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

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. NATCO PHARMA LIMITED and NATCO PHARMA INC., *Defendants*.	Civil Action No. 3:24-10624 **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 Natco Pharma Limited and Natco Pharma Inc., (collectively, "Natco"), 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 Natco 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. 12,144,810 ("the '810 patent").

2. Natco Pharma Limited notified Plaintiffs by letter dated December 28, 2022 ("Natco's Notice Letter") that it had submitted to FDA ANDA No. 218044 ("Natco'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, ("Natco's ANDA Product") prior to the expiration of U.S. Patent Nos. 7,449,464 ("the '464 patent"), 8,475,842 ("the '842 patent"), and 8,859,562 ("the '562 patent"). Natco subsequently sent Plaintiffs a second letter dated June 14, 2023, stating that Natco was seeking approval for Natco's ANDA prior to the expiration of U.S. Patent No. 11,633,396 ("the '396 patent").

3. Plaintiffs filed suit against Natco in this District, asserting that Natco's ANDA infringes the '464 patent, the '842 patent, the '396 patent, and the '562 patent. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, 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 '842 and the '396 patents, as well as Natco's

Affirmative Defenses and Counterclaims related to those patents. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 51. Plaintiffs subsequently filed suit against Natco, asserting that Natco'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. Natco Pharma Ltd.*, Civ. No. 24-5887, 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 '464 and the '530 patents. *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 121. Plaintiffs then filed suit against Natco, asserting that Natco's ANDA infringes U.S. Patent No. 12,048,695. *See AstraZeneca Pharms L.P. v. Natco Pharma Ltd.*, Civ. No. 24-8162, 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.

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 Natco Pharma Limited is a company organized and existing under the laws of the Republic of India with a principal place of business at Natco House Road No. 2, Banjara Hills 500 034, Hyderabad, India. On information and belief, Natco Pharma Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs, including through various operating subsidiaries and/or agents.

10. On information and belief, defendant Natco Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Natco Pharma Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

11. On information and belief, Natco Pharma Inc. is a wholly owned subsidiary of Natco Pharma Limited and is controlled by Natco Pharma Limited.

12. On information and belief, Natco Pharma Limited and Natco Pharma Inc. acted in concert to prepare and submit Natco's ANDA to the FDA.

13. On information and belief, Natco Pharma Limited and Natco Pharma Inc. know and intend that upon approval of Natco's ANDA, Natco Pharma Limited will manufacture Natco's ANDA Product and Natco Pharma Limited and Natco Pharma Inc. will directly or indirectly import Natco's ANDA Product into the United States and market, sell, and distribute Natco's ANDA Product throughout the United States, including in New Jersey.

14. On information and belief, following any FDA approval of Natco's ANDA, Natco Pharma Limited and Natco Pharma Inc. will act in concert to distribute and sell Natco's ANDA Product throughout the United States, including in 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 Natco Pharma Limited and Natco Pharma Inc.

18. Natco Pharma Limited and Natco Pharma Inc. are subject to personal jurisdiction in New Jersey because, among other things, Natco Pharma Limited and Natco Pharma 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, Natco Pharma Limited and Natco Pharma 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 Natco Pharma Limited and Natco Pharma Inc. because, among other things, on information and belief: (1) Natco Pharma Limited filed Natco's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's ANDA Product in the United States, including New Jersey; and (2) upon approval of Natco's ANDA, Natco Pharma Limited and Natco Pharma Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Natco's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Natco'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 Natco's ANDA, Natco'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 Natco Pharma Limited and Natco Pharma Inc. because those entities (1) engage in patent litigation concerning Natco's ANDA products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g.*, *Gilead Scis., Inc. v. Natco Pharma Ltd*., Civ. No. 11-1455, Dkt. No. 24 (D.N.J. Sept. 30, 2011).

21. Additionally, Natco Pharma Limited and Natco Pharma Inc. have filed Answers and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 36 (D.N.J. Sept. 5, 2023); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 24-5887 (consolidated to Civ. No. 23-796), Dkt. No. 97 (D.N.J. Jul. 8, 2024); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 24-8162 (consolidated to

Civ. No. 23-796), Dkt. No. 128 (D.N.J. Sept. 30, 2024). In those Answers, Natco Pharma Limited and Natco Pharma Inc. have consented to personal jurisdiction in this District.

22. For the above reasons, it would not be unfair or unreasonable for Natco Pharma Limited and Natco Pharma 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 1–212 as if fully set forth herein.

24. Venue is proper in this District as to Natco Pharma Limited pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Natco Pharma 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 Natco Pharma Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Natco Pharma 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) Natco filed Natco's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's ANDA Product in the United States, including New Jersey; and (2) upon approval of Natco's ANDA, Natco will market, distribute, offer for sale, sell, and/or import Natco's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Natco's ANDA Product in New Jersey.

26. Venue is proper in this District as to Natco Pharma Limited and Natco Pharma Inc. because those entities (1) engage in patent litigation concerning Natco's ANDA products in this District, and (2) do not contest that venue is proper in this District. *See, e.g.*, *Gilead Scis., Inc. v. Natco Pharma Ltd.*, Civ. No. 11-1455, Dkt. No. 24 (D.N.J. Sept. 30, 2011).

27. Additionally, Natco Pharma Limited and Natco Pharma Inc. have filed Answers and asserted counterclaims in related actions in this District. *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 36 (D.N.J. Sept. 5, 2023); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 24-5887 (consolidated to Civ. No. 23-796), Dkt. No. 97 (D.N.J. Jul. 8, 2024); *AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 24-8162 (consolidated to Civ. No. 23-796), Dkt. No. 128 (D.N.J. Sept. 30, 2024). In those Answers, Natco Pharma Limited and Natco Pharma Inc. have consented to venue in this District.

Factual Background

28. 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.

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

30. The purpose of Natco's submission of Natco'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 Natco's ANDA Product.

31. Following receipt of Natco's Notice Letter, on February 10, 2023, Plaintiffs filed suit against Natco alleging that Natco's ANDA infringes certain patents, including the '464 and '562 patents. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 23-796, Dkt. No. 1. That suit is currently pending in this District.

32. On information and belief, Natco 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, Natco does not challenge 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, Natco will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Natco's ANDA Product immediately and imminently upon FDA approval of Natco's ANDA.

33. On October 30, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '810 patent, and indicated that the '810 patent would issue on November 19, 2024.

34. On November 14, 2024, Plaintiffs notified Natco's outside counsel of the upcoming issuance of the '810 patent.

35. On information and belief, Natco intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product prior to the expiration of the '810 patent.

Count I – Infringement of the '810 Patent Under 35 U.S.C. § 271(e)(2)

36. Plaintiffs incorporate each of the preceding paragraphs 1–35 as if fully set forth herein.

37. On November 19, 2024, the USPTO duly and lawfully issued the '810 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 '810 patent is attached hereto as Exhibit A.

38. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '810 patent. Plaintiffs collectively possess all exclusive rights and interests in the '810 patent.

39. The '810 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.

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

41. LYNPARZA® is covered by claim 1 of the '810 patent, and the '810 patent will be listed in connection with LYNPARZA® in the FDA's Orange Book.

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

43. Natco received notice of the '810 patent at least as of November 14, 2024, when Plaintiffs notified Natco's outside counsel of the upcoming issuance of the '810 patent.

44. On information and belief, Natco intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Natco's ANDA Product prior to the expiration of the '810 patent.

45. Natco's submission of Natco's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's ANDA Product prior to the expiration of the '810 patent was an act of infringement of the '810 patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Natco's ANDA Product would infringe at least claim 1 of the '810 patent, either literally or under the doctrine of equivalents.

47. On information and belief, the use of Natco's ANDA Product in accordance with and as directed by Natco's proposed labeling for Natco's ANDA Product would infringe claim 1 of the '810 patent.

48. On information and belief, Natco plans and intends to, and will, actively induce infringement of the '810 patent and knows that Natco's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Natco plans and intends to, and will, contribute to infringement of the '810 patent after approval of Natco's ANDA.

49. The foregoing actions by Natco constitute and/or will constitute infringement of the '810 patent, active inducement of infringement of the '810 patent, and contribution to the infringement by others of the '810 patent.

50. On information and belief, Natco has acted with full knowledge of the '810 patent and without a reasonable basis for believing that it would not be liable for the infringing of the'810 patent, actively inducing infringement of the '810 patent, and contributing to the infringement by others of the '810 patent.

51. Unless Natco is enjoined from infringing the '810 patent, actively inducing the infringement of the '810 patent, and contributing to the infringement by others of the '810 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the '810 Patent

52. Plaintiffs incorporate each of the preceding paragraphs 1–51 as if fully set forth herein.

53. 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 Natco on the other regarding infringement and/or invalidity of the '810 patent.

54. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Natco's ANDA Product with its proposed labeling, or any other Natco drug product that is covered by or whose use is covered by the '810 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '810 patent, and that the claims of the '810 patent are valid and enforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that the '810 patent has been infringed under 35 U.S.C. § 271(e)(2) by Natco's submission to the FDA of Natco's ANDA;
2. A judgment that the '810 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 Natco's ANDA and for Natco to make, use, offer for sale, sell, market, distribute, or import Natco's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '810 patent, shall not be earlier than the expiration date of the '810 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 Natco, 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 Natco's ANDA Product, or any product the

making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '810 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '810 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 Natco's ANDA shall be a date that is not earlier than the expiration date of the '810 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 Natco's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '810 patent, prior to the expiration date of the '810 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '810 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: November 20, 2024

Respectfully submitted,

s/Charles H. Chevalier

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