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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, and MSD INTERNATIONAL BUSINESS GMBH Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED, Defendants.	Civil Action No.: 3:25-234 (RK)(TJB) *Document Filed Electronically*

ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Defendants") for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs") state as follows:

All averments not expressly admitted are denied.

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 Zydus 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. 12,178,816 ("the '816 patent").

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint purports to be an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., alleging infringement of U.S. Patent No. 12,178,816 ("the '816 patent"). Defendants further admit that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 219893 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of olaparib tablets, 100 mg and 150 mg as described in ANDA No. 219893 ("Zydus USA's Proposed ANDA Product") in or into the United States. Defendants further admit that ANDA No. 219893 identifies LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, as the Reference Listed Drug. Defendants further admit that ANDA No. 219893 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '816 patent. Defendants deny all other allegations in paragraph 1.

2. Zydus notified Plaintiffs by letter dated November 5, 2024 ("Zydus's Notice Letter") that it had submitted to FDA ANDA No. 219893 ("Zydus'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 ("Zydus's ANDA Product"), prior to the expiration of U.S. Patent No. 8,859,562 ("the '562 patent"); U.S. Patent No. 8,475,842 ("the '842 patent"); U.S. Patent No. 11,633,396 ("the '396 patent"); U.S. Patent No. 11,975,001 ("the '001 patent"); and U.S. Patent No. 12,048,695 ("the '695 patent").

ANSWER: The allegations in paragraph 2 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA transmitted a

letter dated November 5, 2024 ("Zydus USA's Notice Letter") to KuDOS Pharmaceuticals Ltd ("KuDOS"), The University of Sheffield, and AstraZeneca PLC and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), stating that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA's Notice Letter states in part that ANDA No. 219893 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to U.S. Patent Nos. 8,475,842 ("the '842 patent"), 8,859,562 ("the '562 patent"), 11,633,396 ("the '396 patent"), 11,975,001 ("the '001 patent"), and 12,048,695 ("the '695 patent"). Defendants deny all other allegations in paragraph 2.

3. Plaintiffs filed suit against Zydus in this District, asserting that Zydus's ANDA infringes the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent. *See AstraZeneca Pharms. L.P. v. Zydus Pharms. (USA) Inc.*, Civ. No. 24-cv-10458, Dkt. No. 1. Plaintiffs subsequently filed against Zydus, alleging that Zydus's ANDA infringes U.S. Patent No. 12,144,810. *See AstraZeneca Pharms. L.P. v. Zydus Pharms. (USA) Inc.*, Civ. 24-10629, Dkt. No. 1. Those cases were consolidated with other litigation involving Plaintiffs' patent infringement claims relating to generic Olaparib tablets. *See AstraZeneca Pharms. L.P. v Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 160.

ANSWER: Admitted.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore deny them.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore deny them.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 6 and therefore deny them.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 7 and therefore deny them.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 8 and therefore deny them.

9. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey and having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

ANSWER: Admitted.

10. Upon information and belief, Defendant Zydus Lifesciences Limited is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad, Gujarat, India, 382481.

ANSWER: Admitted.

11. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Zydus Lifesciences Limited.

ANSWER: Admitted.

12. Upon information and belief, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. acted in concert to prepare and submit Zydus's ANDA to the FDA.

Upon information and belief, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. know and intend that upon approval of Zydus's ANDA, Zydus Lifesciences Limited (or another entity affiliated with Zydus Lifesciences Limited) will manufacture Zydus's ANDA Product, and Zydus Pharmaceuticals (USA) Inc. will directly or indirectly import Zydus's ANDA Product into the United States and market, sell, and distribute Zydus's ANDA Product throughout the United States, including in New Jersey.

ANSWER: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 12.

13. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. acts as Zydus Lifesciences Limited's agent in the United States, including with respect to the filing of Zydus's ANDA and the marketing, sale, and distribution of Zydus's ANDA Product in the United States.

ANSWER: Denied.

14. Upon information and belief, following any FDA approval of Zydus's ANDA, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. will act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within New Jersey.

ANSWER: The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 14.

Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1–14 as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-14, as if fully set forth herein.

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

ANSWER: The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 16.

17. 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 Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc.

ANSWER: The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 17.

18. Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. are subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. have purposefully availed themselves of the benefits and protections of New Jersey's laws such that those entities would reasonably anticipate being haled into court here. On information and belief, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in the State of New Jersey, and therefore transact business within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Defendants deny all other allegations in paragraph 18.

19. In addition, this Court has personal jurisdiction over Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. because, among other things, on information and belief: (1) Zydus Pharmaceuticals (USA) Inc. filed Zydus's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Zydus's ANDA, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Zydus's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Zydus's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Zydus's ANDA, Zydus's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants further admit that Zydus USA sells pharmaceutical products in the United States,

including generic pharmaceuticals products manufactured by Zydus Lifesciences. Defendants deny all other allegations in paragraph 19.

20. This Court has personal jurisdiction over Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. because those entities (1) engage in patent litigation concerning Zydus's products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g.*, *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023).

ANSWER: The allegations in paragraph 20 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus Lifesciences and Zydus USA have engaged in patent litigation in this District regarding Abbreviated New Drug Applications submitted by Zydus USA. Defendants admit that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus Lifesciences stated that it "does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Defendants also admit that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus USA stated that it "does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Defendants deny all other allegations of paragraph 20.

21. Additionally, this Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. because, on information and belief, Zydus Pharmaceuticals (USA) Inc. maintains its principal place of business in this District.

ANSWER: The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA has a principal

place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants deny all other allegations in paragraph 21.

22. For the above reasons, it would not be unfair or unreasonable for Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

ANSWER: The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 22.

Venue

23. Plaintiffs incorporate each of the preceding paragraphs 1–22 as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-22, as if fully set forth herein.

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

ANSWER: The allegations in paragraph 24 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus Lifesciences is a corporation organized under the laws of India, having its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad, Gujarat 382481, India. Defendants deny all other allegations in paragraph 24.

25. Venue is proper in this District as to Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Zydus Pharmaceuticals (USA) Inc. has committed, or will commit, an act of infringement in this District, and has a regular and established place of business in this District. On information and belief, among other things, (1) Zydus filed Zydus's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Zydus's ANDA, Zydus will market, distribute, offer for sale, sell, and/or import Zydus's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Zydus's ANDA Product in New Jersey. Further, on information and belief, Zydus Pharmaceuticals (USA) Inc. maintains its principal place of business in this District.

ANSWER: The allegations in paragraph 25 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants admit that Zydus USA is a corporation organized and existing under the laws of the State New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants deny all other allegations in paragraph 25.

26. Venue is proper in this District as to Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. because those entities (1) engage in patent litigation concerning Zydus's products in this District, and (2) do not contest that venue is proper in this District. *See, e.g.*, *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023).

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus Lifesciences and Zydus USA have engaged in patent litigation in this District regarding Abbreviated New Drug

Applications submitted by Zydus USA. Defendants further admit that Zydus USA is a corporation organized and existing under the laws of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants admit that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus Lifesciences stated that it "does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Defendants also admit that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus USA stated that it "does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Defendants deny all other allegations in 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: Defendants admit that FDA's Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists "LYNPARZA" as Proprietary Name and "OLAPARIB" as Active Ingredient in connection with NDA No. 208558. Defendants further admit on information and belief that the prescribing information for LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, revised November 6, 2023, states:

---------- INDICATIONS AND USAGE ----------

Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

Ovarian cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.1, 2.1)
- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious *BRCA* mutation, and/or
  - genomic instability.

  Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.2, 2.1)
- for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.3, 2.1)

Breast cancer

- for the adjuvant treatment of adult patients with deleterious or suspected deleterious g*BRCA*m human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.4, 2.1)
- for the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.5, 2.1)

Pancreatic cancer

- for the maintenance treatment of adult patients with deleterious or suspected deleterious g*BRCA*m metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.6, 2.1)

Prostate cancer

- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with

Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 27 and therefore deny them.

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

ANSWER: Defendants admit that Zydus USA's Notice Letter states that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA's Notice Letter states that ANDA No. 219893 contains data from bioavailability or bioequivalence studies to obtain approval to engage in the commercial manufacture, use, or sale of Zydus USA's Proposed ANDA Product. Defendants further admit that ANDA No. 219893 identifies LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, as the Reference Listed Drug. Defendants deny all other allegations in paragraph 28.

29. The purpose of Zydus's submission of Zydus'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 Zydus's ANDA Product.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 29.

30. In Zydus's Notice Letter, Zydus stated that it had submitted Paragraph IV Certifications to FDA alleging that the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent were invalid, unenforceable, and/or not infringed, and that Zydus is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent.

ANSWER: Defendants admit that Zydus USA's Notice Letter states in part that ANDA No. 219893 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent. Defendants deny all other allegations in paragraph 30.

31. Following receipt of Zydus's Notice Letter, on November 12, 2024, Plaintiffs filed suit against Zydus alleging that Zydus's ANDA infringes certain patents, including the '562, '842, '396, '001, and '695 patents. *See AstraZeneca Pharms. L.P. v. Zydus Pharms*. (USA) Inc., Civ. No. 24-10629, Dkt. No. 1. That suit is currently pending in this District.

ANSWER: Admitted.

32. On information and belief, Zydus intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent.

ANSWER: The allegations in paragraph 32 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent. Defendants deny all other allegations in paragraph 32.

33. On information and belief, Zydus 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, Zydus 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, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon FDA approval of Zydus's ANDA.

ANSWER: The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that FDA's Orange Book, lists U.S. Patent Nos. 8,143,241, 8,071,579, and 7,449,464 in connection with NDA No. 208558 for LYNPARZA®. Defendants further admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer

for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent. Defendants deny all other allegations in paragraph 33.

34. On December 11, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '816 patent, and indicated that the '816 patent would issue on December 31, 2024.

ANSWER: The allegations in paragraph 34 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the United States Patent and Trademark Office ("USPTO") issued an Issue Notification for the '816 patent on December 11, 2024. Defendants further admit that the '816 patent lists December 31, 2024 as the Date of the Patent. Defendants deny all other allegations in paragraph 34.

35. On December 16, 2024, Plaintiffs notified Zydus's outside counsel of the upcoming issuance of the '816 patent. Zydus's counsel later indicted Zydus's awareness of the '816 patent in a schedule proposed jointly with the other Defendants in the consolidated litigation, which was transmitted to Plaintiffs on December 17, 2024.

ANSWER: The allegations in paragraph 35 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on December 16, 2024, Plaintiffs sent Defendants' outside counsel a copy of a preliminary amendment for "Application No.: To Be Assigned, Continuation of 18/755,544" titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." Defendants deny all other allegations in paragraph 35.

36. On information and belief, Zydus intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of the '816 patent.

ANSWER: The allegations in paragraph 36 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA

No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA's Notice Letter states in part that ANDA No. 219893 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '562 patent, the '842 patent, the '396 patent, the '001 patent, and the '695 patent. Defendants deny all other allegations in paragraph 36.

COUNT I – Infringement of the '816 Patent Under 35 U.S.C. § 271(e)(2)

37. Plaintiffs incorporate each of the preceding paragraphs 1–36 as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-36, as if fully set forth herein.

38. On December 31, 2024, the USPTO duly and lawfully issued the '816 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 '816 patent is attached hereto as Exhibit A.

ANSWER: The allegations in paragraph 38 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '816 patent is entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One" and lists December 31, 2024 as the Date of the Patent. Defendants further admit that what purports to be a copy of the '816 patent is attached to the Complaint as Exhibit A. Defendants deny all other allegations in paragraph 38.

39. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '816 patent. Plaintiffs collectively possess all exclusive rights and interests in the '816 patent.

ANSWER: The allegations in paragraph 39 are legal conclusions to which no answer is required. To the extent an answer is required, denied.

40. The '816 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, know by the international nonproprietary name olaparib and certain excipients.

ANSWER: The allegations in paragraph 40 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that the allegations in paragraph 40 completely and accurately recite the claims of the '816 patent and therefore deny the allegations in paragraph 40.

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

ANSWER: Defendants admit that FDA's Orange Book lists "LYNPARZA" as Proprietary Name and "OLAPARIB" as Active Ingredient in connection with NDA No. 208558. Defendants deny all other allegations in paragraph 41.

42. LYNPARZA® is covered by claim 1 of the '816 patent, and the '816 patent will be listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Defendants admit that the '816 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 42 and therefore deny them.

43. On information and belief, following the expiration of those patents that Zydus chose not to challenge, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon FDA approval of Zydus's ANDA.

ANSWER: The allegations in paragraph 43 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '562 patent, the

’842 patent, the ’396 patent, the ’001 patent, and the ’695 patent. Defendants deny all other allegations in paragraph 43.

44. Zydus received notice of the ’816 patent at least as of December 16, 2024, when Plaintiffs notified Zydus’s outside counsel of the upcoming issuance of the ’816 patent.

ANSWER: The allegations in paragraph 44 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that on December 16, 2024, Plaintiffs sent Defendants’ outside counsel a copy of a preliminary amendment for “Application No.: To Be Assigned, Continuation of 18/755,544” titled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One.” Defendants deny all other allegations in paragraph 44.

45. On information and belief, Zydus intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus’s ANDA Product prior to the expiration of the ’816 patent.

ANSWER: The allegations in paragraph 45 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA’s Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219893 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’562 patent, the ’842 patent, the ’396 patent, the ’001 patent, and the ’695 patent. Defendants deny all other allegations in paragraph 45.

46. Zydus’s submission of Zydus’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus’s ANDA Product prior to the expiration of the ’816 patent was an act of infringement of the ’816 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

47. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product would infringe at least claim 1 of the '816 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

48. On information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for Zydus's ANDA Product would infringe at least claim 1 of the '816 patent.

ANSWER: Denied.

49. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '816 patent and knows that Zydus's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Zydus plans and intends to, and will, contribute to infringement of the '816 patent after approval of Zydus's ANDA.

ANSWER: Denied.

50. The foregoing actions by Zydus constitute and/or will constitute infringement of the '816 patent, active inducement of infringement of the '816 patent, and contribution to the infringement by others of the '816 patent.

ANSWER: Denied.

51. On information and belief, Zydus has acted with full knowledge of the '816 patent and without a reasonable basis for believing that it would not be liable for the infringing of the '816 patent, actively inducing infringement of the '816 patent, and contributing to the infringement by others of the '816 patent.

ANSWER: Denied.

52. Unless Zydus is enjoined from infringing the '816 patent, actively inducing the infringement of the '816 patent, and contributing to the infringement by others of the '816 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT II – Declaratory Judgment of Infringement of the '816 Patent

53. Plaintiffs incorporate each of the preceding paragraphs 1–52 as if fully set forth herein.

ANSWER: Defendants repeat and re-allege their answers to each of the preceding paragraphs 1-52, as if fully set forth herein.

54. 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 Zydus on the other regarding infringement and/or invalidity of the '816 patent.

ANSWER: The allegations in paragraph 54 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint against Defendants purports to be a civil action alleging infringement of the '816 patent. Defendants deny all other allegations in paragraph 54.

55. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '816 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '816 patent, and that the claims of the '816 patent are valid and enforceable.

ANSWER: Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiffs are entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorney's fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,178,816)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 219893 and/or the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus USA's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '816 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,178,816)

On information and belief, the claims of the '816 patent are invalid for failure to comply with one or more provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws 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.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Counterclaimants"), by their attorneys, allege the following counterclaims against Plaintiffs/Counterclaim Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Counterclaim Defendants").

THE PARTIES

1. Zydus USA is an entity organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

2. Zydus Lifesciences is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

3. Upon information and belief, 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.

4. Upon information and belief, 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.

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

6. Upon information and belief, 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.

7. Upon information and belief, 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.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq*., 21 U.S.C. § 355(j)(5)(C)(i), and 35 U.S.C. § 271(e)(5).

9. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimants in this district.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II), and because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimants in this district.

REGULATORY FRAMEWORK

11. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

12. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ORANGE-BOOK-LISTED PATENTS FOR LYNPARZA®

13. Upon information and belief, AstraZeneca Pharmaceuticals LP is the holder of NDA No. 208558 for LYNPARZA® (olaparib) oral tablets, 100 mg and 150 mg.

14. United States Patent No. 12,178,816 ("the '816 patent"), titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1- Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One" —a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit A—was issued on December 31, 2024. According to the USPTO's Patent Assignment Search database, Reel 069201, Frame 0771, the '816 patent is assigned to AstraZeneca UK Limited. FDA's Orange Book lists the expiration date of the '816 patent as October 7, 2029.

15. Upon information and belief, the '816 patent is owned by AstraZeneca UK Limited.

16. Upon information and belief, Counterclaim Defendants submitted on January 24, 2025, the '816 patent to FDA for listing in the Orange Book in connection with NDA No. 208558 for LYNPARZA® (olaparib) oral tablets, 100 mg and 150 mg. Accordingly, Counterclaim Defendants maintain and have affirmatively represented that the '816 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell olaparib tablets before the expiration of the '816 patent has a reasonable apprehension of suit with respect to the '816 patent.

ZYDUS USA'S ANDA

17. On September 6, 2024, Zydus USA submitted ANDA No. 219893 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of olaparib tablets, 100 mg and 150 mg ("Zydus USA's Proposed ANDA Product").

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,178,816)

18. Counterclaimants repeat and reallege the allegations in paragraphs 1-17 above as though fully set forth herein.

19. By asserting their claim against Counterclaimants for infringement of the ’816 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’816 patent.

20. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus USA’s Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’816 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,178,816)

21. Counterclaimants repeat and reallege the allegations in paragraphs 1-20 above as though fully set forth herein.

22. By asserting their claim against Counterclaimants for infringement of the ’816 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’816 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

23. The claims of the ’816 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants respectfully request that the Court enter judgment against Counterclaim Defendants as follows:

A. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’816 patent;

B. A declaration that the claims of the ’816 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that Counterclaim Defendants take nothing by their Complaint;

D. A dismissal of Counterclaim Defendants’ Complaint with prejudice;

E. An award to Counterclaimants of their reasonable costs and attorneys’ fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

Dated: March 11, 2025

By: *s/ Theodora McCormick*

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same Plaintiffs have asserted the patent in this case in the following pending matters in this Judicial District: *AstraZeneca Pharmaceuticals LP, et al. v. Cipla Limited et al.*, C.A. No. 3:25-00233 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al, v. Sandoz Inc.*, C.A. No. 3:25-00231 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Natco Pharma Limited et al.*, C.A. No. 3:25-00230 (D.N.J.). Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ Theodora McCormick
Theodora McCormick

Dated: March 11, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ Theodora McCormick
Theodora McCormick

Dated: March 11, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendants' Answer, Affirmative Defenses, and Counterclaims was filed and served on all counsel of record via ECF on March 11, 2025.

s/ Theodora McCormick
Theodora McCormick

Dated: March 11, 2025