Eric I. Abraham (eabraham@hillwallack.com)
William P. Murtha (wmurtha@hillwallack.com)
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08540
T: (609) 924-0808
F: (609) 452-1888

Laura A. Lydigsen (*pro hac vice* pending)
Mark H. Remus (*pro hac vice* pending)
Mary E. LaFleur (*pro hac vice* pending)
CROWELL & MORING LLP
455 North Cityfront Plaza Drive
NBC Tower, Suite 3600
Chicago, IL 60611
T: (312) 321-4200
F: (312) 321-4299
llydigsen@crowell.com
mremus@crowell.com
mlafleur@crowell.com

Ryan Seewald (*pro hac vice* pending)
CROWELL & MORING LLP
1601 Wewatta Street, Suite 815
Denver, CO 80202
T: (303) 524-8660
rseewald@crowell.com

Attorneys for Defendant Sandoz Inc.

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

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD and MSD INTERNATIONAL BUSINESS GMBH, Plaintiffs, v. NATCO PHARMA LIMITED and NATCO PHARMA, INC.,	Civil Action No.: 3:23-cv-796 (Consolidated)

Defendants.

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ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

Civil Action No.: 3:24-cv-641

DEFENDANT SANDOZ INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Sandoz Inc. ("Sandoz") hereby files its Answer, Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed on February 2, 2024 by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield, 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. 7,449,464 ("the '464 patent"); U.S. Patent No. 8,475,842 ("the '842 patent"); U.S. Patent No. 8,859,562 ("the '562 patent"); and U.S. Patent No. 11,633,396 ("the '396 patent"). These patents are referred to collectively herein as 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. 7,449,464 ("'464 patent"), U.S. Patent No. 8,475,842 ("'842 patent"), U.S. Patent No. 8,859,562 ("'562 patent"), and U.S. Patent No. 11,633,396 ("'396 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 Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 1.

2. Sandoz 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 the Patents-in-Suit.

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 the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 2.

The Parties

3. 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 3 and on that basis denies these allegations.

4. 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 4 and on that basis denies these allegations.

5. 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 5 and on that basis denies these allegations.

6. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

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 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 7 and on that basis denies these allegations.

8. 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 8.

9. 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 9.

Jurisdiction

10. Plaintiffs incorporate each of the preceding paragraphs 1-9 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.

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

ANSWER:

Paragraph 11 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 limited 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. Sandoz denies the remaining allegations of Paragraph 11.

12. 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 12 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 12.

13. 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 ANDA No. 217936.

ANSWER:

Paragraph 13 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 13.

14. 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 14 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 14.

15. 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 this ANDA, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of Sandoz's ANDA.

ANSWER:

Paragraph 15 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 15.

16. 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 Paragraph IV Certifications to obtain approval for Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 16.

17. 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 17 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 17.

18. 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 18.

19. 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.*, No. 18-cv-11026, ECF No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, No. 17-cv-10129, ECF No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, No. 17-cv-08825, ECF No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Lab'ys Priv. Ltd.*, No. 17-cv-05302, ECF 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 19 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 19, and states that the filings in those cases speak for themselves. Sandoz denies the remaining allegations of Paragraph 19.

20. 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 ANDA No. 217936 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 20 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 20.

21. 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 sale and 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. At the time Sandoz sent notice of the Paragraph IV Certifications, it was reasonably foreseeable that Sandoz would be sued within 45 days in this Judicial District, where Sandoz is located. 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 21 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's ANDA contains Paragraph IV Certifications to obtain approval for Sandoz's ANDA Product before the expiration of the Patents-in-Suit. 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. 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 22 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 22.

Venue

23. Plaintiffs incorporate each of the preceding paragraphs 1-22 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.

24. Venue is proper in this District under 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 24 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 24.

25. 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 25 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 25.

26. 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 26 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 26.

Factual Background

27. 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 27 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 27.

28. 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 its 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 28 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 28.

29. In Sandoz's Notice Letter, Sandoz stated that it had submitted Paragraph IV Certifications to FDA alleging that the '464, '842, '562, and '396 patents 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 '464, '842, '562, and '396 patents.

ANSWER:

Sandoz admits that Sandoz's ANDA contains Paragraph IV Certifications to obtain approval for Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Sandoz's Notice letter speaks for itself. Sandoz denies the remaining allegations of Paragraph 29.

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

ANSWER:

Paragraph 30 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 further admits that Sandoz's ANDA contains Paragraph IV Certifications to obtain approval for Sandoz's ANDA Product before the expiration of the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 30.

31. In an exchange of correspondence, counsel for Plaintiffs and counsel for Sandoz discussed the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Sandoz's ANDA and any Drug Master File referred to therein, and Sandoz refused to produce samples of Sandoz's ANDA Product and other internal documents and material relevant to infringement.

ANSWER:

Sandoz admits that Sandoz's Notice Letter included an "Offer of Confidential Access" pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Sandoz further admits that the parties did not reach an agreement regarding access to Sandoz's ANDA because Plaintiffs refused the terms proposed with Sandoz's Notice Letter and instead made unreasonable demands for materials beyond those properly within scope of an Offer of Confidential Access under section 355(j)(5)(C)(i)(iii). Sandoz denies the remaining allegations of Paragraph 31.

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

ANSWER:

Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz's Notice Letter was dated December 29, 2023 and that Plaintiffs' Complaint was filed on February 2, 2024. Sandoz denies the remaining allegations of Paragraph 32.

Count I – Infringement of the '464 Patent Under 35 U.S.C. § 271(e)(2)

33. Plaintiffs incorporate each of the preceding paragraphs 1-32 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.

34. On November 11, 2008, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '464 patent, entitled "Phthalazinone Derivatives." A copy of the '464 patent is attached hereto as Exhibit A.

ANSWER:

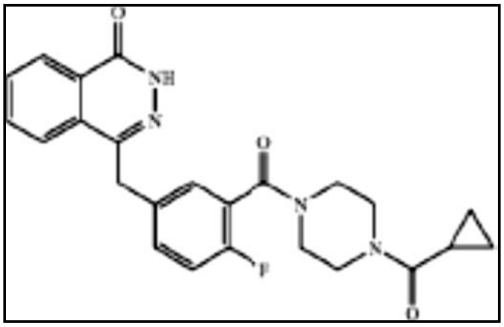
Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit A of Plaintiffs' Complaint purports to be a copy of the '464 patent. Sandoz further admits that the face of the '464 patent states that the '464 patent purports to have been issued on November 11, 2008. Sandoz further admits on its face, the '464 patent is titled "Phthalazinone Derivatives." Sandoz denies the remaining allegations of Paragraph 34.

35. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the '464 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the '464 patent.

ANSWER:

Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the online records of the U.S. Patent and Trademark Office ("USPTO") list Kudos Pharmaceuticals Limited as the assignee of the '464 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35 and on that basis denies these allegations.

36. The ’464 patent claims, *inter alia*, a compound of Formula III, shown below, or isomers, salts, or solvates thereof.



ANSWER:

Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the ’464 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 36.

37. The compound of Formula III is the compound that is known by the international nonproprietary name olaparib. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER:

Paragraph 37 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 indicates that the active ingredient in LYNPARZA® is olaparib. Sandoz further admits that Section 11 of the package insert provides the same chemical structure for olaparib as the compound of Formula III. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 37 and on that basis denies these allegations.

38. LYNPARZA® is covered by Claims 1 and 2 of the ’464 patent, and the ’464 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

ANSWER:

Paragraph 38 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the '464 patent in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 38.

39. 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 '464 patent was an act of infringement of the '464 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 39 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 '464 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 39.

40. On information and belief, Sandoz's ANDA Product contains olaparib.

ANSWER:

Sandoz admits the allegations of Paragraph 40.

41. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe Claims 1 and 2 of the '464 patent, either literally or under the doctrine of equivalents.

ANSWER:

Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 41.

42. 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 Claims 1 and 2 of the '464 patent.

ANSWER:

Paragraph 42 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 42

43. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '464 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Paragraph 43 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 43.

44. 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 '464 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 '464 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 44.

45. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '464 patent, active inducement of infringement of the '464 patent, and contribution to the infringement by others of the '464 patent.

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. On information and belief, Sandoz has acted with full knowledge of the '464 patent and without a reasonable basis for believing that it would not be liable for infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent.

ANSWER:

Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 46.

47. In Sandoz's Notice Letter, Sandoz did not contest infringement of Claims 1 and 2 of the '464 patent on any basis other than the alleged invalidity of those claims.

ANSWER:

Paragraph 47 contains legal conclusions to which no response is required. Sandoz's Notice Letter speaks for itself. To the extent a response is required, Sandoz denies the allegations of Paragraph 47.

48. Unless Sandoz is enjoined from infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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.

Count II – Declaratory Judgment of Infringement of the '464 Patent

49. Plaintiffs incorporate each of the preceding paragraphs 1-48 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.

50. 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 '464 patent.

ANSWER:

Paragraph 50 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 50.

51. 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 '464 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '464 patent, and that the claims of the '464 patent are valid.

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.

Count III – Infringement of the '842 Patent Under 35 U.S.C. § 271(e)(2)

52. Plaintiffs incorporate each of the preceding paragraphs 1-51 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.

53. On July 2, 2013, the USPTO duly and lawfully issued the '842 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 '842 patent is attached hereto as Exhibit B.

ANSWER:

Paragraph 53 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 '842 patent. Sandoz further admits that the face of the '842 patent states that the '842 patent purports to have been issued on July 2, 2013. Sandoz further admits on its face, the '842 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 53.

54. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the '842 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the '842 patent.

ANSWER:

Paragraph 54 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 '842 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 54 and on that basis denies these allegations.

55. The '842 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

ANSWER:

Paragraph 55 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the '842 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 55.

56. LYNPARZA® is covered by one or more claims of the '842 patent, including at least claims 1 and 7 of the '842 patent, and the '842 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER:

Paragraph 56 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 '842 patent in the Orange Book in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 56.

57. 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 '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 57 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 '842 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 57.

58. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product would infringe at least claims 1 and 7 of the '842 patent, recited above, either literally or under the doctrine of equivalents.

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.

59. On information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe at least claims 1 and 7 of the '842 patent.

ANSWER:

Paragraph 59 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 59.

60. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '842 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 60.

61. 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 '842 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 '842 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 61.

62. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '842 patent, active inducement of infringement of the '842 patent, and contribution to the infringement by others of the '842 patent.

ANSWER:

Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 62.

63. On information and belief, Sandoz has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent.

ANSWER:

Paragraph 63 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 63.

64. Unless Sandoz is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER:

Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 64.

Count IV – Declaratory Judgment of Infringement of the '842 Patent

65. Plaintiffs incorporate each of the preceding paragraphs 1-64 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.

66. 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 '842 patent.

ANSWER:

Paragraph 66 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 66.

67. 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 '842 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are valid.

ANSWER:

Paragraph 67 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 67.

Count V – Infringement of the '396 Patent Under 35 U.S.C. § 271(e)(2)

68. Plaintiffs incorporate each of the preceding paragraphs 1-67 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.

69. On April 25, 2023, the USPTO duly and lawfully issued the '396 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 '396 patent is attached hereto as Exhibit C.

ANSWER:

Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit C of Plaintiffs' Complaint purports to be a copy of the '396 patent. Sandoz further admits that the face of the '396 patent states that the '396 patent purports to have been issued on April 25, 2023. Sandoz further admits on its face, the '396 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 69.

70. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the '396 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the '396 patent.

ANSWER:

Paragraph 70 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 '396 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 70 and on that basis denies these allegations.

71. The '396 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

ANSWER:

Paragraph 71 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the '842 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 71.

72. LYNPARZA® is covered by one or more claims of the '396 patent, including at least claim 1 of the '396 patent, and the '396 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER:

Paragraph 72 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 '396 patent in the Orange Book in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 72.

73. 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 '396 patent was an act of infringement of the '396 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 73 contains legal conclusions to which no response is required. Sandoz does not contest this Court's subject matter jurisdiction solely for the alleged infringement of the '396 patent under 35 U.S.C. § 271(e)(2), and expressly reserves the right to contest subject matter jurisdiction as to other allegations. To the extent a response is required, Sandoz denies the remaining allegations of Paragraph 73.

74. 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 '396 patent, recited above, either literally or under the doctrine of equivalents.

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. 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 '396 patent.

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.

76. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '396 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER:

Paragraph 76 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 76.

77. 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 '396 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 '396 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 77 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 77.

78. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '396 patent, active inducement of infringement of the '396 patent, and contribution to the infringement by others of the '396 patent.

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.

79. On information and belief, Sandoz has acted with full knowledge of the '396 patent and without a reasonable basis for believing that it would not be liable for infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent.

ANSWER:

Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 79.

80. Unless Sandoz is enjoined from infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER:

Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 80.

Count VI – Declaratory Judgment of Infringement of the '396 Patent

81. Plaintiffs incorporate each of the preceding paragraphs 1-80 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.

82. 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 '396 patent.

ANSWER:

Paragraph 82 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 82.

83. 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 '396 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '396 patent, and that the claims of the '396 patent are valid.

ANSWER:

Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 83.

Count VII – Infringement of the '562 Patent Under 35 U.S.C. § 271(e)(2)

84. Plaintiffs incorporate each of the preceding paragraphs 1-83 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.

85. On October 14, 2014, the USPTO duly and lawfully issued the '562 patent, entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer." A copy of the '562 patent is attached hereto as Exhibit D.

ANSWER:

Paragraph 85 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Exhibit D of Plaintiffs' Complaint purports to be a copy of the '562 patent. Sandoz further admits that the face of the '562 patent states that the '562 patent purports to have been issued on October 14, 2014. Sandoz further admits on its face, the '562 patent is titled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer." Sandoz denies the remaining allegations of Paragraph 85.

86. Plaintiff The University of Sheffield is the assignee of the '562 patent. Plaintiffs The University of Sheffield, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the '562 patent.

ANSWER:

Paragraph 86 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 The University of

Sheffield as the assignee of the ’562 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 86 and on that basis denies these allegations.

87. The ’562 patent claims, *inter alia*, a method of treatment of cancer cells defective in homologous recombination (HR).

ANSWER:

Paragraph 87 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the claims of the ’562 patent speak for themselves. Sandoz denies the remaining allegations of Paragraph 87.

88. Methods of using LYNPARZA® are covered by Claim 1 of the ’562 patent, and the ’562 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

ANSWER:

Paragraph 88 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Orange Book lists the ’562 patent in connection with NDA No. 208558 for LYNPARZA®. Sandoz denies the remaining allegations of Paragraph 88.

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 prior to the expiration of the ’562 patent was an act of infringement of the ’562 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 89 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 ’562 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 89.

90. 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 Claim 1 of the '562 patent.

ANSWER:

Paragraph 90 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 90.

91. On information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '562 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 '562 patent after approval of Sandoz's ANDA.

ANSWER:

Paragraph 91 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 91.

92. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '562 patent, active inducement of infringement of the '562 patent, and contribution to the infringement by others of the '562 patent.

ANSWER:

Paragraph 92 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 92.

93. On information and belief, Sandoz has acted with full knowledge of the '562 patent and without a reasonable basis for believing that it would not be liable for the infringing of the '562 patent, and contributing to the infringement by others of the '562 patent.

ANSWER:

Paragraph 93 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 93.

94. In Sandoz's Notice Letter, Sandoz did not contest infringement of Claim 1 of the '562 patent on any basis other than the alleged invalidity of that claim.

ANSWER:

Paragraph 94 contains legal conclusions to which no response is required. Sandoz's Notice Letter speaks for itself. To the extent a response is required, Sandoz denies the allegations of Paragraph 94.

95. Unless Sandoz is enjoined from infringing the '562 patent, actively inducing the infringement of the '562 patent, and contributing to the infringement by others of the '562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER:

Paragraph 95 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 95.

Count VIII – Declaratory Judgment of the '562 Patent

96. Plaintiffs incorporate each of the preceding paragraphs 1-95 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.

97. 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 infringement and/or invalidity of the '562 patent.

ANSWER:

Paragraph 97 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 97.

98. 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 '562 patent, will infringe, induce

the infringement of, and contribute to the infringement by others of the '562 patent, and that the claims of the '562 patent are valid.

ANSWER:

Paragraph 98 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz denies the allegations of Paragraph 98.

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 PATENTS-IN-SUIT)

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 '464, '842, '396, and '562 patents, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of the products described in ANDA No. 217936 has not infringed, does not infringe, and would not infringe any valid claim of the Patents-in-Suit for at least the reasons set forth in Sandoz's Notice Letter dated December 29, 2023.

SECOND DEFENSE
(INVALIDITY OF THE PATENTS-IN-SUIT)

One or more claims of the '464, '842, '396, and '562 patents 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. For example, without limitation, the Patents-in-Suit are invalid for at least the reasons set forth in Sandoz's Notice Letter dated December 29, 2023.

THIRD DEFENSE
(FAILURE TO STATE A CLAIM FOR DIRECT INFRINGEMENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported direct infringement of the '464, '842, '396, and '562 patents. 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.

FOURTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INDIRECT INFRINGEMENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported indirect infringement of the '464, '842, '396, and '562 patents. 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.

FIFTH 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.

SIXTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

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

SEVENTH 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.

EIGHTH 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, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, "Plaintiffs"), 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 ("ANDA") No. 217936, and upon approval by the U.S. Food and Drug Administration ("FDA") 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 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.

6. Plaintiff/Counterclaim-Defendant The University of Sheffield purports to be a Royal Charter company organized and existing under the laws of England and Wales, having its address at Western Bank, Sheffield S10 2TN, 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 Kudos Pharmaceuticals Limited purports to be the assignee of U.S. Patent No. 7,449,464 ("'464 patent"), U.S. Patent No. 8,475,842 ("'842 patent"), U.S. Patent No. 8,859,562 ("'562 patent"), and U.S. Patent No. 11,633,396 ("'396 patent") (collectively, "Patents-in-Suit").

9. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and MSD International Business GmbH purport to possess all exclusive rights and interests in the Patents-in-Suit.

10. 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

11. 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).

12. 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 under 21 U.S.C. § 355(j)(5)(C).

13. 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.

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

BACKGROUND

15. On February 2, 2024, Plaintiffs/Counterclaim-Defendants filed a Complaint for Patent Infringement ("Complaint") in this Court alleging that the commercial manufacture, use, offer for sales, sale, and/or importation of Sandoz's Proposed ANDA Product before the expiration of the Patents-in-Suit would constitute infringement of the '464, '842, '396, and '562 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 Patents-in-Suit.

16. By virtue of Plaintiffs' Complaint, an immediate and justiciable controversy exists between Sandoz, on the one hand, and Plaintiffs, 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 Patents-in-Suit.

PATENTS-IN-SUIT

17. The face of the '464 patent indicates it was issued by the U.S. Patent and Trademark Office ("USPTO") on or about November 11, 2008.

18. The face of the '842 patent indicates it was issued by the USPTO on or about July 2, 2013.

19. The face of the '396 patent indicates it was issued by the USPTO on or about April 25, 2023.

20. The face of the '562 patent indicates it was issued by the USPTO on or about October 14, 2014.

21. Plaintiffs/Counterclaim-Defendants purport and claim to have the right to enforce the Patents-in-Suit.

22. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants caused the FDA to publish the Patents-in-Suit in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), in connection with NDA No. 208558 for LYNPARZA®.

23. By maintaining the listing of the Patents-in-Suit in the Orange Book for NDA No. 208558 for LYNPARZA®, Plaintiffs/Counterclaim-Defendants have represented that the Patents-in-Suit 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 Patents-in-Suit.

SANDOZ'S ANDA NO. 217936

24. Sandoz submitted ANDA No. 217936 with FDA seeking approval to engage in the commercial marketing of Sandoz's ANDA Product before the expiration of the Patents-in-Suit.

25. 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 ("Sandoz's Notice Letter"), stating that Sandoz's ANDA No. 217936 included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), alleging that the Patents-in-Suit are invalid, unenforceable, and will not be infringed by the commercial manufacture, use or sale of Sandoz's ANDA Product.

26. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), Sandoz's Notice Letter included an Offer of Confidential Access ("OCA") to ANDA No. 217936 for the holder of NDA No. 208558 and owners of the Patents-in-Suit so that each could determine whether Sandoz's ANDA Product infringes any valid claim of the Patents-in-Suit.

27. Sandoz's OCA to its ANDA No. 217936 complied with the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III), which states in relevant part that the offer shall be for "confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

28. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the Federal Drug and Cosmetic Act, Sandoz attached to its Notice Letter a detailed statement of the factual and legal bases for Sandoz's Paragraph IV Certifications ("Sandoz's Detailed Statement").

29. 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.

30. By letter dated January 11, 2024, Plaintiffs demanded revisions to Sandoz's OCA that would have removed many of the restrictions placed by the OCA on access to Sandoz's confidential information. Plaintiffs' letter also demanded Sandoz's confidential documents and things other than a copy of Sandoz's ANDA.

31. Sandoz responded to Plaintiffs' demands by letter dated January 19, 2024 and Sandoz's counsel spoke with Plaintiffs' counsel on January 25, 2024 to discuss potential resolution over the parties' dispute over the terms of the OCA. During the January 25 discussion, Plaintiffs' counsel indicated Plaintiffs were unlikely to negotiate further with respect to the terms of the OCA.

32. On February 2, 2024, Plaintiffs/Counterclaim-Defendants filed this infringement action under 35 U.S.C. § 271(e)(2), asserting the Patents-in-Suit against Sandoz.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '464 PATENT)

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

34. 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). 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 '464 patent.

35. Sandoz seeks a declaration that no valid or enforceable claim of the '464 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 217936.

36. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '464 patent.

37. In Sandoz's Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Detailed Statement.

38. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 217936 would infringe the '464 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 products described in Sandoz's ANDA No. 217936 within the United States has not infringed and will not infringe, directly and/or indirectly, the '464 patent.

39. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 217936 has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '464 patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '464 PATENT)

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

41. 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) and seeks a declaration that the claims of the '464 patent are invalid. 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 '464 patent.

42. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '464 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '464 patent and the claims thereof 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.

43. Sandoz is entitled to a declaration that the claims of the '464 patent are invalid.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '842 PATENT)

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

45. 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). 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 '842 patent.

46. Sandoz seeks a declaration that no valid or enforceable claim of the '842 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 217936.

47. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '842 patent.

48. In Sandoz's Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Detailed Statement.

49. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 217936 would infringe the '842 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 products described in Sandoz's ANDA No. 217936 within the United States has not infringed and will not infringe, directly and/or indirectly, the '842 patent.

50. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 217936 has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '842 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '842 PATENT)

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

52. 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) and seeks a declaration that the claims of the '842 patent are invalid. 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 '842 patent.

53. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '842 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '842 patent and the claims thereof 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.

54. Sandoz is entitled to a declaration that the claims of the '842 patent are invalid.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '396 PATENT)

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

56. 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). 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 '396 patent.

57. Sandoz seeks a declaration that no valid or enforceable claim of the '396 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 217936.

58. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '396 patent.

59. In Sandoz's Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Detailed Statement.

60. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 217936 would infringe the '396 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 products described in Sandoz's ANDA No. 217936 within the United States has not infringed and will not infringe, directly and/or indirectly, the '396 patent.

61. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 217936 has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '396 patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '396 PATENT)

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

63. 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) and seeks a declaration that the claims of the '396 patent are invalid. 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 '396 patent.

64. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '396 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '396 patent and the claims thereof 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.

65. Sandoz is entitled to a declaration that the claims of the '396 patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '562 PATENT)

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

67. 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). 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 '562 patent.

68. Sandoz seeks a declaration that no valid or enforceable claim of the '562 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA No. 217936.

69. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), Sandoz's Detailed Statement provides factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '562 patent.

70. In Sandoz's Detailed Statement, Sandoz expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in Sandoz's Detailed Statement.

71. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA No. 217936 would infringe the '562 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 products described in Sandoz's ANDA No. 217936 within the United States has not infringed and will not infringe, directly and/or indirectly, the '562 patent.

72. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA No. 217936 has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '562 patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '562 PATENT)

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

74. 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) and seeks a declaration that the claims of the '562 patent are invalid. 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 '562 patent.

75. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '562 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '562 patent and the claims thereof 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.

76. Sandoz is entitled to a declaration that the claims of the '562 patent are invalid.

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 ’464, ’842, ’396, and ’562 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 ’464 patent;

D. declaring that the claims of the ’464 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 ’842 patent;

F. declaring that the claims of the ’842 patent are invalid;

G. 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 ’396 patent;

H. declaring that the claims of the ’396 patent are invalid;

I. 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 ’562 patent;

J. declaring that the claims of the ’562 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: April 5, 2024

Respectfully submitted,

/s/ Eric I. Abraham

Eric I. Abraham (eabraham@hillwallack.com)
William P. Murtha (wmurtha@hillwallack.com)
HILL WALLACK LLP
21 Roszel Road
Princeton, NJ 08540
T: (609) 924-0808
F: (609) 452-1888

Laura A. Lydigsen (*pro hac vice* pending)
Mark H. Remus (*pro hac vice* pending)
Mary E. LaFleur (*pro hac vice* pending)
CROWELL & MORING LLP
455 North Cityfront Plaza Drive
NBC Tower, Suite 3600
Chicago, IL 60611
T: (312) 321-4200
F: (312) 321-4299
llydigsen@crowell.com
mremus@crowell.com
mlafleur@crowell.com

Ryan Seewald (*pro hac vice* pending)
CROWELL & MORING LLP
1601 Wewatta Street
Suite 815
Denver, CO 80202
T: (303) 524-8660
F: (303) 524-8650
rseewald@crowell.com

Attorneys for Defendant Sandoz Inc.