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

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, and MSD INTERNATIONAL BUSINESS GMBH, *Plaintiffs*, v. SANDOZ INC., *Defendant*.	Civil Action No.: 3:24-5889

DEFENDANT SANDOZ INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT ('530 AND '001 PATENTS)

Defendant Sandoz Inc. ("Sandoz") hereby files its Answer, Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed on May 7, 2024 by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs").

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., which arises out of the submission by Sandoz of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 11,970,530 (the "'530 patent") and U.S. Patent No. 11,975,001 (the "'001 patent") (collectively, the "Patents-in-Suit").

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs' Complaint purports to state an action for infringement of U.S. Patent No. 11,970,530 ("'530 patent") and U.S. Patent No. 11,975,001 ("'001 patent") (collectively, "Patents-in-Suit") and that this action purports to arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* Sandoz further admits that the action purports to relate to Abbreviated New Drug Application No. 217936 ("Sandoz's ANDA"), filed by Sandoz with the U.S. Food and Drug Administration ("FDA"), which seeks approval of olaparib tablets, 100 mg and 150 mg ("Sandoz's ANDA Product"). Sandoz further admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States before the expiration of the '001 patent. Sandoz denies the remaining allegations of Paragraph 1.

2. Sandoz Inc. notified Plaintiffs by letter dated December 29, 2023 ("Sandoz's Notice Letter") that it had submitted to FDA ANDA No. 217936 ("Sandoz's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg, ("Sandoz's ANDA Product") prior to the expiration of U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562.

ANSWER:

Sandoz admits that it sent Plaintiffs a Notice Letter ("Sandoz's Notice Letter"), dated December 29, 2023, that informed Plaintiffs that Sandoz's ANDA contains certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to obtain FDA approval for Sandoz's ANDA Product before the expiration of U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562. Sandoz denies the remaining allegations of Paragraph 2.

3. Plaintiffs filed suit against Sandoz in this District, asserting that Sandoz's ANDA infringes U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 1 (consolidated into Civ. No. 23-796, see Dkt. No. 59). That suit is currently pending in this District. The parties subsequently stipulated to the dismissal without prejudice of Plaintiffs' infringement claims based on U.S. Patent No. 7,449,464, as well as Sandoz's Affirmative Defenses and Counterclaims related to that patent. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796 (Consol.), Dkt. No. 70.

ANSWER:

Sandoz admits that Plaintiffs filed suit against Sandoz in this District and asserted that Sandoz's ANDA allegedly infringes U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562. In response, Sandoz asserted Affirmative Defenses and Counterclaims of noninfringement and invalidity of these patents. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. Nos. 1 & 14 (consolidated with Civ. No. 23-796, Dkt. No. 59). Sandoz further admits that the suit is currently pending in this District. Sandoz further admits that the parties subsequently stipulated to the dismissal without prejudice of Plaintiffs' infringement claims based on U.S. Patent No. 7,449,464, as well as Sandoz's Affirmative Defenses and Counterclaims of nonfringement and invalidity related to that patent. *See AstraZeneca Pharms.*

L.P. v. Natco Pharma Ltd., Civ. No. 23-796 (Consol.), Dkt. No. 70. Sandoz denies the remaining allegations of Paragraph 3.

The Parties

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4 and on that basis denies these allegations.

5. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5 and on that basis denies these allegations.

6. Plaintiff AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 6 and on that basis denies these allegations.

7. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 7 and on that basis denies these allegations.

8. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8 and on that basis denies these allegations.

9. On information and belief, defendant Sandoz 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. On 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 Delaware and maintains a place of business at 100 College Road West, Princeton, New Jersey 08540-6604. Sandoz further admits that it markets pharmaceutical products, including in the United States. Sandoz denies the remaining allegations of Paragraph 9.

10. On 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:

Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 10.

Jurisdiction

11. Plaintiffs incorporate each of the preceding paragraphs 1–10 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely for the alleged infringement of the '001 patent, and expressly reserves the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 12.

13. 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:

Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 13.

14. Sandoz is subject to personal jurisdiction in New Jersey because Sandoz is a corporation with a principal place of business in New Jersey. This Court also has personal jurisdiction over Sandoz because, *inter alia*, on information and belief, Sandoz has continuous and systematic contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell Sandoz's ANDA Product in the State of New Jersey after approval of Sandoz's ANDA.

ANSWER:

Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 14.

15. On information and belief, Sandoz is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

ANSWER:

Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it markets pharmaceutical products, including in the United States. Sandoz denies the remaining allegations of Paragraph 15.

16. On information and belief, Sandoz, through its own actions and 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 within the State of New Jersey, and stands to benefit from the approval of Sandoz's ANDA.

ANSWER:

Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 16.

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

ANSWER:

Sandoz admits that Sandoz's ANDA contains at least one Paragraph IV Certification. Sandoz denies the remaining allegations of Paragraph 17.

18. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz intends to market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including within the State of New Jersey, that will, as explained below, infringe upon Plaintiffs' rights in the Patents-in-Suit protecting their LYNPARZA® products. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz knows and intends that Sandoz's ANDA Product will be marketed, used, distributed, offered for sale, or sold in the United States, including within the State of New Jersey.

ANSWER:

Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 18.

19. On information and belief, Sandoz is registered to do business in the State of 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 Sandoz Inc. is listed under the Entity Identification Number 0100097265 on the State of New Jersey's Business Records Service website. Sandoz further admits that Sandoz Inc. is listed under Registration Number 5003732 on the State of New Jersey's Department of Health website. Sandoz denies the remaining allegations of Paragraph 19.

20. Sandoz has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*,

Amgen Inc. v. Sandoz Inc., Civ. No. 18-11026, Dkt. No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, Civ. No. 17-10129, Dkt. No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, Civ. No. 17-08825, Dkt. No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Lab'ys Priv. Ltd.*, Civ. No. 17-05302, Dkt. No. 28 (D.N.J. Nov. 17, 2017). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz further admits that it filed answers and counterclaims before this Court in the civil actions listed in Paragraph 20, and states that the filings in those cases speak for themselves. Sandoz denies the remaining allegations of Paragraph 20.

21. This Court also has personal jurisdiction over Sandoz at least because, *inter alia*, (a) Sandoz has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product in the United States, including in the State of New Jersey; (b) Sandoz, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Sandoz's ANDA Product in the United States, including in the State of New Jersey and to residents of this Judicial District, upon approval of Sandoz's ANDA, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in the State of New Jersey; and (c) Sandoz has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if Sandoz's ANDA is approved, Sandoz's ANDA Product charged with infringing the Patents-in-Suit would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER:

Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. In addition, Sandoz does not

contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 21.

22. 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 manufacture LYNPARZA® drug products for use throughout the United States, including in this Judicial District. On information and belief, Sandoz filed Sandoz's ANDA with Paragraph IV Certifications, which was purposefully directed to the State of New Jersey, where Sandoz is located. As a result, the consequences of Sandoz's actions were, and will be, suffered in the State of New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in the State of New Jersey. On information and belief, Sandoz's actions will injure Plaintiffs by displacing at least some, if not all, of Plaintiffs' sales of LYNPARZA® drug products in this Judicial District, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of LYNPARZA® drug products in this Judicial District.

ANSWER:

Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's ANDA contains at least one Paragraph IV Certification. In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 22.

23. On information and belief, Sandoz has also engaged in substantial, systematic, and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over Sandoz in New Jersey.

ANSWER:

Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest

personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 23.

24. Additionally, Sandoz has filed an Answer and asserted counterclaims in a related action in this District, *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-00641, Dkt. No. 14 (D.N.J. April 5, 2024). In that Answer, Sandoz has consented to personal jurisdiction in this District.

ANSWER:

Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz filed an Answer, Affirmative Defenses, and Counterclaims in this District in *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-00641, Dkt. No. 14 (D.N.J. April 5, 2024). In addition, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 24.

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 here.

ANSWER:

Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 25.

Venue

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

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

27. Venue is proper in this District pursuant to 28 U.S.C. § 1391, because 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:

Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. In addition, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 27.

28. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. On information and belief, among other things, (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 New Jersey; 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:

Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it maintains a place of business in Princeton, New Jersey. Sandoz further admits it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. In addition, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 28.

29. Venue is proper in this District as to Sandoz because Sandoz (a) engages in patent litigation concerning Sandoz's ANDA Products in this District, and (b) does not contest that venue is proper in this District.

ANSWER:

Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 29.

30. Additionally, Sandoz has filed an Answer and asserted counterclaims in a related action in this District, *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-00641, Dkt. No. 14 (D.N.J. April 5, 2024). In that Answer, Sandoz has consented to venue in this District.

ANSWER:

Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz filed an Answer, Affirmative Defenses, and Counterclaims in this District in *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-00641, Dkt. No. 14 (D.N.J. April 5, 2024). In addition, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party, including Plaintiffs. Sandoz denies the remaining allegations of Paragraph 30.

Factual Background

31. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast, pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

ANSWER:

Paragraph 31 contains legal conclusions to which no response is required. To the extent an answer is required, Sandoz admits that the package insert for LYNPARZA® dated 11/2023 available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208558s028lbl.pdf lists

certain types of ovarian, breast, pancreatic, and prostate cancer under the section titled "1 Indications and Usage." Sandoz further admits that the package insert states under the section titled "12.1 Mechanism of Action" that "Olaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes . . . ." Sandoz denies the remaining allegations in Paragraph 31.

32. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is olaparib tablets, 100 mg and 150 mg. In Sandoz's Notice Letter, Sandoz states that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Sandoz's ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. On information and belief, Sandoz's ANDA product is a generic version of LYNPARZA®.

ANSWER:

Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. Sandoz's Notice Letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 32.

33. The purpose of Sandoz's submission of Sandoz's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

ANSWER:

Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 217936 to FDA seeking approval to market Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations of Paragraph 33.

34. Following receipt of Sandoz's Notice Letter, on February 2, 2024, Plaintiffs filed suit against Sandoz alleging that Sandoz's ANDA infringes certain patents, including U.S. Patent Nos. 8,475,842, 11,633,396, and 8,859,562. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 1 (consolidated into Civ. No. 23-796, *see* Dkt. No. 59). That suit is currently pending in this District.

ANSWER:

Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs filed suit against Sandoz alleging that Sandoz's ANDA infringes certain patents, including U.S. Patent Nos. 8,475,842, 11,633,396, and 8,859,562. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 1 (consolidated into Civ. No. 23-796, *see* Dkt. No. 59). That suit is currently pending in this District. Sandoz denies the remaining allegations of Paragraph 34.

35. On information and belief, Sandoz has not challenged U.S. Patent No. 8,143,241 or U.S. Patent No. 8,071,579, which are listed in connection with LYNPARZA® in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Sandoz has not challenged U.S. Patent No. 7,449,464, which is listed in connection with LYNPARZA® in the FDA's Orange Book and expires on September 8, 2027. On information and belief, following the expiration of those patents, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

ANSWER:

Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 35.

36. On April 10, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '530 patent, and indicated that the '530 patent would issue on April 30, 2024. On April 17, 2024, the U.S. Patent and Trademark Office issued an Issue Notification of the '001 patent, and indicated that the '001 patent would issue on May 7, 2024.

ANSWER:

Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that, according to the records of the U.S. Patent and Trademark Office ("USPTO"), the USPTO issued an Issue Notification for the '530 patent on April 10, 2024 which indicated that the '530 patent would issue on April 30, 2024, and that the USPTO issued an Issue Notification for the '001 patent on April 17, 2024 which indicated that

the ’001 patent would issue on May 7, 2024. Sandoz denies the remaining allegations of Paragraph 36.

37. On April 24, 2024, Plaintiffs notified Sandoz’s outside counsel of the upcoming issuance of the Patents-in-Suit. Plaintiffs also indicated that they anticipated that Sandoz would file a Paragraph IV Certification to FDA alleging the Patents-in-Suit are invalid, unenforceable, and/or not infringed, and that Sandoz would seek 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. Plaintiffs received no substantive response from Sandoz as of the date of this Complaint.

ANSWER:

Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Plaintiffs prematurely contacted Sandoz regarding patents that did not yet exist and were not yet listed in FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”), and then Plaintiffs prematurely filed suit alleging infringement against Sandoz before the Patents-in-Suit were listed in the Orange Book. Sandoz further states that, between February 21, 2024 and April 5, 2024, Plaintiffs negotiated a schedule in the related litigation (submitted to the Court on April 5, 2024) without informing the Court or the parties of Plaintiffs’ intent to assert the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 37.

38. On information and belief, Sandoz intends to seek 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:

Paragraph 38 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it seeks approval of Sandoz’s ANDA Product before the expiration of the ’001 patent. Sandoz denies the remaining allegations of Paragraph 38.

Count I – Alleged Infringement of the '530 Patent Under 35 U.S.C. § 271(e)(2)

39. Plaintiffs incorporate each of the preceding paragraphs 1–38 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

40. On April 30, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '530 patent, entitled "Methods of Treating Homologous Recombination Deficient Cancer." A copy of the '530 patent is attached hereto as Exhibit A.

ANSWER:

Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit A of Plaintiffs' Complaint purports to be a copy of the '530 patent. Sandoz further admits that the face of the '530 patent states that the '530 patent purports to have been issued on April 30, 2024. Sandoz further admits on its face, the '530 patent is titled "Methods of Treating Homologous Recombination Deficient Cancer." Sandoz denies the remaining allegations of Paragraph 40.

41. Plaintiff AstraZeneca AB is an assignee of the '530 patent. Plaintiffs collectively possess all exclusive rights and interests in the '530 patent.

ANSWER:

Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list AstraZeneca AB as the assignee of the '530 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 41 and on that basis denies these allegations.

42. The '530 patent claims, *inter alia*, a method for treating ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and/or pancreatic cancer in a subject, the method comprising administering to the subject a therapeutically effective amount of bevacizumab, and a therapeutically effective amount of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One (olaparib).

ANSWER:

Paragraph 42 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the '530 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 42.

43. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 43 and on that basis denies these allegations.

44. Methods of using LYNPARZA® are covered by at least one claim of the '530 patent, and the '530 patent will be listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER:

Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the '530 patent in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 44.

45. On information and belief, Sandoz has not challenged U.S. Patent No. 8,143,241 or U.S. Patent No. 8,071,579, which are listed in connection with LYNPARZA® in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Sandoz has not challenged U.S. Patent No. 7,449,464, which is listed in connection with LYNPARZA® in the FDA's Orange Book and expires on September 8, 2027. On information and belief, following the expiration of those patents, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

ANSWER:

Paragraph 45 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 45.

46. Sandoz received notice of the '530 patent at least as of April 24, 2024, when Plaintiffs notified Sandoz's outside counsel of the upcoming issuance of the Patents-in-Suit.

ANSWER:

Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs notified Sandoz's outside counsel on April 24, 2024 that it expected the Patents-in-Suit to issue. Sandoz denies the remaining allegations of Paragraph 46.

47. On information and belief, Sandoz intends to seek 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:

Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it seeks approval of Sandoz's ANDA Product before the expiration of the '001 patent. Sandoz denies the remaining allegations of Paragraph 47.

48. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '530 patent was an act of infringement of the '530 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 48 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 48.

49. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claim 1 of the '530 patent, either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 49 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 49.

50. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '530 patent.

ANSWER:

Paragraph 50 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 50.

51. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '530 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Paragraph 51 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 51.

52. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '530 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '530 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 52 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 52.

53. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '530 patent, active inducement of infringement of the '530 patent, and contribution to the infringement by others of the '530 patent.

ANSWER:

Paragraph 53 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 53.

54. On information and belief, Sandoz has acted with full knowledge of the '530 patent and without a reasonable basis for believing that it would not be liable for infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent.

ANSWER:

Paragraph 54 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 54.

55. Unless Sandoz is enjoined from infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER:

Paragraph 55 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 55.

Count II – Declaratory Judgment of Alleged Infringement of the '530 Patent

56. Plaintiffs incorporate each of the preceding paragraphs 1–55 as if fully set forth herein.

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding the validity and/or infringement of the '530 patent.

ANSWER:

Paragraph 57 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs' Complaint purports to state an action that arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sandoz denies the remaining allegations of Paragraph 57.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '530 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '530 patent, and that the claims of the '530 patent are valid.

ANSWER:

Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 58.

Count III – Alleged Infringement of the '001 Patent Under 35 U.S.C. § 271(e)(2)

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

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

60. On May 7, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '001 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl-]-2H-Phthalazin-1-One." A copy of the '001 patent is attached hereto as Exhibit B.

ANSWER:

Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit B of Plaintiffs' Complaint purports to be a copy of the '001 patent. Sandoz further admits that the face of the '001 patent states that the '001 patent purports to have been issued on May 7, 2024. Sandoz further admits on its face, the '001 patent is titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." Sandoz denies the remaining allegations of Paragraph 60.

61. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '001 patent. Plaintiffs collectively possess all exclusive rights and interests in the '001 patent.

ANSWER:

Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the USPTO list KuDOS

Pharmaceuticals Limited as the assignee of the '001 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 61 and on that basis denies these allegations.

62. The '001 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl-]-2H-Phthalazin-1-One, known by the international nonproprietary name olaparib, and certain excipients.

ANSWER:

Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the '001 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 62.

63. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 63 and on that basis denies these allegations.

64. LYNPARZA® is covered by at least one claim of the '001 patent, and the '001 patent will be listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER:

Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that one or more of Plaintiffs caused the FDA to list the '001 patent in the Orange Book in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 64.

65. On information and belief, Sandoz has not challenged U.S. Patent No. 8,143,241 or U.S. Patent No. 8,071,579, which are listed in connection with LYNPARZA® in the FDA's Orange Book and expire on August 12, 2027. On information and belief, Sandoz has not challenged U.S. Patent No. 7,449,464, which is listed in connection with LYNPARZA® in the FDA's Orange Book and expires on September 8, 2027. On information and belief, following the expiration of those patents, Sandoz will engage in the manufacture, use, offer for sale, sale,

marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon FDA approval of Sandoz's ANDA.

ANSWER:

Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 65.

66. Sandoz received notice of the '001 patent at least as of April 24, 2024, when Plaintiffs notified Sandoz's outside counsel of the upcoming issuance of the Patents-in-Suit.

ANSWER:

Paragraph 66 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs notified Sandoz's outside counsel on April 24, 2024 that it expected the Patents-in-Suit to issue. Sandoz denies the remaining allegations of Paragraph 66.

67. On information and belief, Sandoz intends to seek 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:

Paragraph 67 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it seeks approval of Sandoz's ANDA Product before the expiration of the '001 patent. Sandoz denies the remaining allegations of Paragraph 67.

68. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '001 patent was an act of infringement of the '001 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 68 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz does not contest this Court's subject matter jurisdiction solely for the alleged infringement of the '001 patent under 35 U.S.C. § 271(e)(2), and expressly reserves

the right to contest subject matter jurisdiction as to other allegations. Sandoz denies the remaining allegations of Paragraph 68.

69. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claim 1 of the '001 patent, either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 69.

70. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claim 1 of the '001 patent.

ANSWER:

Paragraph 70 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 70.

71. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '001 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Paragraph 71 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 71.

72. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '001 patent and that Sandoz's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '001 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 72 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 72.

73. The foregoing actions by Sandoz constitute and/or will constitute infringement of the ’001 patent, active inducement of infringement of the ’001 patent, and contribution to the infringement by others of the ’001 patent.

ANSWER:

Paragraph 73 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 73.

74. On information and belief, Sandoz has acted with full knowledge of the ’001 patent and without a reasonable basis for believing that it would not be liable for infringing the’001 patent, actively inducing infringement of the ’001 patent, and contributing to the infringement by others of the ’001 patent.

ANSWER:

Paragraph 74 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 74.

75. Unless Sandoz is enjoined from infringing the ’001 patent, actively inducing infringement of the ’001 patent, and contributing to the infringement by others of the ’001 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER:

Paragraph 75 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 75.

Count IV – Declaratory Judgment of Alleged Infringement of the ’001 Patent

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

ANSWER:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

77. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding validity and/or infringement of the ’001 patent.

ANSWER:

Paragraph 77 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiffs' Complaint purports to state an action that arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sandoz denies the remaining allegations of Paragraph 77.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '001 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '001 patent, and that the claims of the '001 patent are valid.

ANSWER:

Paragraph 78 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 78.

RESPONSES TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Sandoz further denies that Plaintiffs are entitled to any of the relief set forth in their "Prayer for Relief" or to any relief whatsoever.

DEFENSES

Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Sandoz asserts the following defenses:

FIRST DEFENSE
(NON-INFRINGEMENT OF THE '530 PATENT)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any

valid and/or enforceable claims of the ’530 patent, either literally or by the doctrine of equivalents.

SECOND DEFENSE
(NON-INFRINGEMENT OF THE ’001 PATENT)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz’s ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid and/or enforceable claims of the ’001 patent, either literally or by the doctrine of equivalents.

THIRD DEFENSE
(INVALIDITY OF THE ’530 PATENT)

One or more claims of the ’530 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

FOURTH DEFENSE
(INVALIDITY OF THE ’001 PATENT)

One or more claims of the ’001 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

FIFTH DEFENSE
(FAILURE TO STATE A CLAIM FOR
DIRECT INFRINGEMENT OF THE '530 PATENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported direct infringement of the '530 patent. The Complaint contains only conclusory allegations including that "the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe [the Patents-in-Suit], either literally or under the doctrine of equivalents." As such, Plaintiffs' Complaint fails to state a claim for direct infringement.

SIXTH DEFENSE
(FAILURE TO STATE A CLAIM FOR
DIRECT INFRINGEMENT OF THE '001 PATENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported direct infringement of the '001 patent. The Complaint contains only conclusory allegations including that "the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe [the Patents-in-Suit], either literally or under the doctrine of equivalents." As such, Plaintiffs' Complaint fails to state a claim for direct infringement.

SEVENTH DEFENSE
(FAILURE TO STATE A CLAIM FOR
INDIRECT INFRINGEMENT OF THE '530 PATENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported indirect infringement of the '530 patent. The Complaint contains only conclusory allegations including that "actions by Sandoz constitute and/or will constitute infringement of the [Patents-in-Suit], active inducement of infringement of the [Patents-in-Suit], and contribution to the infringement by others of the [Patents-in-Suit]." As such, Plaintiffs' Complaint fails to state a claim for either induced infringement or contributory infringement.

EIGHTH DEFENSE
(FAILURE TO STATE A CLAIM FOR
INDIRECT INFRINGEMENT OF THE '001 PATENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported indirect infringement of the '001 patent. The Complaint contains only conclusory allegations including that "actions by Sandoz constitute and/or will constitute infringement of the [Patents-in-Suit], active inducement of infringement of the [Patents-in-Suit], and contribution to the infringement by others of the [Patents-in-Suit]." As such, Plaintiffs' Complaint fails to state a claim for either induced infringement or contributory infringement.

NINTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INFRINGEMENT
UNDER 35 U.S.C. § 271(e)(2) FOR THE '530 PATENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported infringement under 35 U.S.C. § 271(e)(2) for the '530 patent.

TENTH DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION
UNDER 35 U.S.C. § 271(e)(2) FOR THE '530 PATENT)

The Court lacks subject matter jurisdiction over Plaintiffs' claims for infringement of the '530 patent under 35 U.S.C. § 271(e)(2).

ELEVENTH DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION UNDER 35 U.S.C. § 271(a), (b), (c))

The Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and (c) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2022.

TWELFTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

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

THIRTEENTH DEFENSE
(SAFE HARBOR UNDER 35 U.S.C. § 271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), Sandoz's actions do not constitute infringement.

FOURTEENTH DEFENSE
(ADDITIONAL DEFENSES DISCOVERY MAY REVEAL)

Any additional defenses that discovery may reveal.

RESERVATION OF DEFENSES

Sandoz hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules and the U.S. Patent Law and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including unenforceability.

COUNTERCLAIMS OF SANDOZ INC.

Defendant/Counterclaim-Plaintiff Sandoz Inc. ("Sandoz") brings the following Counterclaims against Plaintiffs/Counterclaim-Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs/Counterclaim-Defendants"), and states as follows:

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that Sandoz is free to continue to seek approval of its Abbreviated New Drug Application No. 217936 and upon approval by the U.S. Food and Drug Administration to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in ANDA No. 217936.

THE PARTIES

2. Defendant/Counterclaim-Plaintiff Sandoz is a corporation organized and existing under the laws of Delaware, with a place of business at 100 College Road West, Princeton, New Jersey 08540-6604, United States.

3. Plaintiff/Counterclaim-Defendant AstraZeneca Pharmaceuticals LP purports to be a limited partnership organized and existing under the laws of the state of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff/Counterclaim-Defendant AstraZeneca UK Limited purports to be a private company limited organized and existing under the laws of laws of England and Wales, having a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

5. Plaintiff/Counterclaim-Defendant AstraZeneca AB purports to be a limited company organized and existing under the laws of Sweden, having a registered office at SE-151 85, Södertälje, Sweden.

6. Plaintiff/Counterclaim-Defendant KuDOS Pharmaceuticals Limited purports to be a private company limited organized and existing under the laws of England and Wales, having a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

7. Plaintiff/Counterclaim-Defendant MSD International Business GmbH purports to be a company with limited liability organized and existing under the laws of Switzerland, having a registered office at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

8. Plaintiff/Counterclaim-Defendant AstraZeneca AB purports to be the assignee of U.S. Patent No. 11,970,530 ("'530 patent").

9. Plaintiff/Counterclaim-Defendant KuDOS Pharmaceuticals Limited purports to be the assignee of U.S. Patent No. 11,975,001 ("'001 patent").

10. Plaintiffs/Counterclaim-Defendants AstraZeneca AB, KuDOS Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH purport to possess all exclusive rights and interests in the '530 and '001 patents.

11. Plaintiff/Counterclaim-Defendant AstraZeneca Pharmaceuticals LP purports to be the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

JURISDICTION AND VENUE

12. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

13. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and/or under 21 U.S.C. § 355(j)(5)(C).

14. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Sandoz in this District, and/or because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

15. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C).

BACKGROUND

16. Sandoz filed Abbreviated New Drug Application ("ANDA") No. 217936 ("Sandoz's ANDA") with the U.S. Food and Drug Administration ("FDA"), which seeks approval of olaparib tablets, 100 mg and 150 mg ("Sandoz's ANDA Product").

17. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Plaintiffs/Counterclaim-Defendants a notice letter dated December 29, 2023, stating that Sandoz's ANDA No. 217936 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562 are invalid, unenforceable, and will not be infringed by the commercial manufacture, use or sale of Sandoz's ANDA Product.

18. Sandoz's Notice Letter initiated a 45-day statutory period during which Plaintiffs/Counterclaim-Defendants had the opportunity to file an action for patent infringement.

19. On February 2, 2024, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, KuDOS Pharmaceuticals Limited, The University of Sheffield and MSD International Business GmbH filed suit against Sandoz in this District and asserted that Sandoz's ANDA allegedly infringes U.S. Patent Nos. 7,449,464, 8,475,842, 11,633,396, and 8,859,562. In response, Sandoz asserted Affirmative Defenses and Counterclaims of noninfringement and invalidity of these patents. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. Nos. 1 & 14 (consolidated with Civ. No. 23-796, Dkt. No. 59).

20. On March 27, 2024, the Court entered a stipulation consolidating Civil Actoin No. 24-641 with Civ. No. 23-796, which was a previously-filed suit in which Plaintiffs/Counterclaim-Defendants alleged infringement of U.S. Patent Nos. 7,449,464 and 8,859,562 against Natco Pharma Limited and Natco Pharma Inc. (collectively, "Natco").

21. On April 22, 2024, the parties subsequently stipulated to the dismissal without prejudice of Plaintiffs/Counterclaim-Defendants' infringement claims based on U.S. Patent No. 7,449,464, as well as Sandoz's Affirmative Defenses and Counterclaims of nonfringement and invalidity related to that patent. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796 (Consol.), Dkt. No. 70.

22. Between February 21, 2024 and April 5, 2024, Plaintiffs/Counterclaim-Defendants, Sandoz, and Natco negotiated a schedule in Civ. No. 23-796, which was submitted to the Court on April 5, 2024.

23. On April 22, 2024, the parties participated in a telephonic status conference before Judge Bongiovanni, during which they discussed, *inter alia*, the case schedule.

24. On April 24, 2024, the Court entered an Amended Scheduling Order adjusting the schedule in view of the consolidation of the action pending against Sandoz with Civ. No. 23-796. Dkt. No. 71.

25. Despite knowing about the upcomining issue dates of the '530 patent and '001 patents, on or before April 5, 2024, Plaintiffs/Counterclaim-Defendants said nothing to Sandoz during the negotiations over the consolidation and scheduling of Civ. No. 23-796 about the '530 and '001 patents or Plaintiffs/Counterclaim-Defendants' desire to add these patents to the existing litigation.

26. Plaintiffs/Counterclaim-Defendants said nothing to the Court at the April 22, 2024 status conference regarding the '530 and '001 patents.

27. Two days after the status conference and after the amended schedule had been entered, Plaintiffs/Counterclaim-Defendants notified Sandoz for the first time that they expected the '530 and '001 patents to issue and that Plaintiffs/Counterclaim-Defendants intended to list

them in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), in connection with NDA No. 208558 for LYNPARZA®. In the same April 24, 2024 email in which Plaintiffs/Counterclaim-Defendants informed Sandoz of the '530 and '001 patents, Plaintiffs/Counterclaim-Defendants requested that the '530 and '001 patents be added to Civ. No. 23-796 and that the schedule again be modified.

28. On May 7, 2024, Plaintiffs/Counterclaim-Defendants filed a second Complaint for Patent Infringement ("Complaint") in this Court alleging that the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed ANDA Product before the expiration of the '530 and '001 patents would constitute infringement of the '530 and '001 patents, either literally or under the doctrine of equivalents. Plaintiffs/Counterclaim-Defendants further alleged that Sandoz will actively induce infringement of, and/or contribute to infringement by others of the '530 and '001 patents.

29. After Plaintiffs/Counterclaim-Defendants filed the above-captioned suit, Sandoz sent a second notice letter pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), stating that Sandoz's ANDA No. 217936 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that the '001 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Sandoz's ANDA Product.

30. By virtue of Plaintiffs/Counterclaim-Defendants' Complaint, an immediate and justiciable controversy exists between Sandoz, on the one hand, and Plaintiffs/Counterclaim-Defendants, on the other, regarding whether the products described in Sandoz's ANDA No. 217936 ("Sandoz's ANDA Product") infringe any valid and enforceable claim of the '001 patent.

PATENTS-IN-SUIT

31. The face of the ’530 patent indicates it was issued by the U.S. Patent and Trademark Office (“USPTO”) on or about April 30, 2024.

32. The face of the ’001 patent indicates it was issued by the USPTO on or about May 7, 2024.

33. Plaintiffs/Counterclaim-Defendants purport and claim to have the right to enforce the ’530 and ’001 patents.

34. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants caused the FDA to publish the ’530 and ’001 patents in the Orange Book, in connection with NDA No. 208558 for LYNPARZA®.

35. By maintaining the listing of the ’530 and ’001 patents in the Orange Book for NDA No. 208558 for LYNPARZA®, Plaintiffs/Counterclaim-Defendants have represented that the ’530 and ’001 patents cover olaparib tablets, and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Sandoz, that is not licensed by Plaintiffs/Counterclaim-Defendants and files an ANDA seeking approval to market olaparib tablets before the expiration of the ’530 and ’001 patents.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE ’530 PATENT)

36. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

37. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

38. To the extent the ’530 patent is not dismissed, there is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the non-infringement of the ’530 patent because Plaintiffs/Counterclaim-Defendants assert that Sandoz’s ANDA Product would infringe the ’530 patent. Sandoz disputes that Plaintiffs/Counterclaim-Defendants have properly stated a claim for infringement of the ’530 patent or that a case or controversy would otherwise exist.

39. Sandoz seeks a declaration that no valid or enforceable claim of the ’530 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz’s ANDA Product.

40. To the extent not dismissed, because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of Sandoz’s ANDA Product would infringe the ’530 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the Snadoz’s ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the ’530 patent.

41. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz’s ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’530 patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE ’530 PATENT)

42. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

43. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)©.

44. To the extent the '530 patent is not dismissed, there is an actual, substantial, and continuing case or controversy between Sandoz and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '530 patent because Plaintiffs/Counterclaim-Defendants assert that Sandoz's ANDA Product would infringe at least one valid claim of the '530 patent. Sandoz disputes that Plaintiffs/Counterclaim-Defendants have properly stated a claim for infringement of the '530 patent or that a case or controversy would otherwise exist.

45. Sandoz is entitled to a declaration that the claims of the '530 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '001 PATENT)

46. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

47. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

48. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a

declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the ’001 patent.

49. Sandoz seeks a declaration that no valid or enforceable claim of the ’001 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of Sandoz’s ANDA Product.

50. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of Sandoz’s ANDA Product would infringe the ’001 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of Sandoz’s ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the ’001 patent.

51. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of Sandoz’s ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the ’001 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE ’001 PATENT)

52. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

53. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

54. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a

declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the ’001 patent.

55. Sandoz is entitled to a declaration that the claims of the ’001 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Sandoz respectfully requests that this Court enter a Judgment and Order:

A. dismissing the Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that Sandoz and the products described in ANDA No. 217936 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the ’530 and ’001 patents;

C. declaring that Sandoz and the products described in ANDA No. 217936 have not infringed, are not infringing and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the ’530 patent;

D. declaring that the claims of the ’530 patent are invalid;

E. declaring that Sandoz and the products described in ANDA No. 217936 have not infringed, are not infringing and will not infringe (either literally or under the doctrine of

equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '001 patent;

F. declaring that the claims of the '001 patent are invalid;

K. declaring this an exceptional case under 35 U.S.C. § 285 and awarding Sandoz attorney fees, costs, and expenses; and

L. granting Sandoz such other and further relief as this Court deems just and proper.

Dated: July 8, 2024

Respectfully submitted,

/s/ Eric I. Abraham

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Attorneys for Defendant Sandoz Inc.

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2024, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: July 8, 2024

Respectfully submitted,

By: */s/ Eric I. Abraham*
Eric I. Abraham