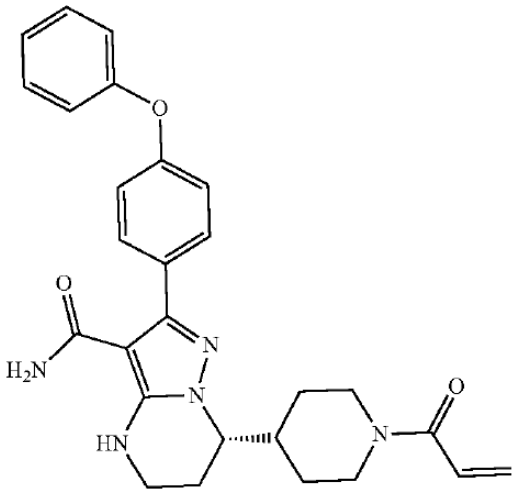
143. According to MSN's Second Notice Letter, MSN's ANDA Product contains zanubrutinib.

144. Upon information and belief, MSN's ANDA Product and the use of MSN's ANDA Product are covered by one or more claims of the '437 patent, either literally or under the doctrine of equivalents.

145. As an example, claim 1 of the '437 patent recites:

Crystalline Form A of Compound 1,

Compound 1



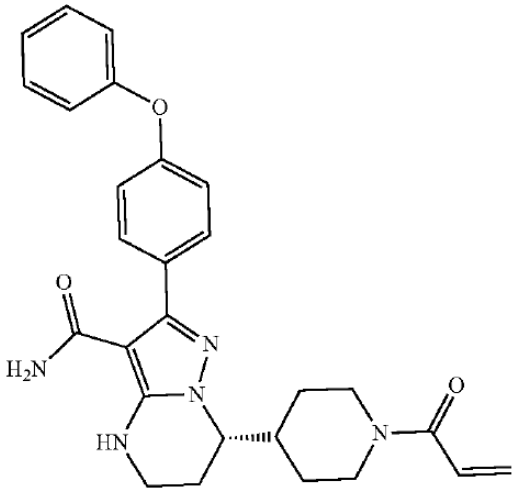
made by crystallizing the crystalline Form A of Compound 1 from an amorphous form of Compound 1, wherein the crystalline Form A is characterized by an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 16.4±0.2º and 21.4±0.2º.

146. Upon information and belief, MSN's ANDA Product contains the Crystalline Form A of Compound 1, as recited in Claim 1.

147. As a further example, claim 11 of the '437 patent recites:

Crystalline Form A of Compound 1,

Compound 1



wherein:

(i) the crystalline Form A is characterized by an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 16.4±0.2º and 21.4±0.2º; and

(ii) the crystalline Form A

(a) does not change its crystal form after being stored at about 80° C. for 2 days;

(b) does not change its crystal form after being stored at about 25° C. under 60% relative humidity for up to 24 months; or

(c) does not change its crystal form after being stored at about 40° C. under 75% relative humidity for up to 6 months.

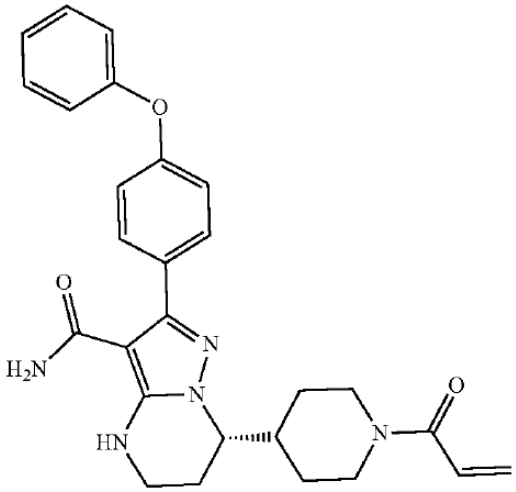
148. Upon information and belief, MSN's ANDA Product contains the Crystalline Form A of Compound 1 as recited in in Claim 11.

149. Claim 20 of the '437 patent recites:

A composition comprising:

Crystalline Form A 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°, 16.4±0.2º and 21.4±0.2º;

and an amorphous form of Compound 1.

150. Upon information and belief, MSN's ANDA Product contains the Crystalline Form A of Compound 1 and an amorphous form of Compound 1, as recited in Claim 20.

151. Upon information and belief, MSN's ANDA Product infringes claims 1 through 29 of the '437 patent, literally or under the doctrine of equivalents.

152. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before the expiration of the '437 patent was an act of infringement of the '437 patent under 35 U.S.C. § 271(e)(2)(A).

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

154. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '437 patent.

155. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '437 patent.

156. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '437 patent when MSN's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. MSN's activities will be done with knowledge of the '437 patent and specific intent to infringe that patent.

157. Upon information and belief, MSN knows that MSN's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '437 patent, that MSN's ANDA Product is not a staple article or commodity of commerce, and that MSN's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, MSN plans and intends to, and will, contribute to infringement of the '437 patent immediately and imminently upon approval of MSN's ANDA.

158. Notwithstanding MSN's knowledge of the claims of the '437 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's ANDA Product with its product labeling following FDA approval of MSN's ANDA prior to the expiration of the '437 patent.

159. The foregoing actions by MSN constitute and/or will constitute infringement of the '437 patent; active inducement of infringement of the '437 patent; and/or contribution to the infringement by others of the '437 patent.

160. Upon information and belief, MSN has acted with full knowledge of the '437 patent and without a reasonable basis for believing that it would not be liable for infringement of the '437 patent; active inducement of infringement of the '437 patent; and/or contribution to the infringement by others of the '437 patent.

161. BeiGene will be substantially and irreparably damaged by infringement of the '437 patent.

162. Unless MSN is enjoined from infringing the '437 patent, actively inducing infringement of the '437 patent, and contributing to the infringement by others of the '437 patent, BeiGene will suffer irreparable injury. BeiGene has no adequate remedy at law.

Count VIII - Declaratory Judgment of Infringement of the '437 Patent

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

164. 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 MSN on the other regarding MSN's infringement, active inducement of infringement, and contribution to the infringement by others of the '437 patent.

165. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of MSN's ANDA Product with its proposed labeling, or any other MSN drug product that is covered by or whose use is covered by the '437 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '437 patent.

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 MSN's submission to the FDA of MSN's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of MSN'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 MSN, and all persons acting in concert with MSN, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of MSN'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 MSN'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*
Liza M. Walsh
Katelyn O'Reilly
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102-5310
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
lmalakoff@walsh.law

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Michael Xun Liu
Christie K. Corn
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
cmandernach@wc.com
mliu@wc.com
ccorn@wc.com

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

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.

Dated: March 8, 2024

By: *s/ Liza M. Walsh*
Liza M. Walsh
Katelyn O'Reilly
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102-5310
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
lmalakoff@walsh.law

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Michael Xun Liu
Christie K. Corn
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
cmandernach@wc.com
mliu@wc.com
ccorn@wc.com

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

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*
Liza M. Walsh
Katelyn O'Reilly
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102-5310
(973) 757-1100
lwalsh@walsh.law
koreilly@walsh.law
lmalakoff@walsh.law

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Michael Xun Liu
Christie K. Corn
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024
(202) 434-5000
dberl@wc.com
cmandernach@wc.com
mliu@wc.com
ccorn@wc.com

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