Theodora McCormick
Lauren B. Cooper
Epstein Becker & Green, P.C.
150 College Road West, Suite 301
Princeton, New Jersey 08540
Telephone: (609) 455-1540

Attorneys for Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED, Defendants.	Civil Action No.: 24-10458 (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, "Zydus") for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, The University of Sheffield, 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. 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") (collectively, the "Patents-in-Suit").

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits 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 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") (collectively, "the patents-in-suit"). Zydus further admits 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's Proposed ANDA Product") in or into the United States. Zydus further admits that ANDA No. 219893 identifies LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, as the Reference Listed Drug. Zydus further admits that ANDA No. 219893 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zydus denies 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 the Patents-in-Suit.

ANSWER: The allegations in paragraph 2 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA transmitted a letter dated November 5, 2024 ("Zydus USA's Notice Letter") to KuDOS Pharmaceuticals Ltd ("KuDOS"), The University of Sheffield ("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's Proposed ANDA Product in or into the United States. Zydus further admits 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 patents-in-suit. Zydus denies all other allegations in 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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

5. 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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore denies them.

6. 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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 6 and therefore denies them.

7. 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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 7 and therefore denies 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: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 8 and therefore denies 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 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, Zydus admits 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. Zydus further admits that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus denies 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, Zydus admits 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. Zydus further admits that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 14.

Jurisdiction

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

ANSWER: Zydus repeats and re-alleges its 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, Zydus does not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as

they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits 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. Zydus further admits that ANDA No. 219893 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus further admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceuticals products manufactured by Zydus Lifesciences. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus Lifesciences and Zydus USA have engaged in patent litigation in this District regarding Abbreviated New Drug Applications submitted by Zydus USA. Zydus admits that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus stated 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." Zydus denies 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, Zydus admits that Zydus Pharmaceuticals (USA) Inc. has a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Zydus denies 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, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 22.

Venue

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

ANSWER: Zydus repeats and re-alleges its 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 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's Proposed ANDA Product. Zydus admits 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. Zydus denies 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 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's Proposed ANDA Product. Zydus admits 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. Zydus admits 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. Zydus denies 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, Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus Lifesciences and Zydus USA have engaged in patent litigation in this District regarding Abbreviated New Drug Applications submitted by Zydus USA. Zydus further admits 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. Zydus further admits that in *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, Civ. No. 22-2964, Dkt. No. 77 (D.N.J. July 24, 2023), Zydus stated it "do[es] not contest venue in this Court solely for purposes of Plaintiffs' claims against Defendants in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Zydus denies 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: Zydus admits 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. Zydus further admits 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

Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 27 and therefore denies 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: Zydus admits 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. Zydus further admits that ANDA No. 219893 identifies LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, as the Reference Listed Drug. Zydus further admits that ANDA No. 219893 contains bioequivalence data required by applicable regulations. Zydus denies 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: Zydus admits 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. Zydus denies 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 Patents-in-Suit 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 Patents-in-Suit.

ANSWER: Zydus admits 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. Zydus

further admits 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 patents-in-suit. Zydus denies all other allegations in paragraph 30.

31. 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 Patents-in-Suit.

ANSWER: The allegations in paragraph 31 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits 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. Zydus further admits 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 patents-in-suit. Zydus denies all other allegations in paragraph 31.

32. 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 32 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits 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®. Zydus further admits 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. Zydus further admits 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 patents-in-suit. Zydus denies all other allegations in paragraph 32.

33. This action is being commenced within forty-five days from the date Plaintiffs received Zydus's Notice Letter.

ANSWER: The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA's Notice Letter is dated November 5, 2024. Zydus further admits that Plaintiffs commenced an action by filing its Complaint on November 12, 2024. Zydus denies all other allegations in paragraph 33.

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

34. Plaintiffs incorporate each of the preceding paragraphs 1–33 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-33, as if fully set forth herein.

35. 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 A.

ANSWER: The allegations in paragraph 35 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '562 patent is entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer" and lists October 14, 2014 as the Date of Patent. Zydus further admits that what purports to be a copy of the '562 patent is attached to the Complaint as Exhibit A. Zydus denies all other allegations in paragraph 35.

36. Plaintiff The University of Sheffield is the assignee of the '562 patent. Plaintiffs collectively possess all exclusive rights and interests in the '562 patent.

ANSWER: The allegations in paragraph 36 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '562 patent lists The University of Sheffield as the assignee.

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

ANSWER: The allegations in paragraph 37 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 37 completely and accurately recite the claims of the '562 patent and therefore deny the allegations in paragraph 37.

38. 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: The allegations in paragraph 38 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '562 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Zydus denies all other allegations in paragraph 38.

39. 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 '562 patent was an act of infringement of the '562 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

40. 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 claim 1 of the '562 patent.

ANSWER: Denied.

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

ANSWER: Denied.

42. The foregoing actions by Zydus 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: Denied.

43. On information and belief, Zydus 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: Denied.

44. Unless Zydus 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: Denied.

Count II – Declaratory Judgment of Infringement of the ’562 Patent

45. Plaintiffs incorporate each of the preceding paragraphs 1–44 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-44, as if fully set forth herein.

46. 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 ’562 patent.

ANSWER: The allegations in paragraph 46 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs’ Complaint against Zydus purports to be a civil action alleging infringement of the ’562 patent. Zydus denies all other allegations in paragraph 46.

47. 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 ’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 and enforceable.

ANSWER: Denied.

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

48. Plaintiffs incorporate each of the preceding paragraphs 1–47 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-47, as if fully set forth herein.

49. 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: The allegations in paragraph 49 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent is entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One" and lists July 2, 2013 as the Date of the Patent. Zydus further admits that what purports to be a copy of the '842 patent is attached to the Complaint as Exhibit B. Zydus denies all other allegations in paragraph 49.

50. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '842 patent. Plaintiffs collectively possess all exclusive rights and interests in the '842 patent.

ANSWER: The allegations in paragraph 50 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent lists KuDOS Pharmaceuticals Limited as the assignee. Zydus denies all other allegations in paragraph 50.

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

ANSWER: The allegations in paragraph 51 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 51 completely and accurately recite the claims of the '842 patent and therefore deny the allegations in paragraph 51.

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

ANSWER: The allegations in paragraph 51 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Zydus denies all other allegations in paragraph 52.

53. 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 '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

54. 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 '842 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

55. 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 '842 patent.

ANSWER: Denied.

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

ANSWER: Denied.

57. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent and 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 '842 patent after approval of Zydus's ANDA.

ANSWER: Denied.

58. The foregoing actions by Zydus 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: Denied.

59. On information and belief, Zydus 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: Denied.

60. Unless Zydus 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: Denied.

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

61. Plaintiffs incorporate each of the preceding paragraphs 1–60 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges their answers to each of the preceding paragraphs 1-60, as if fully set forth herein.

62. 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 validity and/or infringement of the ’842 patent.

ANSWER: The allegations in paragraph 62 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admit that Plaintiffs’ Complaint against Zydus purports to be a civil action alleging infringement of the ’842 patent. Zydus denies all other allegations in paragraph 62.

63. 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 ’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 and enforceable.

ANSWER: Denied.

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

64. Plaintiffs incorporate each of the preceding paragraphs 1–63 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-63, as if fully set forth herein.

65. 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: The allegations in paragraph 65 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admit that the ’396 patent is entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One” and lists April 25, 2023 as the Date of the Patent. Zydus further admits that what purports to be a copy of the ’396 patent is attached to the Complaint as Exhibit C. Zydus denies all other allegations in paragraph 65.

66. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the ’396 patent. Plaintiffs collectively possess all exclusive rights and interests in the ’396 patent.

ANSWER: The allegations in paragraph 66 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the ’396 patent lists KuDOS Pharmaceuticals Limited as the assignee. Zydus denies all other allegations in paragraph 66.

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

ANSWER: The allegations in paragraph 67 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 67 completely and accurately recite the claims of the ’396 patent and therefore deny the allegations in paragraph 67.

68. 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: The allegations in paragraph 68 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '396 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Zydus denies all other allegations in paragraph 68.

69. 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 '396 patent was an act of infringement of the '396 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

70. 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 '396 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. 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 '396 patent.

ANSWER: Denied.

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

ANSWER: Denied.

73. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '396 patent and 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 '396 patent after approval of Zydus's ANDA.

ANSWER: Denied.

74. The foregoing actions by Zydus 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: Denied.

75. On information and belief, Zydus 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: Denied.

76. Unless Zydus 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: Denied.

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

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

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-76, as if fully set forth herein.

78. 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 validity and/or infringement of the ’396 patent.

ANSWER: The allegations in paragraph 78 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs’ Complaint against Zydus purports to be a civil action alleging infringement of the ’396 patent. Zydus denies all other allegations in paragraph 78.

79. 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 ’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 and enforceable.

ANSWER: Denied.

Count VII – Infringement of the ’001 Patent Under 35 U.S.C. § 271(e)(2)

80. Plaintiffs incorporate each of the preceding paragraphs 1–79 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-79, as if fully set forth herein.

81. On May 7, 2024, the USPTO duly and lawfully issued the ’001 patent, entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One.” A copy of the ’001 patent is attached hereto as Exhibit D.

ANSWER: The allegations in paragraph 81 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the ’001 patent is entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One” and lists May 7, 2024 as the Date of the Patent. Zydus further admits that what purports to be a copy of the ’001 patent is attached to the Complaint as Exhibit D. Zydus denies all other allegations in paragraph 81.

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

ANSWER: The allegations in paragraph 82 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the ’001 patent lists KuDOS Pharmaceuticals Limited as the assignee. Zydus denies all other allegations in paragraph 82.

83. The ’001 patent claims, *inter alia*, an immediate-release pharmaceutical composition comprising a solid dispersion comprising olaparib and certain excipients.

ANSWER: The allegations in paragraph 83 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 83 completely and accurately recite the claims of the ’001 patent and therefore deny the allegations in paragraph 83.

84. LYNPARZA® is covered by one or more claims of the '001 patent, including at least claim 1 of the '001 patent, and the '001 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: The allegations in paragraph 84 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admit that the '001 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Zydus denies all other allegations in paragraph 84.

85. 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 '001 patent was an act of infringement of the '001 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

86. 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 '001 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

87. 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 '001 patent.

ANSWER: Denied.

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

ANSWER: Denied.

89. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '001 patent and 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 '001 patent after approval of Zydus's ANDA.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count VIII – Declaratory Judgment of Infringement of the ’001 Patent

93. Plaintiffs incorporate each of the preceding paragraphs 1–92 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-92, as if fully set forth herein.

94. 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 validity and/or infringement of the ’001 patent.

ANSWER: The allegations in paragraph 94 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs’ Complaint against Zydus purports to be a civil action alleging infringement of the ’001 patent. Zydus denies all other allegations in paragraph 94.

95. 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 ’001 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’001 patent, and that the claims of the ’001 patent are valid and enforceable.

ANSWER: Denied.

Count IX – Infringement of the ’695 Patent Under 35 U.S.C. § 271(e)(2)

96. Plaintiffs incorporate each of the preceding paragraphs 1–95 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-95, as if fully set forth herein.

97. On July 30, 2024, the USPTO duly and lawfully issued the ’695 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 ’695 patent is attached hereto as Exhibit E.

ANSWER: The allegations in paragraph 97 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the ’695 patent is entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One” and lists July 30, 2024 as the Date of the Patent. Zydus further admits that what purports to be a copy of the ’695 patent is attached to the Complaint as Exhibit E. Zydus denies all other allegations in paragraph 97.

98. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the ’695 patent. Plaintiffs collectively possess all exclusive rights and interests in the ’695 patent.

ANSWER: The allegations in paragraph 98 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the ’695 patent lists KuDOS Pharmaceuticals Limited as the assignee. Zydus denies all other allegations in paragraph 98.

99. The ’695 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a tablet comprising a solid dispersion comprising olaparib and certain excipients.

ANSWER: The allegations in paragraph 99 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 99 completely and accurately recite the claims of the ’695 patent and therefore deny the allegations in paragraph 99.

100. LYNPARZA® is covered by one or more claims of the '695 patent, including at least claim 1 of the '695 patent, and the '695 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: The allegations in paragraph 100 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '695 patent is listed in FDA's Orange Book in connection with NDA No. 208558 for LYNPARZA®. Zydus denies all other allegations in paragraph 100.

101. 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 '695 patent was an act of infringement of the '695 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

102. 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 '695 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

103. 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 '695 patent.

ANSWER: Denied.

104. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '695 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Denied.

105. On information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '695 patent and 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 '695 patent after approval of Zydus's ANDA.

ANSWER: Denied.

106. The foregoing actions by Zydus constitute and/or will constitute infringement of the '695 patent, active inducement of infringement of the '695 patent, and contribution to the infringement by others of the '695 patent.

ANSWER: Denied.

107. On information and belief, Zydus has acted with full knowledge of the '695 patent and without a reasonable basis for believing that it would not be liable for infringing the '695 patent, actively inducing infringement of the '695 patent, and contributing to the infringement by others of the '695 patent.

ANSWER: Denied.

108. Unless Zydus is enjoined from infringing the '695 patent, actively inducing infringement of the '695 patent, and contributing to the infringement by others of the '695 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count X – Declaratory Judgment of Infringement of the '695 Patent

109. Plaintiffs incorporate each of the preceding paragraphs 1–108 as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-108, as if fully set forth herein.

110. 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 validity and/or infringement of the '695 patent.

ANSWER: The allegations in paragraph 110 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Plaintiffs' Complaint against Zydus purports to be a civil action alleging infringement of the '695 patent. Zydus denies all other allegations in paragraph 110.

111. 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 '695 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '695 patent, and that the claims of the '695 patent are valid and enforceable.

ANSWER: Denied.

PRAYER FOR RELIEF

Zydus specifically denies that Plaintiffs are entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and pray for judgment in favor of Zydus dismissing this action with prejudice, and awarding Zydus 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. 8,859,562)

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'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 '562 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,859,562)

On information and belief, the claims of the '562 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.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 8,475,842)

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'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 '842 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,475,842)

On information and belief, the claims of the ’842 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.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,633,396)

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’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 ’396 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,633,396)

On information and belief, the claims of the ’396 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.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,975,001)

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’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 ’001 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,975,001)

On information and belief, the claims of the ’001 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.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,048,695)

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’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 ’695 patent.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,048,695)

On information and belief, the claims of the ’695 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

Zydus hereby reserves 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, "Zydus" or "Counterclaimants"), by their attorneys, allege the following counterclaims against Plaintiffs/Counterclaim Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, The University of Sheffield, 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, 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.

8. 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

9. 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).

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

11. 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 Zydus in this district.

REGULATORY FRAMEWORK

12. 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. 98417, 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.

13. 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®

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

15. United States Patent No. 8,859,562 ("the '562 patent"), titled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer" —a copy of which Counterclaim Defendants purported to attach to its Complaint as Exhibit A—was issued on October 14, 2014. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel 017968, Frame 0155, the '562 patent is assigned to The University of Sheffield. FDA's Orange Book lists the expiration date of the '562 patent as August 4, 2031.

16. Upon information and belief, the '562 patent is owned by The University of Sheffield.

17. Upon information and belief, Counterclaim Defendants submitted the '562 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 '562 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell olaparib tablets before the expiration of the '562 patent has a reasonable apprehension of suit with respect to the '562 patent.

18. United States Patent No. 8,475,842 ("the '842 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 B—was issued on July 2, 2013. According to the USPTO's Patent Assignment Search database, Reel 062567, Frame 0182, the '842 patent is assigned to KuDOS Pharmaceuticals Limited. FDA's Orange Book lists the expiration date of the '842 patent as December 31, 2029.

19. Upon information and belief, the '842 patent is owned by KuDOS Pharmaceuticals Limited.

20. Upon information and belief, Counterclaim Defendants submitted the '842 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 '842 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell olaparib tablets before the expiration of the '842 patent has a reasonable apprehension of suit with respect to the '842 patent.

21. United States Patent No. 11,633,396 ("the '396 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 C—was issued on April 25, 2023. According to the USPTO's Patent Assignment Search database, Reel 061290, Frame 0452, the '396 patent is assigned to KuDOS Pharmaceuticals Limited. FDA's Orange Book lists the expiration date of the '396 patent as October 7, 2029.

22. Upon information and belief, the '396 patent is owned by KuDOS Pharmaceuticals Limited.

23. Upon information and belief, Counterclaim Defendants submitted the '396 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 '396 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell olaparib tablets before the expiration of the '396 patent has a reasonable apprehension of suit with respect to the '396 patent.

24. United States Patent No. 11,975,001 ("the '001 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 D—was issued on May 7, 2024. According to the USPTO's Patent Assignment Search database, Reel 067193, Frame 0056, the '001 patent is assigned to KuDOS Pharmaceuticals Limited. FDA's Orange Book lists the expiration date of the '001 patent as October 7, 2029.

25. Upon information and belief, the ’001 patent is owned by KuDOS Pharmaceuticals Limited.

26. Upon information and belief, Counterclaim Defendants submitted the ’001 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 ’001 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell olaparib tablets before the expiration of the ’001 patent has a reasonable apprehension of suit with respect to the ’001 patent.

27. United States Patent No. 12,048,695 (“the ’695 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 E—was issued on July 30, 2024. According to the USPTO’s Patent Assignment Search database, Reel 067902, Frame 0373, the ’695 patent is assigned to KuDOS Pharmaceuticals Limited. FDA’s Orange Book lists the expiration date of the ’695 patent as October 7, 2029.

28. Upon information and belief, the ’695 patent is owned by KuDOS Pharmaceuticals Limited.

29. Upon information and belief, Counterclaim Defendants submitted the ’695 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 ’695 patent claims the approved drug LYNPARZA® (olaparib) tablets or a method of using that drug. Therefore, any ANDA applicant, including Zydus,

attempting to sell olaparib tablets before the expiration of the '695 patent has a reasonable apprehension of suit with respect to the '695 patent.

ZYDUS USA'S ANDA

30. 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's Proposed ANDA Product").

31. Because Zydus USA seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the proposed products described in ANDA No. 219893 before the expiration of the '842, '562 , '396, '001, and '695 patents (collectively, "the patents-in-suit"), ANDA No. 219893 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the patents-in-suit.

32. Zydus USA sent a letter dated November 5, 2024, notifying KuDOS Pharmaceuticals Ltd ("KuDOS"), The University of Sheffield ("Sheffield"), and AstraZeneca PLC and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca") 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 olaparib tablets, 100 mg and 150 mg, and that ANDA No. 219893 includes a Paragraph IV Certification with respect to the patents-in-suit ("Zydus USA's Notice Letter").

33. In Zydus USA's Notice Letter, Zydus USA included a detailed statement of the factual and legal bases in support of Zydus's Paragraph IV Certification for the '562, '842, '296, '001 and '695 patents.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,859,562)

34. Zydus repeats and realleges the allegations in paragraphs 1-33 above as though fully set forth herein.

35. By asserting their claim against Zydus for infringement of the '562 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '562 patent.

36. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus'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 '562 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,859,562)

37. Zydus repeats and realleges the allegations in paragraphs 1-36 above as though fully set forth herein.

38. By asserting their claim against Zydus for infringement of the '562 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '562 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.

39. The claims of the '562 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.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,475,842)

40. Zydus repeat and reallege the allegations in paragraphs 1-39 above as though fully set forth herein.

41. By asserting their claim against Zydus for infringement of the ’842 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the ’842 patent.

42. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus’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 ’842 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,475,842)

43. Zydus repeats and realleges the allegations in paragraphs 1-42 above as though fully set forth herein.

44. By asserting their claim against Zydus for infringement of the ’842 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the ’842 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.

45. The claims of the ’842 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.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,633,396)

46. Zydus repeat and reallege the allegations in paragraphs 1-45 above as though fully set forth herein.

47. By asserting their claim against Zydus for infringement of the '396 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '396 patent.

48. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus'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 '396 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,633,396)

49. Zydus repeats and realleges the allegations in paragraphs 1-48 above as though fully set forth herein.

50. By asserting their claim against Zydus for infringement of the '396 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '396 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.

51. The claims of the '396 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.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,975,001)

52. Zydus repeats and realleges the allegations in paragraphs 1-51 above as though fully set forth herein.

53. By asserting their claim against Zydus for infringement of the '001 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '001 patent.

54. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus'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 '001 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,975,001)

55. Zydus repeats and realleges the allegations in paragraphs 1-54 above as though fully set forth herein.

56. By asserting their claim against Zydus for infringement of the '001 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '001 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.

57. The claims of the '001 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.

COUNT IX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,048,695)

58. Zydus repeats and realleges the allegations in paragraphs 1-57 above as though fully set forth herein.

59. By asserting their claim against Zydus for infringement of the '695 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '695 patent.

60. The commercial manufacture, use, offer for sale, sale, and/or importation in or into the United States of Zydus'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 '695 patent.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,048,695)

61. Zydus repeats and realleges the allegations in paragraphs 1-60 above as though fully set forth herein.

62. By asserting their claim against Zydus for infringement of the '695 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '695 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.

63. The claims of the '695 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, Zydus respectfully request that the Court enter judgment against Counterclaim Defendants as follows:

A. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’562 patent;

B. A declaration that the claims of the ’562 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 Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’842 patent;

D. A declaration that the claims of the ’842 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;

E. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’396 patent;

F. A declaration that the claims of the ’396 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;

G. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’001 patent;

H. A declaration that the claims of the ’001 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;

I. A declaration that Zydus has not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the ’695 patent;

J. A declaration that the claims of the ’695 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;

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

L. A dismissal of Counterclaim Defendants Complaint with prejudice;

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

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

Dated: December 19, 2024

By: */s/ Theodora McCormick*

Theodora McCormick
Lauren B. Cooper
Epstein Becker & Green, P.C.
150 College Road West, Suite 301
Princeton, New Jersey 08540
Telephone: (609) 455-1540
Facsimile: (609) 228-5318

Of counsel
Michael J. Gaertner (to be admitted *pro hac vice*)
James T. Peterka (to be admitted *pro hac vice*)
Emily L. Savas (to be admitted *pro hac vice*)
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606
(312) 443-0700
mgaertner@lockelord.com
jpeterka@lockelord.com
esavas@lockelord.com

Attorneys for Zydus Lifesciences Ltd., and Zydus Pharmaceuticals (USA) Inc.

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 patents-in-suit 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. 3:24-07346 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Cipla Limited et al.*, C.A. No. 3:24-08167 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Sandoz Inc.*, C.A. No. 3:24-00641 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Sandoz Inc.*, C.A. No. 3:24-05889 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Sandoz Inc.*, C.A. No. 3:24-08164 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Natco Pharma, Inc. et al.*, C.A. No. 3:23-00796 (D.N.J.); *AstraZeneca Pharmaceuticals LP, et al. v. Natco Pharma Limited et al.*, C.A. No. 3:24-05887 (D.N.J.); *AstraZeneca Pharmaceuticals, LP et al. v. Natco Pharma Limited et al.*, C.A. No. 3:24-08162 (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: December 19, 2024

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: December 19, 2024

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendants' Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on December 19, 2024.

/s/ Theodora McCormick
Theodora McCormick

Dated: December 19, 2024