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Counsel for Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH

IN THE 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. 25-234 **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs"), by their attorneys, file this Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus"), and allege the following:

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").

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").

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. 24-10458, Dkt. No. 1. Plaintiffs subsequently filed suit 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. No. 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.

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.

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.

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.

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.

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.

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.

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.

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

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.

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.

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.

Jurisdiction

15. Plaintiffs incorporate 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.

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.

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.

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.

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).

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.

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.

Venue

23. Plaintiffs incorporate 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.

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.

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).

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.

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®.

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.

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.

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.

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.

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.

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.

35. On December 16, 2024, Plaintiffs notified Zydus's outside counsel of the upcoming issuance of the '816 patent. Zydus's counsel later indicated 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.

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.

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.

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.

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

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.

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

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

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that the '816 patent has been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;
2. A judgment that the '816 patent is valid and enforceable;
3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of Zydus's ANDA and for Zydus to make, use, offer for sale, sell, market, distribute, or import Zydus's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '816 patent, shall not be earlier than the expiration date of the '816 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
4. A preliminary and permanent injunction pursuant to 35 U.S.C. § 371(e)(4)(B) enjoining Zydus, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Zydus's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '816 patent, or the inducement of or the contribution to any of

the foregoing, prior to the expiration date of the ’816 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

5. An order pursuant to this Court’s equitable power that the effective date of any final approval of Zydus’s ANDA shall be a date that is not earlier than the expiration date of the ’816 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
6. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Zydus’s ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’816 patent, prior to the expiration date of the ’816 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the ’816 patent;
7. A declaration that this is an exceptional case and an award of attorneys’ fees pursuant to 35 U.S.C. § 285;
8. An award of Plaintiffs’ costs and expenses in this action; and
9. Such further and other relief as this Court may deem just and proper.

Dated: January 9, 2025

Respectfully submitted,

Charles H. Chevalier

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