Eric I. Abraham (eabraham@hillwallack.com)
William P. Murtha (wmurtha@hillwallack.com)
HILL WALLACK LLP
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08543-5226
(609) 734-6358

Charles B. Klein (cklein@winston.com) (*Pro Hac Vice*)
Jovial Wong (jwong@winston.com) (*Pro Hac Vice*)
WINSTON & STRAWN LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5977

Eimeric Reig-Plessis (ereigplessis@winston.com) (*Pro Hac Vice*)
WINSTON & STRAWN LLP
101 California Street, 35th Floor
San Francisco, California 94111
(415) 591-6808

Annie R. Steiner (asteiner@winston.com) (*Pro Hac Vice*)
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601
(312) 558-6092

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BEIGENE USA, INC. and BEIGENE SWITZERLAND GMBH, Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No.: 3:24-cv-1972 **ANSWER, DEFENSES, AND COUNTERCLAIMS OF DEFENDANT SANDOZ INC. TO SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Sandoz Inc. ("Sandoz"), by and through the undersigned attorneys, submits its answer, affirmative defenses, and counterclaim to the Second Amended Complaint ("Complaint") for patent infringement of Plaintiffs BeiGene USA, Inc. ("BeiGene USA") and BeiGene Switzerland GmbH ("BeiGene Switzerland") (together, "BeiGene" or "Plaintiffs"). Sandoz denies all allegations in Plaintiffs' Complaint except those admitted specifically below. This pleading is based upon Sandoz's knowledge of its own activities, and upon information and belief as to the activities of others.

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"), U.S. Patent No. 11,591,340 ("the '340 patent"), U.S. Patent No. 11,851,437 ("the '437 patent"), and U.S. Patent No. 11,884,674 ("the '674 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that this is an action alleging infringement of the '117 patent, the '340 patent, the '437 patent, and the '674 patent. Sandoz denies all remaining allegations.

2. Sandoz notified Plaintiffs by letter dated January 24, 2024 ("Sandoz's First 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 '117 patent and the '340 patent.

ANSWER: Sandoz admits that it sent Plaintiffs a letter dated January 24, 2024 ("Sandoz's First Notice Letter") notifying Plaintiffs that it had submitted Sandoz's ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Products before the expiration

of the ’117 patent and the ’340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

3. On March 8, 2024, Plaintiffs filed the present action, in which Plaintiffs alleged that Sandoz’s submission of Sandoz’s ANDA infringes the ’117 and ’340 patents. D.I. 1.

ANSWER: Sandoz admits that Plaintiffs filed the present action on March 8, 2024 alleging infringement of the ’117 patent and the ’340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

4. Sandoz notified Plaintiffs by letter dated March 7, 2024 (“Sandoz’s Second Notice Letter”) that it had submitted to the FDA Sandoz’s ANDA, 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 the ’437 patent.

ANSWER: Sandoz admits that it sent Plaintiffs a letter dated March 7, 2024 (“Sandoz’s Second Notice Letter”) notifying Plaintiffs that it had submitted Sandoz’s ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz’s ANDA Products before the expiration of the ’437 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

5. Plaintiffs received Sandoz’s Second Notice Letter on March 8, 2024, after Plaintiffs already filed their complaint for patent infringement of the ’117 and ’340 patents.

ANSWER: Sandoz admits that BeiGene USA received Sandoz’s Second Notice Letter on March 8, 2024. Sandoz admits that BeiGene Switzerland received Sandoz’s Second Notice Letter after Plaintiffs had filed their complaint as to the ’117 and ’340 patents. Sandoz lacks sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

6. On March 19, 2024, Plaintiffs filed the First Amended Complaint, in which Plaintiffs alleged that Sandoz’s submission of Sandoz’s ANDA infringes the ’117, ’340, and ’437 patents. D.I. 7.

ANSWER: Sandoz admits that Plaintiffs filed a First Amended Complaint on March 19, 2024 alleging infringement of the '117, '340, and '437 patents. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

7. Sandoz notified Plaintiffs by letter dated April 30, 2024 ("Sandoz's Third Notice Letter," and together with Sandoz's First Notice Letter and Sandoz's Second Notice Letter, "Sandoz's Notice Letters") that it had submitted to the FDA Sandoz's ANDA, 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 the '674 patent.

ANSWER: Sandoz admits that it sent Plaintiffs a letter dated April 30, 2024 ("Sandoz's Third Notice Letter") notifying Plaintiffs that it had submitted Sandoz's ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Products before the expiration of the '674 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

THE PARTIES

8. 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.

ANSWER: Sandoz lacks sufficient knowledge or information to form a belief as to the allegations of this paragraph, and therefore denies the same.

9. 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.

ANSWER: Sandoz lacks sufficient knowledge or information to form a belief as to the allegations of this paragraph, and therefore denies the same.

10. 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.

ANSWER: Sandoz admits that it is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz further admits that it seeks regulatory approval of and sells generic products in the United States. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

11. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Products. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

JURISDICTION

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

ANSWER: Sandoz incorporates its answers to 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz does not contest subject-matter jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest subject-matter jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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 Sandoz.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

15. 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.

ANSWER: Sandoz admits that it has a principal place of in New Jersey. Sandoz further admits that it seeks regulatory approval of and sells generic products in the United States. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

16. 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.

ANSWER: Sandoz admits that it is registered in New Jersey under Entity Identification Number 0100097265 and with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

17. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product throughout the United States.

Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

18. 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").

ANSWER: Sandoz admits that it submitted ANDA No. 218957 with the FDA with a Paragraph IV Certification seeking FDA approval to manufacture, use, or sell Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

19. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product throughout the United States. Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

20. 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.

ANSWER: Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

21. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

22. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product throughout the United States. Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

23. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product throughout the United States. Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

24. 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it did not contest personal jurisdiction for the civil actions listed in paragraph 24 for purposes of those actions only. Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

25. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

VENUE

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

27. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz does not contest that venue is proper in New Jersey for purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

28. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it has a principal place of business in New Jersey. Sandoz further admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product throughout the United States. Sandoz does not contest that venue is proper in New Jersey for purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

29. 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Sandoz admits that it did not contest venue for the civil actions listed in paragraph 29 for purposes of those actions only. Sandoz does not contest that venue is proper in New Jersey for purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

31. 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.

ANSWER: Sandoz admits that the BRUKINSA® Prescribing Information, revised in March 2024, states the following:

> BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:
>
> - Mantle cell lymphoma (MCL) who have received at least one prior therapy. (1.1) This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
> - Waldenström's macroglobulinemia (WM). (1.2)
> - Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti–CD20-based regimen. (1.3) This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
> - Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). (1.4)
> - Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy. (1.5) This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Sandoz further admits that the BRUKINSA® Prescribing Information provides that the active ingredient in BRUKINSA® is zanubrutinib. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

32. In Sandoz's Notice Letters, Sandoz stated that the subject of Sandoz's ANDA is zanubrutinib capsules, 80 mg. In Sandoz's Notice Letters, 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®.

ANSWER: Sandoz admits that Sandoz's Notice Letters notified Plaintiffs that Sandoz filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell zanubrutinib capsules 80 mg. Sandoz admits that Sandoz's Notice Letters stated that ANDA No. 218957 was submitted under 21 U.S.C. § 355(j)(1) and (2)(A) and contained the required bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

33. In Sandoz's Notice Letters, 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.

ANSWER: Sandoz admits that Sandoz's Notice Letters notified Plaintiffs that Sandoz's ANDA No. 218957 includes a Paragraph IV Certification seeking FDA approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Sandoz admits that its Notice Letters provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) regarding the Patents-in-Suit. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

34. 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.

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product. Sandoz further admits that ANDA No. 218957 is not accessible to the public. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

36. In Sandoz's Notice Letters, 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.

ANSWER: Sandoz admits that Sandoz's Notice Letters each contained an "Offer of Confidential Access." Sandoz denies that the "Offer of Confidential Access" was subject to any unreasonably restrictive conditions. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

37. 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.

ANSWER: Sandoz admits that counsel for Plaintiffs and counsel for Sandoz discussed the terms of the "Offer for Confidential Access" contained in Sandoz's Notice Letters but were unable to agree on the terms. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

38. This action was commenced within 45 days from the date Plaintiffs received Sandoz's First Notice Letter.

ANSWER: Sandoz admits that Plaintiffs filed the present action on March 8, 2024, which was within 45 days of receipt of Sandoz's First Notice Letter.

39. The First Amended Complaint was filed within 45 days from the date Plaintiffs received Sandoz's Second Notice Letter.

ANSWER: Sandoz admits that Plaintiffs filed the First Amended Complaint on March 19, 2024, which was within 45 days of receipt of Sandoz's Second Notice Letter.

40. This Second Amended Complaint is being filed within 45 days from the date Plaintiffs received Sandoz's Third Notice Letter.

ANSWER: Sandoz admits that Plaintiffs filed the Second Amended Complaint on May 15, 2024, which was within 45 days of receipt of Sandoz's Second Notice Letter.

COUNT I
[Alleged] Infringement of the '117 Patent

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

ANSWER: Sandoz incorporates its answers to 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.

ANSWER: Sandoz admits that a purported copy of the '117 patent is attached to Plaintiffs' Complaint as Exhibit A, and that, on its face, the '117 patent is titled "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" and bears an issuance date of February 23, 2021. Sandoz denies that the '117 patent was duly or legally issued. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that the face of the '117 patent names Zhiwei Wang, Yunhang Guo, and Gongyin Shi as purported inventors.

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

ANSWER: Sandoz admits that the face of the '117 patent lists BeiGene Switzerland GmbH as the alleged assignee. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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").

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the '117 patent is listed in the FDA's Orange Book in connection with BRUKINSA®. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

46. In Sandoz's First 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.

ANSWER: Sandoz admits that Sandoz's First Notice Letter notified Plaintiffs that Sandoz submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '117 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

47. In Sandoz's First 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.

ANSWER: Sandoz admits that Sandoz's First Notice Letter notified Plaintiffs that Sandoz's ANDA No. 218957 includes a Paragraph IV Certification seeking FDA approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '117 patent. Sandoz admits that its First Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)

regarding the '117 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that it submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell zanubrutinib capsules 80 mg. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

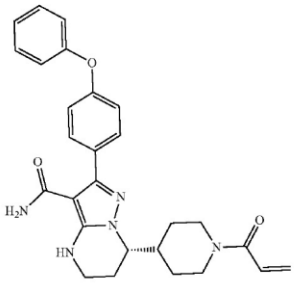
49. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '117 patent, either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

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

A crystalline form of Compound 1,

Compound 1

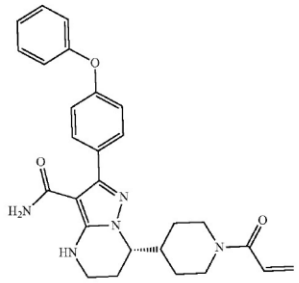


wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2° and 21.4±0.2°.

ANSWER: Sandoz admits that 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.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that its ANDA Product contains a crystalline form of Compound 1, as recited in claim 1 of the '117 patent.

52. 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.

ANSWER: Sandoz admits that 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."

53. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that its ANDA Product is a pharmaceutical composition comprising a therapeutically effective amount of the crystalline form of the compound recited in claim 1 of the '117 patent.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that its ANDA Product is expected to contain one or more excipients. Except as expressly admitted, Sandoz denies the remaining allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

56. 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

57. 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.

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

58. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

59. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

60. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

61. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

62. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '117 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

63. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

64. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

65. BeiGene will be substantially and irreparably damaged by infringement of the ’117 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

66. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT II
Declaratory Judgment of [Alleged] Infringement of the ’117 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

68. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs’ Complaint purports to bring an action for infringement of the ’117 patent, and that the action purports to arise under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

69. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT III
[Alleged] Infringement of the '340 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

71. 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.

ANSWER: Sandoz admits that a purported copy of the '340 patent is attached to Plaintiffs' Complaint as Exhibit B, and that, on its face, the '340 patent is titled "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" and bears an issuance date of February 28, 2023. Sandoz denies that the '340 patent was duly or legally issued. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that the face of the '340 patent names Zhiwei Wang, Yunhang Guo, Gongyin Shi, and Lai Wang as purported inventors.

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

ANSWER: Sandoz admits that the face of the '340 patent lists BeiGene Switzerland GmbH as the purported assignee. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

74. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the '340 patent is listed in the FDA's Orange Book in connection with BRUKINSA®. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

75. In Sandoz's First 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 '340 patent.

ANSWER: Sandoz admits that Sandoz's First Notice Letter notified Plaintiffs that Sandoz submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

76. In Sandoz's First Notice Letter, Sandoz also notified Plaintiffs 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.

ANSWER: Sandoz admits that Sandoz's First Notice Letter notified Plaintiffs that Sandoz's ANDA No. 218957 includes a Paragraph IV Certification seeking FDA approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '340 patent. Sandoz admits that its First Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)

regarding the ’340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that it submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell zanubrutinib capsules 80 mg. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

78. In Sandoz’s Third Notice Letter, Sandoz notified BeiGene that Sandoz had filed updated Paragraph IV certifications with respect to the ’340 patent. Sandoz also notified BeiGene that it was maintaining its Paragraph IV certifications with respect to the ’340 patent for the same factual and legal basis as previously described in Sandoz’s First Notice Letter.

ANSWER: Sandoz admits that Sandoz’s Third Notice Letter notified BeiGene that Sandoz provided an updated Paragraph IV Certification to the FDA with respect to the ’340 patent to address newly listed use codes U-3727, U-3728, and U-3729, which were added to the Orange Book in connection with the ’340 patent and BRUKINSA®. Sandoz admits that the Third Notice Letter notified BeiGene that Sandoz was maintaining its Paragraph IV certifications with respect to the ’340 patent for the same factual and legal basis as previously described in Sandoz’s First Notice Letter. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

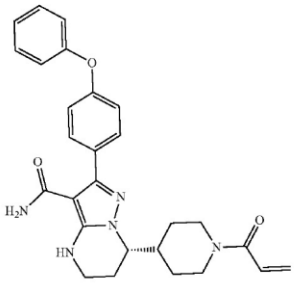
79. Upon information and belief, the use of Sandoz’s ANDA Product in accordance with and as directed by Sandoz’s proposed labeling for that product would infringe one or more claims of the ’340 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

80. 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

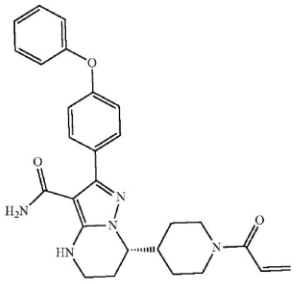


wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

ANSWER: Sandoz admits that 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.

81. 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.

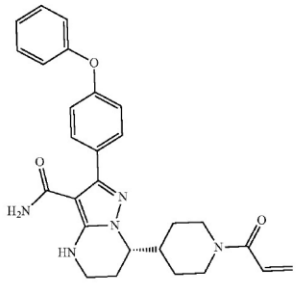
ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that the use of its ANDA Product in accordance with and as directed by Sandoz’s proposed label would involve treating mantle cell lymphoma by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim

1 of the ’340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

82. 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

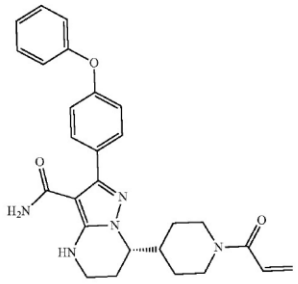


wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

ANSWER: Sandoz admits that 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

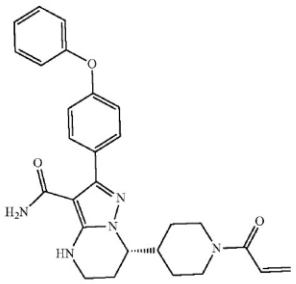


wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2º and 21.4±0.2º.

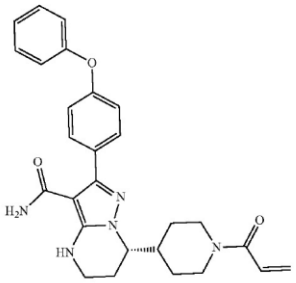
83. Upon information and belief, the use of Sandoz’s ANDA Product in accordance with and as directed by Sandoz’s proposed label would involve treating Waldenström's macroglobulinemia in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that the use of its ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating Waldenström's macroglobulinemia by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 8 of the '340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

84. 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±0.2°, and 21.4±0.2°.

ANSWER: Sandoz admits that 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±0.2°, and 21.4±0.2°.

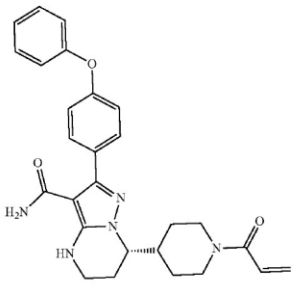
85. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating marginal zone lymphoma in a subject, including by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 14.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that the use of its ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating marginal zone lymphoma by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 14 of the '340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

86. 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

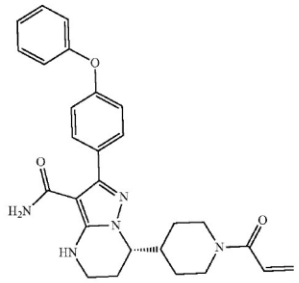


wherein the crystalline form exhibits an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 15.6±0.2°, 16.4±0.2°, and 21.4±0.2°.

ANSWER: Sandoz admits that 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±0.2°, and 21.4±0.2°.

87. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that the use of its ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating chronic lymphocytic leukemia or small lymphocytic lymphoma by administering to the subject in need thereof a crystalline form of Compound 1 as recited in claim 21 of the '340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

88. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

89. 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).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

90. 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.

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

91. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

92. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

93. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

94. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

95. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '340 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

96. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

97. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

99. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT IV
Declaratory Judgment of [Alleged] Infringement of the '340 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

101. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs' Complaint purports to bring an action for infringement of the '340 patent, and that the action purports to arise under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

102. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT V
[Alleged] Infringement of the '437 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

104. 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 C), was duly and legally issued on December 26, 2023.

ANSWER: Sandoz admits that a purported copy of the '437 patent is attached to Plaintiffs' Complaint as Exhibit A, and that, on its face, the '437 patent is titled "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" and bears an issuance date of December 26, 2023. Sandoz denies that the '437 patent was duly or legally issued. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that the face of the '437 patent names Zhiwei Wang, Yunhang Guo, and Gongyin Shi as purported inventors.

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

ANSWER: Sandoz admits that the face of the '437 patent lists BeiGene Switzerland GmbH as the purported assignee. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

107. 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the '437 patent is listed in the FDA's Orange Book in connection with BRUKINSA®. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

108. In Sandoz's Second Notice Letter, Sandoz also notified BeiGene that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '437 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '437 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.

ANSWER: Sandoz admits that Sandoz's Second Notice Letter notified Plaintiffs that Sandoz submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '437 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

109. In Sandoz's First Notice Letter, Sandoz also notified Plaintiffs that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '437 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '437 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.

ANSWER: Sandoz admits that Sandoz's First Notice Letter notified Plaintiffs that Sandoz's ANDA No. 218957 includes a Paragraph IV Certification seeking FDA approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '437 patent. Sandoz admits that its First Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) regarding the '437 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

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

ANSWER: Sandoz admits that it submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell zanubrutinib capsules 80 mg. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

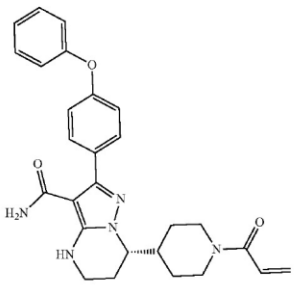
111. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '437 patent, either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

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

Crystalline Form A of Compound 1,

Compound 1

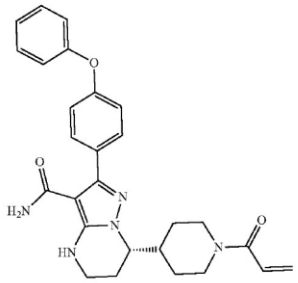


made by crystallizing the crystalline Form A of Compound 1 from an amorphous form of Compound 1, wherein the crystalline Form A is characterized by an X-ray powder diffraction pattern comprising diffraction peaks having 2θ angle values at 14.8±0.2°, 16.4±0.2° and 21.4±0.2°.

ANSWER: Sandoz admits that 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±0.2° and 21.4±0.2°.

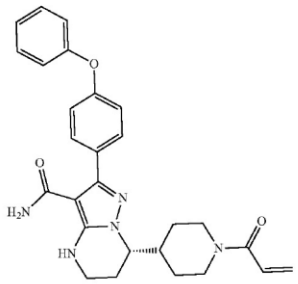
113. Upon information and belief, Sandoz's ANDA Product contains the Crystalline Form A of Compound 1, as recited in Claim 1.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that its ANDA Product contains the Crystalline Form A of Compound 1, as recited in claim 1 of the '437 patent.

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

Crystalline Form A of Compound 1,

Compound 1



wherein:

(1) 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±0.2° and 21.4±0.2°; and

(2) the crystalline Form A

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

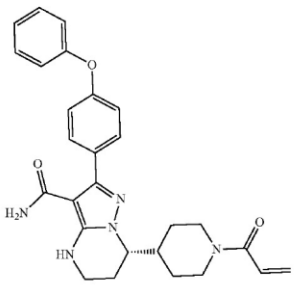
(b) does not change its crystal form after being stored at about 25° C. under 60% relative humidity for up to 24 months; or

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

ANSWER: Sandoz admits that claim 11 of the '437 patent recites:

Crystalline Form A of Compound 1,

Compound 1



wherein:

(1) 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±0.2° and 21.4±0.2°; and

(2) 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.

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

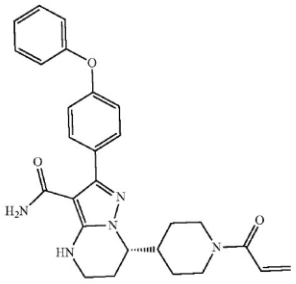
ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that its ANDA Product contains the Crystalline Form A of Compound 1, as recited in in claim 11 of the '437 patent.

116. 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±0.2° and 21.4±0.2°;

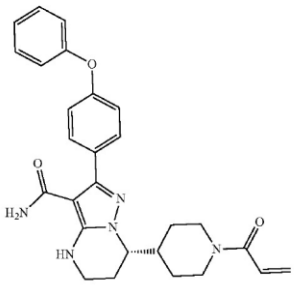
and an amorphous form of Compound 1.

ANSWER: Sandoz admits that 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±0.2° and 21.4±0.2°;

and an amorphous form of Compound 1.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that its ANDA Product contains the Crystalline Form A of Compound 1 and an amorphous form of Compound 1, as recited in claim 20 of the '437 patent.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

119. 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 '437 patent was an act of infringement of the '437 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

120. 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.

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

121. 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 '437 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

122. 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 '437 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

123. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '437 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 '437 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

124. 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 '437 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 '437 patent immediately and imminently upon approval of Sandoz's ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

125. Notwithstanding Sandoz's knowledge of the claims of the '437 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 '437 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

126. The foregoing actions by Sandoz 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

127. Upon information and belief, Sandoz 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

129. Unless Sandoz 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.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT VI
Declaratory Judgment of [Alleged] Infringement of the '437 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

131. 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 '437 patent, and/or the validity of the '437 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs' Complaint purports to bring an action for infringement of the '437 patent, and that the action purports to arise under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

132. 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 '437 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '437 patent, and that the claims of the '437 patent are not invalid.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT VII
[Alleged] Infringement of the '674 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

134. The '674 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 January 30, 2024.

ANSWER: Sandoz admits that a purported copy of the '674 patent is attached to Plaintiffs' Complaint as Exhibit D, and that, on its face, the '674 patent is titled "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" and bears an issuance date of January 30, 2024. Sandoz denies that the '674 patent was duly or legally issued. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

135. The inventors named on the '674 patent are Zhiwei Wang, Yunhang Guo, Gongyin Shi, and Lai Wang.

ANSWER: Sandoz admits that the face of the '674 patent names Zhiwei Wang, Yunhang Guo, Gongyin Shi, and Lai Wang as purported inventors.

136. BeiGene Switzerland GmbH is the owner and assignee of the '674 patent.

ANSWER: Sandoz admits that the face of the '674 patent lists BeiGene Switzerland GmbH as the purported assignee. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

137. Methods of using BRUKINSA® are covered by one or more claims of the '674 patent, which has been listed in connection with BRUKINSA® in the FDA's Orange Book.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the '674 patent is listed in the FDA's Orange Book in connection with BRUKINSA®. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

138. In Sandoz's Third 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 '674 patent.

ANSWER: Sandoz admits that Sandoz's Third Notice Letter notified Plaintiffs that Sandoz submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '674 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

139. In Sandoz's Third Notice Letter, Sandoz also notified BeiGene that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '674 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '674 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.

ANSWER: Sandoz admits that Sandoz's Third Notice Letter notified Plaintiffs that Sandoz's ANDA No. 218957 includes a Paragraph IV Certification seeking FDA approval to manufacture,

use, or sell Sandoz's ANDA Product before the expiration of the '674 patent. Sandoz admits that its Third Notice Letter provided information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) regarding the '674 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

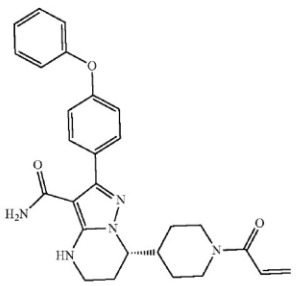
140. According to Sandoz's Third Notice Letter, Sandoz's ANDA Product contains zanubrutinib.

ANSWER: Sandoz admits that it submitted ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell zanubrutinib capsules 80 mg. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

141. 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 '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

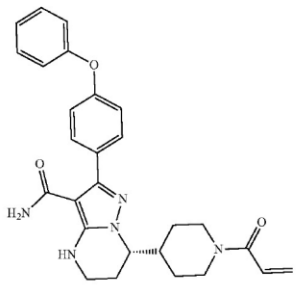
142. As an example, claim 1 of the '674 patent recites:

> A method for treating a B-cell proliferative disease in a subject, comprising administering to the subject in need thereof Compound 1,
>
> Compound 1
>
> 
>
> wherein the B-cell proliferative disease is selected from a group consisting of chronic lymphocytic leukemia, small lymphocytic lymphoma, mantle cell lymphoma, Waldenström's macroglobulinemia, marginal zone lymphoma, and follicular lymphoma; and
>
> Compound 1 is administrated at a dose of 160 mg twice a day (BID).

ANSWER: Sandoz admits that claim 1 of the '437 patent recites:

A method for treating a B-cell proliferative disease in a subject, comprising administering to the subject in need thereof Compound 1,

Compound 1



wherein the B-cell proliferative disease is selected from a group consisting of chronic lymphocytic leukemia, small lymphocytic lymphoma, mantle cell lymphoma, Waldenström's macroglobulinemia, marginal zone lymphoma, and follicular lymphoma; and

Compound 1 is administrated at a dose of 160 mg twice a day (BID).

143. 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 a B-cell proliferative disease in a subject, including by administering to the subject in need thereof Compound 1 at a dose of 160 mg twice a day (BID), as recited in claim 1.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies that the use of its ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating a B-cell proliferative disease by administering to the subject in need thereof Compound 1 at a dose of 160 mg twice a day (BID), as recited in claim 1 of the '674 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

144. 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 28 of the '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

145. 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 '674 patent was an act of infringement of the '674 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

146. 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.

ANSWER: Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

147. 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 '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

148. 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 '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

149. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '674 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 '674 patent and specific intent to infringe that patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

150. 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 '674 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 '674 patent immediately and imminently upon approval of Sandoz's ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

151. Notwithstanding Sandoz's knowledge of the claims of the '674 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 '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it filed ANDA No. 218957 with the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product before the expiration of the '674 patent. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

152. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '674 patent; active inducement of infringement of the '674 patent; and/or contribution to the infringement by others of the '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

153. Upon information and belief, Sandoz has acted with full knowledge of the '674 patent and without a reasonable basis for believing that it would not be liable for infringement of the '674 patent; active inducement of infringement of the '674 patent; and/or contribution to the infringement by others of the '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

154. BeiGene will be substantially and irreparably damaged by infringement of the '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

155. Unless Sandoz is enjoined from infringing the '674 patent, actively inducing infringement of the '674 patent, and contributing to the infringement by others of the '674 patent, BeiGene will suffer irreparable injury. BeiGene has no adequate remedy at law.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

COUNT VIII
Declaratory Judgment of [Alleged] Infringement of the '674 Patent

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

ANSWER: Sandoz incorporates its answers to each of the preceding paragraphs as if fully set forth herein.

157. 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 '674 patent, and/or the validity of the '674 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs' Complaint purports to bring an action for infringement of the '674 patent, and that the action purports to arise under 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Sandoz denies any remaining allegations in this paragraph.

158. 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 '674 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '674 patent, and that the claims of the '674 patent are not invalid.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of this paragraph.

PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent any response is required, Sandoz denies that Plaintiffs are entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Further answering Plaintiffs' Complaint, Sandoz asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Sandoz reserves the right to amend this Answer with additional defenses as further information is obtained. Sandoz asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise denied.

First Defense

The filing of Sandoz's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Patents-in-Suit.

Second Defense

The manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product has not, does not, and would not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

Third Defense

The claims of the Patents-in-Suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

Fourth Defense

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

Fifth Defense

Sandoz's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense

Sandoz has not willfully infringed any claim of the Patents-in-Suit.

Seventh Defense

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

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its counterclaims against Plaintiffs/Counterclaim-Defendants BeiGene USA, Inc. and BeiGene Switzerland GmbH (collectively, "Plaintiffs" or "Counterclaim-Defendants"), Sandoz Inc. ("Sandoz") state as follows:

PARTIES

1. Sandoz Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

2. Counterclaim-Defendants' complaint alleges that BeiGene USA, Inc. 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.

3. Counterclaim-Defendants' complaint alleges that BeiGene Switzerland GmbH 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.

JURISDICTION AND VENUE

4. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Counterclaim-Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their complaint here.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Counterclaim-Defendants' choice of forum.

7. There is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the Patents-in-Suit.

BACKGROUND

The Patents-in-Suit

8. Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 218957 ("Sandoz's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of 80 mg zanubrutinib capsules ("Sandoz's ANDA Product") within the United States.

9. On information and belief, BeiGene USA Inc. holds approved New Drug Application ("NDA") No. 213217 for BRUKINSA® (Zanubrutinib) Oral Capsules 80 mg.

10. On information and belief, BeiGene USA Inc. caused U.S. Patent Nos. 10,927,117 ("the '117 patent"), 11,591,340 ("the '340 patent"), 11,851,437 ("the '437 patent"), and 11,884,674 ("the '674 patent") (collectively, the "patents-in-suit") to be listed in the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the "Orange Book," as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which BeiGene USA Inc. submitted NDA No. 213217.

11. The '117 patent, titled "Crystalline form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetra-hydropyrazolo[1,5-a]pyrimidine-3-carboxamide, preparation, and uses thereof," issued on February 23, 2021.

12. The ’340 patent, titled “Crystalline form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetra-hydropyrazolo[1,5-a]pyrimidine-3-carboxamide, preparation, and uses thereof,” issued on February 28, 2023.

13. The ’437 patent, titled “Crystalline form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetra-hydropyrazolo[1,5-a]pyrimidine-3-carboxamide, preparation, and uses thereof,” issued on December 26, 2023.

14. The ’674 patent, titled “Crystalline form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetra-hydropyrazolo[1,5-a]pyrimidine-3-carboxamide, preparation, and uses thereof,” issued on January 30, 2024.

15. Counterclaim-Defendants’ complaint alleges that BeiGene Switzerland GmbH is the assignee of the Patents-in-Suit.

16. Sandoz’s ANDA contains “Paragraph IV” certifications under 21 U.S.C. § 355 5(j)(2)(A)(vii)(IV) that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz’s ANDA Product.

17. On January 24, 2024, Sandoz sent Counterclaim-Defendants written notice of Sandoz’s Paragraph IV Certifications (“Sandoz’s First Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz’s Notice Letter asserted that the claims of the ’117 and ’340 patents are invalid, unenforceable, and/or will not be infringed by Sandoz’s ANDA or the product or activities described therein.

18. Sandoz’s First Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Sandoz’s ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

19. On March 8, 2024, Counterclaim-Defendants filed the present action alleging infringement of the ’117 and ’340 patents.

20. On March 7, 2024, Sandoz sent Counterclaim-Defendants written notice of Sandoz’s Paragraph IV Certifications (“Sandoz’s Second Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz’s Notice Letter asserted that the claims of the ’437 patent are invalid, unenforceable, and/or will not be infringed by Sandoz’s ANDA or the product or activities described therein.

21. Sandoz’s Second Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Sandoz’s ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

22. On March 19, 2024, Counterclaim-Defendants filed their First Amended Complaint alleging infringement of the patents-in-suit.

23. On April 30, 2024, Sandoz sent Counterclaim-Defendants written notice of Sandoz’s Paragraph IV Certifications (“Sandoz’s Third Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B). Sandoz’s Third Notice Letter asserted that the claims of the ’674 patent are invalid, unenforceable, and/or will not be infringed by Sandoz’s ANDA or the product or activities described therein.

24. Sandoz’s Third Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Sandoz’s ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

25. Sandoz’s Third Notice Letter also notified Counterclaim-Defendants that Sandoz provided an updated Paragraph IV Certification to the FDA with respect to the ’340 patent to address newly listed use codes U-3727, U-3728, and U-3729, which were added to the Orange

Book in connection with the '340 patent and BRUKINSA®. Sandoz notified Counterclaim-Defendants that Sandoz was maintaining its Paragraph IV certifications with respect to the '340 patent for the same factual and legal basis as previously described in Sandoz's First Notice Letter.

26. On May 15, 2024, Counterclaim-Defendants filed their Second Amended Complaint alleging infringement of the patents-in-suit.

27. There has been and now is an actual and justiciable controversy between the parties as to whether Sandoz's ANDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the patents-in-suit.

Listing of Patent Information in the Orange Book

28. FDA regulations require NDA holders to submit "patent information" to the FDA "for each patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product." 21 C.F.R. § 314.53(b); *see also* 21 U.S.C. § 355(c)(2). This patent information is listed in the Orange Book, one purpose of which is to provide notice to ANDA applicants of those patents an NDA holder represents cover the listed product.

29. The U.S. Federal Trade Commission was involved in the discussions leading to the development of section 314.53, provided a detailed study of generic drug entry prior to patent expiration, and asked the FDA to clarify its patent listing rules via Citizen Petition. *See*, *e.g.*, Citizen Petition, O1P-0248 (May 16, 2001). As the FTC explained: "The FDA has proposed to clear away unnecessary roadblocks to the approval of generic drug products. The FDA's important action addressing the competitive problems existing in the approval process for generic drugs, if promulgated and upheld, will [be] an effective way to bring the economic benefits of generic drugs

to consumers more quickly. The Commission urges FDA, however, to make the proposed reforms even more effective by tightening its patent listing requirements." FTC Comments, Dkt. No. 02N-0417 (Dec. 23, 2002).

30. The NDA holder's obligation to submit patent information for method claims includes "use codes" and specific descriptions of the protected methods of use. 21 C.F.R. § 314.53(b)(1).

31. "Use codes" are listed in the Orange Book and are intended to alert ANDA applicants to the existence of a patent that claims an approved use. 21 C.F.R. § 314.53(c)(ii)(P)(3).

32. The FDA expects a high degree of specificity in these use codes so that ANDA applicants may, if they so elect, carve out the protected use from its label and seek approval solely for non-protected uses by submitting what is called a "section viii statement." Thus, under Section 314.53(b)(1), "[t]he applicant *must separately identify each pending or approved method of use and related patent claim(s)*" and "identify *with specificity* the section(s) . . . of the approved labeling that describes the method(s) of use claimed by the patent submitted" (emphasis added).

33. This listing must be "*accurate and detailed*" [*id.*]; the applicant must provide "a description of each approved method of use and related patent claim of the patent being submitted," along with "the specific section . . . of the approved labeling for the drug product that describes the method of use claimed by the patent submitted" and a "description of the patented method of use as required for publication." 21 C.F.R. § 314.53(c)(2)(ii)(P).

34. Form FDA 3542, the form NDA holders must complete in connection with the use code requirements, also mandates that the NDA holder attest to the accuracy of a use code under penalty of perjury and specifically cautions that willfully and knowingly false statements are a criminal offense under 18 U.S.C. § 1001. The instructions to Form 3542 make clear that generic

companies must be able to rely on specific use codes to determine, for example, whether a section viii statement is appropriate: "Each use code must describe only an approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. In other words, the scope of the use code must not extent beyond the scope of the patent claim(s) and, within the boundary established by the patent claim(s), the use code must only describe a patented method of use that has been approved by FDA as reflected in approved product labeling." This instruction prevents the NDA holder from asserting a broad use code that would unnecessarily prevent ANDA applicants from seeking approval for non-protected uses.

35. In fact, the form continues: "If the method of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, then the NDA holder must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted . . . not the broader indication or other approved condition of use that may include, but is broader than, the use claimed by the patent."

36. By placing these strict requirements on the NDA-holder, Section 314.53 and Form FDA 3542 implement a critical component of the Hatch-Waxman statutory scheme because they allow ANDA applicants to know precisely what methods they can carve out under section viii. FDA does not construe patents, so it relies heavily on the good-faith compliance of the NDA holder to provide an accurate and detailed description of the patented method of use.

37. Upon information and belief, Counterclaim-Defendants identified the following seven methods to the FDA through submission of use codes for the '674 patent: U-1745 ("For the treatment of patients with Waldenstrom's macroglobulinemia"); U-2145 ("Treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy"); U-2537

("Treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)"); U-2666 ("Treatment of adult patients with chronic lymphocytic leukemia"); U-3063 ("Relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen"); U-3486 ("Treatment of adult patients with small lymphocytic lymphoma"); and U-3860 ("Treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy").

38. Attached as Exhibit 1 is a true and correct copy of the Orange Book for BRUKINSA® as of July 10, 2024. The Orange Book identifies U-1745, U-2145, U-2537, U-2666, U-3063, U-3486, and U-3860 as use codes associated with the '674 patent.

39. The use codes listed in the Orange Book for the '674 patent are broader than the methods of use claimed by the 674 patent. In particular, none of the use codes listed in the Orange Book for the '674 patent mentions treatment of any condition by administering zanubrutinib "at a dose of 160 mg twice a day (BID)."

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '117 PATENT

40. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

41. Counterclaim-Defendants allege ownership of the '117 patent and have brought claims against Sandoz alleging infringement of the '117 patent.

42. The manufacture, use, or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '117 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

43. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the

United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '117 patent.

44. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '117 patent and is not liable for such infringement.

45. Sandoz is entitled to a declaration that all that the manufacture, use or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '117 patent.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '117 PATENT

46. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

47. Counterclaim-Defendants allege ownership of the '117 patent and have brought claims against Sandoz alleging infringement of the '117 patent.

48. One or more claims of the '117 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

49. The alleged invention of the '117 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '117 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '117 patent and would have had a reasonable expectation of success in doing so.

50. The subject matter claimed in the '117 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

51. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '117 patent.

52. Sandoz is entitled to a declaration that all claims of the '117 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '340 PATENT

53. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

54. Counterclaim-Defendants allege ownership of the '340 patent and have brought claims against Sandoz alleging infringement of the '340 patent.

55. The manufacture, use, or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '340 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

56. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '340 patent.

57. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '340 patent and is not liable for such infringement.

58. Sandoz is entitled to a declaration that all that the manufacture, use or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '340 patent.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '340 PATENT

59. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

60. Counterclaim-Defendants allege ownership of the '340 patent and have brought claims against Sandoz alleging infringement of the '340 patent.

61. One or more claims of the '340 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

62. The alleged invention of the '340 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '340 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '340 patent and would have had a reasonable expectation of success in doing so.

63. The subject matter claimed in the '340 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

64. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the

United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '340 patent.

65. Sandoz is entitled to a declaration that all claims of the '340 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '437 PATENT

66. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

67. Counterclaim-Defendants allege ownership of the '437 patent and have brought claims against Sandoz alleging infringement of the '437 patent.

68. The manufacture, use, or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '437 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

69. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '437 patent.

70. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '437 patent and is not liable for such infringement.

71. Sandoz is entitled to a declaration that all that the manufacture, use or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '437 patent.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE '437 PATENT

72. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

73. Counterclaim-Defendants allege ownership of the '437 patent and have brought claims against Sandoz alleging infringement of the '437 patent.

74. One or more claims of the '437 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

75. The alleged invention of the '437 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '437 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '437 patent and would have had a reasonable expectation of success in doing so.

76. The subject matter claimed in the '437 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

77. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '437 patent.

78. Sandoz is entitled to a declaration that all claims of the '437 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT VII: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '674 PATENT

79. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

80. Counterclaim-Defendants allege ownership of the '674 patent and have brought claims against Sandoz alleging infringement of the '674 patent.

81. The manufacture, use, or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '674 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

82. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '674 patent.

83. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '674 patent and is not liable for such infringement.

84. Sandoz is entitled to a declaration that all that the manufacture, use or sale of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '674 patent.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '674 PATENT

85. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

86. Counterclaim-Defendants allege ownership of the ’674 patent and have brought claims against Sandoz alleging infringement of the ’674 patent.

87. One or more claims of the ’674 patent are invalid under one or provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

88. The alleged invention of the ’674 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’674 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’674 patent and would have had a reasonable expectation of success in doing so.

89. The subject matter claimed in the ’674 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

90. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Sandoz’s ANDA and/or the manufacture, use, or sale in the United States of Sandoz’s ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the ’674 patent.

91. Sandoz is entitled to a declaration that all claims of the ’674 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

COUNT IX: ORDER AND/OR DECLARATION REQUIRING PATENT DE-LISTING OR CORRECTION OF USE CODES

92. Sandoz incorporates by reference the allegations in the foregoing paragraphs of its counterclaims as if fully set forth herein.

93. Under 21 U.S.C. § 355(j)(5)(C)(ii), Sandoz seeks an order requiring Counterclaim-Defendants to de-list the '674 patent from the Orange Book with respect to NDA No. 213217 or to correct the use code information submitted by Counterclaim-Defendants. Sandoz also seeks a declaration that the '674 patent was improperly listed in the Orange Book with respect to NDA No. 213217.

94. Counterclaim-Defendants identified the following seven methods to the FDA through submission of use codes for the '674 patent: U-1745 ("For the treatment of patients with Waldenstrom's macroglobulinemia"); U-2145 ("Treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy"); U-2537 ("Treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)"); U-2666 ("Treatment of adult patients with chronic lymphocytic leukemia"); U-3063 ("Relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen"); U-3486 ("Treatment of adult patients with small lymphocytic lymphoma"); and U-3860 ("Treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy").

95. The claims of the '674 patent require a "method for treating a B-cell proliferative disease in a subject" comprising, among other limitations, administering zanubrutinib "at a dose of 160 mg twice a day (BID)." *See* claim 1.

96. Use codes U-1745, U-2145, U-2537, U-2666, U-3063, U-3486, and U-3860 are not directed or limited to a method of treatment that comprises administering Compound 1 "at a dose of 160 mg twice a day (BID)," as required by the claims of the '674 patent.

97. Sandoz is entitled to an order requiring Counterclaim-Defendants to delist or correct the patent information submitted for NDA No. 213217 concerning the '674 patent. Sandoz is also entitled to a declaration that the '674 patent is improperly listed in the Orange Book, or should be corrected, with respect to NDA No. 213217.

PRAYER FOR RELIEF

WHEREFORE, Sandoz requests that the Court enter judgment in its favor and against Counterclaim-Defendants as follows:

a. Declaring that the filing of Sandoz's ANDA has not infringed and does not infringe any valid and enforceable claim of the '117 patent;

b. Declaring that the filing of Sandoz's ANDA has not infringed and does not infringe any valid and enforceable claim of the '340 patent;

c. Declaring that the filing of Sandoz's ANDA has not infringed and does not infringe any valid and enforceable claim of the '437 patent;

d. Declaring that the filing of Sandoz's ANDA has not infringed and does not infringe any valid and enforceable claim of the '674 patent;

e. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Sandoz's ANDA Product does not and will not infringe any valid and enforceable claim of the '117 patent;

f. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Sandoz's ANDA Product does not and will not infringe any valid and enforceable claim of the '340 patent;

g. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Sandoz's ANDA Product does not and will not infringe any valid and enforceable claim of the '437 patent;

h. Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Sandoz's ANDA Product does not and will not infringe any valid and enforceable claim of the '674 patent;

i. Declaring that the claims of the '117 patent are invalid and/or unenforceable;

j. Declaring that the claims of the '340 patent are invalid and/or unenforceable;

k. Declaring that the claims of the '437 patent are invalid and/or unenforceable;

l. Declaring that the claims of the '674 patent are invalid and/or unenforceable;

m. Declaring and ordering that Counterclaim-Defendants de-list the U.S. Patent No. 11,884,674 from the Orange Book with respect to its NDA for BRUKINSA®, or correct the listed use codes for that patent;

n. Awarding Sandoz its costs and expenses in this action;

o. Declaring this an exceptional case in favor of Sandoz and awarding Sandoz its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

p. Awarding such other and further relief as this Court deems just and proper.

WHEREFORE, Sandoz requests that Counterclaim-Defendants' Complaint be dismissed with prejudice and that Sandoz be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

Dated: July 10, 2024

Respectfully submitted,

/s/ Eric Abraham

Eric I. Abraham
William P. Murtha
HILL WALLACK LLP
21 Roszel Road
P.O. Box 5226
Princeton, New Jersey 08543-5226
(609) 734-6358
eabraham@hillwallack.com
wmurtha@hillwallack.com

Attorneys for Sandoz Inc.

OF COUNSEL:

Charles B. Klein*
Jovial Wong*
WINSTON & STRAWN LLP
1901 L Street NW
Washington, DC 20036
(202) 282-5977
cklein@winston.com
jwong@winston.com

Eimeric Reig-Plessis*
WINSTON & STRAWN LLP
101 California Street, 35th Floor
San Francisco, California 94111
(415) 591-6808
ereigplessis@winston.com

Annie R. Steiner*

WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, Illinois 60601
(312) 558-6092
asteiner@winston.com

**Pro Hac Vice*

CERTIFICATE OF SERVICE

I certify that on July 10, 2024, a true and correct copy of the foregoing was served on Plaintiffs' counsel of record by way of the CM/ECF System and via email.

/s/ Eric Abraham
Eric I. Abraham

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendant Sandoz Inc., certifies that, to the best of his knowledge, the matters in controversy between the named parties is the subject of one related pending action in this District, *Beigene USA, Inc. and Beigene Switzerland GMBH v. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited*, Docket No. No. 24-1971-ZNQ-RLS.

Dated: July 10, 2024

Respectfully submitted,

/s/ Eric I. Abraham