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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. NATCO PHARMA LIMITED, Defendant.	Civil Action No. 3:25-cv-230 (RK) (TJB) **DEFENDANT'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT IN CIVIL ACTION NO. 3:25-cv-230 (RK) (TJB)**

Defendant[1] Natco Pharma Limited ("Natco"), hereby answers the Complaint for Patent Infringement of Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GmbH (collectively, "Plaintiffs"), as follows:

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in Plaintiffs Complaint for Patent Infringement except those specifically admitted below.

NATURE OF 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. 12,178,816 ("the '816 patent").

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking FDA approval to manufacture, use, offer for sale, sell, and/or import 100 mg and 150 mg olaparib tablets ("Natco ANDA Products") prior to the expiration of U.S. Patent No. 12,178,816 ("the '816 patent"). Natco further admits that Plaintiffs purport to state a claim for alleged patent infringement, but denies that Plaintiffs are entitled to any of the relief they seek. Natco denies any and all remaining allegations of Paragraph 1.

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")

[1] Natco Pharma Inc. has been dismissed from Civil Action No. 3:25-cv-230 (RK) (TJB). *See* ECF 12 (dismissing Natco Pharma Inc. without prejudice). Responses here are made on behalf of Natco Pharma Limited only.

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").

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited sent a Notice Letter on December 28, 2022 ("Notice Letter"), which notified Plaintiffs that Natco Pharma Limited had submitted to FDA ANDA No. 218044. Natco further admits Natco Pharma Limited's Notice Letter states that "[t]he ANDA includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of olaparib oral tablet, 100 mg and 150 mg, before the expiration of the '464, '842, and '562 patents…." Natco admits that Natco Pharma Limited sent a subsequent Notice Letter on June 14, 2023 ("Second Notice Letter") stating that "[t]he ANDA now includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of olaparib oral tablet, 100 mg and 150 mg, before the expiration of the '396 patent." Natco further admits Natco Pharma Limited's Notice Letter and Second Notice Letter speak for themselves. Natco denies any and all remaining allegations of Paragraph 2.

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 also 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. Plaintiffs also filed suit against Natco, alleging that Natco's ANDA infringes U.S. Patent No. 12,144,810. *See AstraZeneca Pharms. L.P. v. Natco Pharma Ltd.*, Civ. No. 24-10624, 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.

ANSWER: Paragraph 3 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that the records of any pending litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 3.

THE PARTIES

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, on information and belief, Natco admits that AstraZeneca Pharmaceuticals LP is organized under the laws of the State of Delaware and has a place of business located at 1800 Concord Pike, Wilmington, Delaware 19803. Natco further admits that according to the online records of the FDA, AstraZeneca Pharmaceuticals LP is listed as the holder of New Drug Application ("NDA") No. 208558. Natco is without information sufficient to form a belief as to the remaining allegations in Paragraph 4, and therefore denies the same.

5. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, on information and belief, Natco admits that

AstraZeneca UK Limited has a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom. Natco is without information sufficient to form a belief as to the remaining allegations in Paragraph 5, and therefore denies the same.

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

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco is without information sufficient to form a belief as to the allegations in Paragraph 6, and therefore denies the same.

7. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, on information and belief, Natco admits that KuDOS Pharmaceuticals Limited has a registered office at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom. Natco is without information sufficient to form a belief as to the remaining allegations in Paragraph 7, and therefore denies the same.

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: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco is without information sufficient to form a belief as to the allegations in Paragraph 8, and therefore denies the same.

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.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited is an entity organized and existing under the laws of India having a principal place of business at Natco House Road No. 2, Banjara Hills 500 034, Hyderabad, India. Natco further admits that Natco is in the business of, among other things, selling pharmaceutical products in the United States. Natco denies any and all remaining allegations of Paragraph 9.

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.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Inc. is an entity organized and existing under the laws of the State of Delaware. Natco denies any and all remaining allegations of Paragraph 10.

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

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Inc. is a wholly owned subsidiary of Natco Pharma Limited. Natco denies any and all remaining allegations of Paragraph 11.

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.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to the FDA. Natco denies any and all remaining allegations of Paragraph 12.

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.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to market the Natco ANDA Products within the United States. Natco denies any and all remaining allegations of Paragraph 13.

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.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to market the Natco ANDA Products within the United States. Natco denies any and all remaining allegations of Paragraph 14.

JURISDICTION

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

ANSWER: Natco restates and incorporates by reference each of its responses to 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: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not dispute that this Court has subject matter jurisdiction solely for the alleged infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A). Natco denies any and all remaining allegations of 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 Natco Pharma Limited and Natco Pharma Inc.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco denies any and all remaining allegations of Paragraph 17.

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.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco denies any and all remaining allegations of Paragraph 18.

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.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for

the limited purposes of this action only with respect to Natco Pharma Limited. Natco further admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to market the Natco ANDA Products within the United States. Natco denies any and all remaining allegations of Paragraph 19.

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).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco further admits that the records of any previous litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 20.

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.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco further admits that the records of any previous litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 21.

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.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest personal jurisdiction solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco denies any and all remaining allegations of Paragraph 22.

VENUE

23. Plaintiffs incorporate each of the preceding paragraphs 1–212 [*sic*] as if fully set forth herein.

ANSWER: Natco restates and incorporates by reference each of its responses to Paragraphs 1-22 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.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited is a foreign corporation. Natco further does not contest venue solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco denies any and all remaining allegations of Paragraph 24.

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

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest venue solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco additionally admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to market the Natco ANDA Products within the United States. Natco denies any and all remaining allegations of Paragraph 25.

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).

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest venue solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco further admits that the records of any previous litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 26.

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.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not contest venue solely for the limited purposes of this action only with respect to Natco Pharma Limited. Natco further admits that the records of any previous litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 27.

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.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that what purports to be the FDA-approved Lynparza label states, among other things:

---------- **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 enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.7, 2.1)
- in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCA*m) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza. (1.8, 2.1)

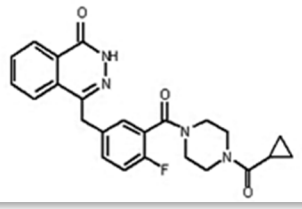
---------- **DOSAGE AND ADMINISTRATION** ----------

- Recommended dosage is 300 mg taken orally twice daily with or without food. See Full Prescribing Information for the recommended duration. (2.2)
- Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. (2.2)
- For moderate renal impairment (CLcr 31-50 mL/min), reduce Lynparza dosage to 200 mg orally twice daily. (2.5)

* * *

11 DESCRIPTION

Olaparib is a poly (ADP-ribose) polymerase (PARP) inhibitor. The chemical name is 4-[(3-{[4-(cyclopropylcarbonyl)piperazin-1-yl]carbonyl}-4-fluorophenyl)methyl] phthalazin-1(2*H*)-one. The empirical molecular formula for Lynparza is $C_{24}H_{23}FN_4O_3$ and the relative molecular mass is 434.46. It has the following chemical structure:



November 2023 Lynparza Label at 1, 9. Natco denies any and all remaining allegations of Paragraph 28.

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®.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited's Notice Letter speaks for itself. Natco denies any and all remaining allegations of Paragraph 29.

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.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Products within and/or into the United States. Additionally, Natco admits that Natco Pharma Limited's Notice Letter speaks for itself. Natco denies any and all remaining allegations of Paragraph 30.

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.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that the records of any pending litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 31.

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.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Products within and/or into the United States prior to the expiration of the '816 patent. Additionally, Natco admits that Natco Pharma Limited's Notice Letter, Second Notice

Letter, and the records of any pending litigations involving Natco Pharma Limited for themselves with respect to what patents Natco has challenged. Natco denies any and all remaining allegations of Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that according to the online records of the United States Patent and Trademark Office ("USPTO"), an Issue Notification for the '816 patent was entered on December 11, 2024 and stated:

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/785,063	12/31/2024	12178816	09963.0102-05000	9872

179001 7590 12/11/2024

Finnegan/AstraZeneca
901 New York Avenue, NW
Washington, DC 20001

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

'816 Patent Issue Notification at 1. Natco denies any and all remaining allegations of Paragraph 33.

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

in a schedule proposed jointly with the other Defendants in the consolidated litigation, which was transmitted to Plaintiffs on December 17, 2024.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that the cited correspondence speaks for itself. Natco denies any and all remaining allegations of Paragraph 34.

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 '816 patent.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Products within and/or into the United States prior to the expiration of the '816 patent. Natco denies any and all remaining allegations of Paragraph 35.

Count I – Infringement of the '816 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.

ANSWER: Natco restates and incorporates by reference each of its responses to Paragraphs 1-35 as if fully set forth herein.

37. On December 31, 2024, the USPTO duly and lawfully issued the '816 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '816 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent Natco is required to answer, Natco admits that according to the online records of the USPTO, the '816 patent, which is titled "IMMEDIATE RELEASE PHARMACEUTICAL FORMULATION OF 4-[3-(4-CYCLOPROPANECARBONYL-PIPERAZINE-1-CARBONYL)-4-FLUORO-BENZYL]-2H-PHTHALAZIN-1-ONE," issued on December 31, 2024. Natco

further admits that what purports to be a true and correct copy of the '816 patent is attached to the Complaint as Exhibit A. Natco denies that the '816 patent was duly and legally issued. Natco denies any and all remaining allegations of Paragraph 37.

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

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 38, and therefore denies any and all remaining allegations of Paragraph 38.

39. 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.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that claim 1 of the '816 patent states:

> The invention claimed is:
> **1**. An immediate-release pharmaceutical composition in the form of a tablet comprising:
>
> (a) an extrudate comprising:
> (i) 100 mg to 200 mg of 4-[3-(4-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluorobenzyl]-2H-phthalazin-1-one (Compound 1);
> (ii) at least one polymer chosen from copovidone, povidone, hypromellose phthalate, hypromellose acetate succinate, 2-hydroxypropyl-β-cyclodextrin, hypromellose, polymethacrylates, hydroxypropyl cellulose, and cellulose acetate phthalate; and
> (iii) at least one glidant; and
> (b) at least one excipient;
> wherein the weight ratio of Compound 1 to the at least one polymer in the extrudate is in the range of from 1:1 to 1:9; and
> wherein the total concentration of Compound 1 in the tablet is in the range of from 10% by weight to 35% by weight.

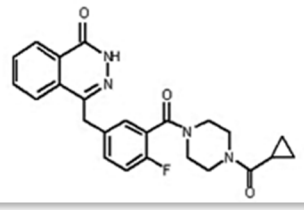
'816 patent at claim 1. Natco denies any and all remaining all remaining allegations of Paragraph 39.

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

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that what purports to be the FDA-approved Lynparza label states, among other things:

11 DESCRIPTION

Olaparib is a poly (ADP-ribose) polymerase (PARP) inhibitor. The chemical name is 4-[(3-{[4-(cyclopropylcarbonyl)piperazin-1-yl]carbonyl}-4-fluorophenyl)methyl] phthalazin-1(2*H*)-one. The empirical molecular formula for Lynparza is $C_{24}H_{23}FN_4O_3$ and the relative molecular mass is 434.46. It has the following chemical structure:



November 2023 Lynparza Label at 9. Natco denies any and all remaining allegations of Paragraph 40.

41. 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.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that the '816 patent is listed in the Orange Book for NDA No. 208558. Natco denies any and all remaining allegations of Paragraph 41.

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.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to manufacture, use, offer for sale, sell, and/or import

the Natco ANDA Products within and/or into the United States prior to the expiration of the '816patent. Additionally, Natco admits that Natco Pharma Limited's Notice Letter, Second Notice Letter, and the records of any pending litigations involving Natco Pharma Limited speak for themselves. Natco denies any and all remaining allegations of Paragraph 42.

43. Natco received notice of the '816 patent at least as of December 16, 2024, when Plaintiffs notified Natco's outside counsel of the upcoming issuance of the '816 patent.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that that the cited correspondence speaks for itself. Natco denies any and all remaining allegations of Paragraph 43.

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 '816 patent.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco admits that Natco Pharma Limited submitted ANDA No. 218044 to FDA seeking approval to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Products within and/or into the United States prior to the expiration of the '816 patent. Natco denies any and all remaining allegations of Paragraph 44.

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 '816 patent was an act of infringement of the '816 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: Denied.

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 at least claim 1 of the '816 patent.

ANSWER: Denied.

48. On information and belief, Natco plans and intends to, and will, actively induce infringement of the '816 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 '816 patent after approval of Natco's ANDA.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Natco restates and incorporates by reference each of its responses to 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 '816 patent.

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent that Natco is required to answer, Natco does not dispute that this Court has subject

matter jurisdiction solely for the purposes of Count II under 28 U.S.C. §§ 2201 and 2202, but denies that Plaintiffs are entitled to any of the relief they seek. Natco denies any and all remaining allegations of Paragraph 53.

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 '816 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '816 patent, and that the claims of the '816 patent are valid and enforceable.

ANSWER: Denied.

PRAYER FOR RELIEF

Natco denies that Plaintiffs are entitled to any of the relief prayed for in the Complaint or to any relief whatsoever, and further request that judgment be entered in favor of Natco, dismissing Plaintiffs' Complaint with prejudice, awarding Natco attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

First Defense

The Complaint fails to state a claim upon which relief can be granted.

Second Defense

The proposed manufacture, use, sale, offer for sale, importation, and/or marketing of the Natco ANDA Products has not infringed, does not infringe, and will not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '816 patent, either literally or under the doctrine of equivalents.

Third Defense

Natco has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '816 patent.

Fourth Defense

Natco has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’816 patent.

Fifth Defense

The claims of the ’816 patent are invalid for failing to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

Sixth Defense

Any additional defenses or counterclaims that discovery may reveal.

* * *

COUNTERCLAIMS

I. Defendant/Counterclaim-Plaintiff Natco Pharma Limited ("Natco"), for its Counterclaims against AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, and MSD International Business GMBH (together "Counterclaim-Defendants"), alleges:

THE PARTIES

1. Natco is an entity organized and existing under the laws of India, having a principal place of business at 8 Natco House Road No. 2, Banjara Hills 500 034, Hyderabad, India.

2. On information and belief, as alleged in Plaintiffs' Complaint, AstraZeneca Pharmaceuticals LP is an entity organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

3. On information and belief, as alleged in Plaintiffs' Complaint, AstraZeneca UK Limited is an entity 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.

4. On information and belief, as alleged in Plaintiffs' Complaint, AstraZeneca AB is an entity organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

5. On information and belief, as alleged in Plaintiffs' Complaint, KuDOS Pharmaceuticals Limited is an entity 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. On information and belief, as alleged in Plaintiffs' Complaint, MSD International Business GmbH is an entity organized and existing under the laws of Switzerland, whose

registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

JURISDICTION

7. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges—and subjected themselves to the jurisdiction—of this forum by suing Natco in this District, and/or because Counterclaim-Defendants conduct substantial business in, and have regular and systematic contact with, this District.

FACTUAL BACKGROUND

Lynparza® (olaparib)

10. AstraZeneca Pharmaceuticals LP purports to be the holder of approved New Drug Application ("NDA") No. 208558, under which the United States Food and Drug Administration ("FDA") granted approval for Olaparib tablets 100 mg and 150 mg marketed in the United States under the trade name Lynparza®.

11. At the time the Complaint was filed, U.S. Patent No. 12,178,816 ("the '816 patent") was not listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with NDA No. 208558.

12. On or about January 24, 2025, the '816 patent was first listed in the Orange Book.

The '816 Patent

13. On or about December 31, 2024, the United States Patent and Trademark Office ("USPTO") issued the '816 patent, titled "IMMEDIATE RELEASE PHARMACEUTICAL FORMULATION OF 4-[3-(4-CYCLOPROPANECARBONYL-PIPERAZINE-1-CARBONYL)-4-FLUORO-BENZYL]-2H-PHTHALAZIN-1-ONE," to Michael Karl Bechtold, Julie Kay Cahill, Katja Maren Fastnacht, Kieran James Lennon, Bernd Harald Liepold, Claudia Bettina Packhaeuser, and Benedikt Steitz.

14. On information and belief, Counterclaim-Defendants allege that KuDOS Pharmaceuticals Limited is the assignee of the '816 patent.

15. On information and belief, Counterclaim-Defendants allege that certain Counterclaim-Defendants have the right to enforce the '816 patent.

16. By listing the '816 patent in the Orange Book, AstraZeneca Pharmaceuticals LP maintains that an infringement suit could be asserted reasonably against a generic Abbreviated New Drug Application ("ANDA") applicant—including Natco—that attempts to seek approval for, and market, a generic version of Lynparza® before the expiration of the '816 patent.

Natco ANDA Product

17. Natco filed ANDA No. 218044 ("Natco ANDA"). The Natco ANDA seeks FDA approval to market olaparib tablets, 100 mg and 150 mg ("Natco ANDA Products").

COUNT I
(Declaratory Judgment of Non-Infringement of the '816 Patent)

18. Natco realleges and incorporates by reference the allegations of paragraphs 1-17 as though fully set forth herein.

19. A present, genuine, and justiciable controversy exists between Natco and Counterclaim-Defendants regarding *inter alia*, whether the manufacture, use, offer for sale, sale,

importation, and/or marketing of the Natco ANDA Products would infringe any valid or enforceable claim of the '816 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

20. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Natco ANDA Products would not infringe any valid or enforceable claim of the '816 patent, either directly or indirectly.

21. Natco is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Natco ANDA Products would not infringe, directly or indirectly, any valid or enforceable claim of the '816 patent, either literally or under the doctrine of equivalents.

COUNT II
(Declaratory Judgment of Invalidity of the '816 Patent)

22. Natco realleges and incorporates by reference the allegations of paragraphs 1-21 as though fully set forth herein.

23. A present, genuine, and justiciable controversy exists between Natco and Counterclaim-Defendants regarding, *inter alia*, the invalidity of the '816 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

24. The '816 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

25. Natco is entitled to a judicial declaration that the '816 patent is invalid for failure to comply with one or more of the requirements in 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or for obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Natco respectfully prays for judgment in its favor and against Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Natco ANDA Products has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '816 patent, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the '816 patent are invalid;

(c) Ordering that Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Natco;

(d) Declaring this case exceptional and awarding Natco its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding Natco such other and further relief as the Court may deem just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant, Natco Pharma Limited

By: *s/ James S. Richter*
James S. Richter
jrichter@midlige-richter.com

Dated: March 11, 2025

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Chicago, IL 60654
Tel: 312 527-2157

CERTIFICATION PURSUANT TO RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is the subject of pending litigation in *AstraZeneca Pharmaceuticals LP et al. v. Natco Pharma Ltd., et al.*, No. 3:23-cv-00796-RK-TJB, pending before the United States District Court for the District of New Jersey.

s/ James S. Richter
James S. Richter

Dated: March 11, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

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

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

s/ James S. Richter
James S. Richter

Dated: March 11, 2025

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of Defendants' foregoing Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement was filed via ECF and served on all counsel of record by electronic mail on March 11, 2025.

s/ James S. Richter
James S. Richter

Dated: March 11, 2025