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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, and MSD INTERNATIONAL BUSINESS GMBH *Plaintiffs*, v. SANDOZ INC., *Defendant*.	Civil Action No. 25-231 **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 Defendant Sandoz Inc., ("Sandoz"), 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 Sandoz of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 12,178,816 ("the '816 patent").

2. Sandoz notified Plaintiffs by letter dated December 29, 2023 ("Sandoz's Notice Letter") that it had submitted to FDA ANDA No. 217936 ("Sandoz's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic olaparib tablets, 100 mg and 150 mg, ("Sandoz's ANDA Product") prior to the expiration of U.S. Patent Nos. 7,449,464 ("the '464 patent"), 8,475,842 ("the '842 patent"), 11,633,396 ("the '396 patent"), and 8,859,562 ("the '852 patent").

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

that Sandoz's ANDA infringes U.S. Patent Nos. 11,970,530 ("the '530 patent") and 11,975,001 ("the '001 patent"). *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-5889, Dkt. No. 1. The cases were consolidated, along 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. 87. The parties subsequently stipulated to the dismissal without prejudice of Plaintiffs' infringement claims based on the '530 patent. *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 121. Plaintiffs also filed suit against Sandoz, asserting that Sandoz's ANDA infringes U.S. Patent No. 12,048,695. *See AstraZeneca Pharms L.P. v. Sandoz Inc.*, Civ. No. 24-8164, Dkt. No. 1. That case was also consolidated, along 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. 108. Plaintiffs also filed suit against Sandoz, alleging that Sandoz's ANDA infringes U.S. Patent No. 12,144,810. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-10627, Dkt. No. 1. That case was also consolidated, along 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. On information and belief, defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. On information and belief, Sandoz is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market.

10. On information and belief, Sandoz knows and intends that upon approval of Sandoz's ANDA, Sandoz will manufacture Sandoz's ANDA Product and Sandoz will directly or indirectly market, sell, and distribute Sandoz's ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

11. Plaintiffs incorporate each of the preceding paragraphs 1–100 as if fully set forth herein.

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

13. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sandoz.

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

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

16. On information and belief, Sandoz, through its own actions and through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA, continues to engage in seeking FDA approval of Sandoz's ANDA, intends to engage in the commercial manufacture, marketing, offer for sale,

sale, or importation of Sandoz's ANDA Product throughout the United States, including within the State of New Jersey, and stands to benefit from the approval of Sandoz's ANDA.

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

18. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz intends to import Sandoz's ANDA Product into the United States and market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including within the State of New Jersey, that will, as explained below, infringe upon Plaintiffs' rights in the '816 patent protecting their LYNPARZA® products. On information and belief, following FDA approval of Sandoz's ANDA, Sandoz knows and intends that Sandoz's ANDA Product will be marketed, used, distributed, offered for sale, or sold in the United States, including within the State of New Jersey.

19. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

20. Sandoz has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Amgen Inc. v. Sandoz Inc.*, Civ. No. 18-11026, Dkt. No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, Civ. No. 17-10129, Dkt. No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, Civ. No. 17-08825, Dkt. No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Lab'ys Priv. Ltd.*, Civ. No. 17-05302, Dkt. No. 28

(D.N.J. Nov. 17, 2017). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

21. This Court also has personal jurisdiction over Sandoz at least because, *inter alia*, (a) Sandoz has filed an ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product in the United States, including in the State of New Jersey; (b) Sandoz, through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell Sandoz's ANDA Product in the United States, including in the State of New Jersey and to residents of this Judicial District, upon approval of Sandoz's ANDA, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in the State of New Jersey; and (c) Sandoz has purposefully availed itself of the privilege of doing business in the State of New Jersey by placing goods into the stream of commerce for distribution throughout the United States, including the State of New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in the State of New Jersey. On information and belief, if Sandoz's ANDA is approved, Sandoz's ANDA Product charged with infringing the '816 patent would, *inter alia*, be marketed, distributed, offered for sale, or sold in the State of New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

22. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture LYNPARZA® drug products for use throughout the United States, including in this Judicial District. On information and belief, Sandoz filed Sandoz's ANDA with Paragraph IV

Certifications, which was purposefully directed to the State of New Jersey, where Sandoz is located. As a result, the consequences of Sandoz's actions were, and will be, suffered in the State of New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in the State of New Jersey.

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

24. Additionally, Sandoz has filed an Answer and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 14 (D.N.J. Apr. 5, 2024); *AstraZeneca Pharms. L.P. v. Sandoz Inc*, Civ. No. 24-5889, Dkt. No. 12 (D.N.J. Jul. 8, 2024); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796 (consolidated), Dkt. No. 130 (D.N.J. Sept. 30, 2024). In those Answers, Sandoz has consented to personal jurisdiction in this District.

25. For the above reasons, it would not be unfair or unreasonable for Sandoz to litigate this action in this District, and the Court has personal jurisdiction over Sandoz here.

Venue

26. Plaintiffs incorporate each of the preceding paragraphs 1–255 as if fully set forth herein.

27. Venue is proper in this District pursuant to 28 U.S.C. § 1391, because Sandoz resides in this District and a substantial part of the events and injury giving rise to Plaintiffs' claims has and continues to occur in this District.

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

things, (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including New Jersey; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey.

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

30. Additionally, Sandoz has filed Answers and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 14 (D.N.J. Apr. 5, 2024); *AstraZeneca Pharms. L.P. v. Sandoz Inc*, Civ. No. 24-5889, Dkt. No. 12 (D.N.J. Jul. 8, 2024); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796 (consolidated), Dkt. No. 130 (D.N.J. Sept. 30, 2024). In those Answers, Sandoz has consented to venue in this District.

Factual Background

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

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

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

34. Following receipt of Sandoz's Notice Letter, on February 2, 2024, Plaintiffs filed suit against Sandoz alleging that Sandoz's ANDA infringes certain patents, including the '842 patent, the '396 patent, and the '852 patent. *See AstraZeneca Pharms. L.P. v. Sandoz Inc.*, Civ. No. 24-641, Dkt. No. 1 (consolidated into Civ. No. 23-796, *see* Dkt. No. 59). That suit is currently pending in this District.

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

36. 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.

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

38. On information and belief, Sandoz intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz 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)

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

40. 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.

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

42. 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, known by the international nonproprietary name olaparib, and certain excipients.

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

44. 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.

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

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

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

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

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

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

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

52. The foregoing actions by Sandoz 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.

53. On information and belief, Sandoz 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, and contributing to the infringement by others of the '816 patent.

54. Unless Sandoz 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

55. Plaintiffs incorporate each of the preceding paragraphs 1–54 as if fully set forth herein.

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Sandoz on the other regarding infringement and/or invalidity of the '816 patent.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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 Sandoz's submission to the FDA of Sandoz'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 Sandoz's ANDA and for Sandoz to make, use, offer for

sale, sell, market, distribute, or import Sandoz'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 Sandoz, 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 Sandoz'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 Sandoz'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 Sandoz'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,

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