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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH, *Plaintiffs*, v. NATCO PHARMA LIMITED and NATCO PHARMA INC., *Defendant*.	Civil Action No. 23-00796 **COMPLAINT FOR PATENT INFRINGMENT** **(Filed Electronically)**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield, 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. 7,449,464 ("the '464"); U.S. Patent No. 8,475,842 ("the '842 patent"); and U.S. Patent No. 8,859,562 ("the '562 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Natco Pharma Ltd. 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 the Patents-in-Suit.

The Parties

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

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

5. 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.

6. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

7. 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.

8. 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, including Natco Pharma Inc.

9. 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.

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

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

12. 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 market, sell, and distribute Natco's ANDA Product throughout the United States, including in New Jersey.

13. 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

14. Plaintiffs incorporate each of the preceding paragraphs 1–13 as if fully set forth herein.

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

16. 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 Ltd. and Natco Pharma Inc.

17. Natco Pharma Ltd. and Natco Pharma Inc. are subject to personal jurisdiction in New Jersey because, among other things, Natco Pharma Ltd. 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 Ltd. 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.

18. In addition, this Court has personal jurisdiction over Natco Pharma Ltd. and Natco Pharma Inc. because, among other things, on information and belief: (1) Natco Pharma Ltd. 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 Ltd. 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 Pharm. 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.

19. This Court has personal jurisdiction over Natco Pharma Ltd. 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 Sciences, Inc. v. Natco Pharma Ltd.*, Civ. No. 11-1455, Dkt. 24 (D.N.J. Sept. 30, 2011).

20. For the above reasons, it would not be unfair or unreasonable for Natco Pharma Ltd. and Natco Pharma Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

Venue

21. Plaintiffs incorporate each of the preceding paragraphs 1–20 as if fully set forth herein.

22. Venue is proper in this District as to Natco Pharma Ltd. pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Natco Pharma Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

23. 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.

24. Venue is proper in this district as to Natco Pharma Ltd. 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 Sciences, Inc. v. Natco Pharma Ltd.*, Civ. No. 11-1455, Dkt. 24 (D.N.J. Sept. 30, 2011).

Factual Background

25. 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 inhibitor.

26. 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 its ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that its 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®.

27. In Natco's Notice Letter, Natco stated that it had submitted a Paragraph IV Certification to FDA alleging that the '464, '842, and '562 patents were invalid, unenforceable, and/or not infringed, and that Natco is seeking 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 '464, '842, and '562 patents.

28. 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 prior to the expiration of the Patents-in-Suit.

29. In an exchange of correspondence, counsel for Plaintiffs and counsel for Natco discussed the terms of Natco's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Natco's ANDA and any Drug Master File referred to therein, and Natco refused to produce samples of Natco's ANDA Product and other internal documents and material relevant to infringement.

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

Count I – Infringement of the '464 Patent Under 35 U.S.C. § 271(e)(2)

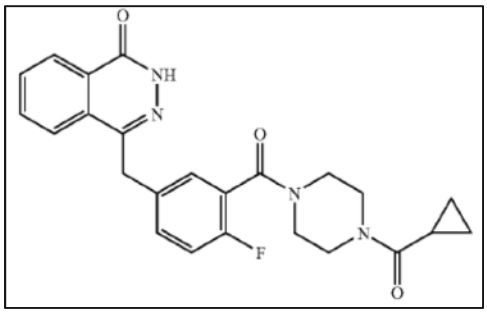
31. Plaintiffs incorporate each of the preceding paragraphs 1–30 as if fully set forth herein.

32. On November 11, 2008, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '464 patent, entitled "Phthalazinone Derivatives." A copy of the '464 patent is attached hereto as Exhibit A.

33. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the '464 patent.

Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd., and MSD International Business GmbH collectively possess all exclusive rights and interests in the '464 patent.

34. The '464 patent claims, *inter alia*, a compound of Formula III, shown below, or isomers, salts, or solvates thereof.



35. The compound of Formula III is the compound that is known by the international nonproprietary name olaparib. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

36. LYNPARZA® is covered by Claims 1 and 2 of the '464 patent, and the '464 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

37. 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 '464 patent was an act of infringement of the '464 patent under 35 U.S.C. § 271(e)(2)(A).

38. On information and belief, Natco's ANDA Product contains olaparib.

39. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Natco's ANDA Product would infringe Claims 1 and 2 of the '464 patent, recited above, either literally or under the doctrine of equivalents.

40. On information and belief, the use of Natco's ANDA Product in accordance with

and as directed by Natco's proposed labeling for that product would infringe Claims 1 and 2 of the '464 patent.

41. On information and belief, Natco plans and intends to, and will, actively induce infringement of the '464 patent when Natco's ANDA is approved, and plans and intends to, and will, do so after approval.

42. On information and belief, Natco knows that Natco's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '464 patent and that Natco's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Natco plans and intends to, and will, contribute to infringement of the '464 patent after approval of Natco's ANDA.

43. The foregoing actions by Natco constitute and/or will constitute infringement of the '464 patent, active inducement of infringement of the '464 patent, and contribution to the infringement by others of the '464 patent.

44. On information and belief, Natco has acted with full knowledge of the '464 patent and without a reasonable basis for believing that it would not be liable for infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent.

45. In Natco's Notice Letter, Natco did not contest infringement of Claims 1 and 2 of the '464 patent on any basis other than the alleged invalidity of those claims.

46. Unless Natco is enjoined from infringing the '464 patent, actively inducing infringement of the '464 patent, and contributing to the infringement by others of the '464 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count II – Declaratory Judgment of Infringement of the '464 Patent

47. Plaintiffs incorporate each of the preceding paragraphs 1–46 as if fully set forth

herein.

48. 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 validity and/or infringement of the ’464 patent.

49. 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 ’464 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’464 patent, and that the claims of the ’464 patent are valid.

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

50. Plaintiffs incorporate each of the preceding paragraphs 1–49 as if fully set forth herein.

51. On July 2, 2013, the USPTO duly and lawfully issued the ’842 patent, entitled “Immediate Release Pharmaceutical Formulation of 4-[3-(4- Cyclopropanecarbonyl-Piperazine-1-Carbonyl)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One.” A copy of the ’842 patent is attached hereto as Exhibit B.

52. Plaintiff Kudos Pharmaceuticals Limited is the assignee of the ’842 patent. Plaintiffs Kudos Pharmaceuticals Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Ltd., and MSD International Business GmbH collectively possess all exclusive rights and interests in the ’842 patent.

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

54. LYNPARZA® is covered by one or more claims of the ’842 patent, including at least claims 1 and 7 of the ’842 patent, and the ’842 patent has been listed in connection with

LYNPARZA® in the FDA's Orange Book.

55. 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 '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

56. 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 claims 1 and 7 of the '842 patent, recited above, either literally or under the doctrine of equivalents.

57. On information and belief, the use of Natco's ANDA Product in accordance with and as directed by Natco's proposed labeling for that product would infringe at least claims 1 and 7 of the '842 patent.

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

59. On information and belief, Natco knows that Natco's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent and that Natco's ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Natco plans and intends to, and will, contribute to infringement of the '842 patent after approval of Natco's ANDA.

60. The foregoing actions by Natco constitute and/or will constitute infringement of the '842 patent, active inducement of infringement of the '842 patent, and contribution to the infringement by others of the '842 patent.

61. On information and belief, Natco has acted with full knowledge of the '842 patent

and without a reasonable basis for believing that it would not be liable for infringing the ’842 patent, actively inducing infringement of the ’842 patent, and contributing to the infringement by others of the ’842 patent.

62. Unless Natco is enjoined from infringing the ’842 patent, actively inducing infringement of the ’842 patent, and contributing to the infringement by others of the ’842 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count IV – Declaratory Judgment of the ’842 Patent

63. Plaintiffs incorporate each of the preceding paragraphs 1–62 as if fully set forth herein.

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

65. 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 ’842 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’842 patent, and that the claims of the ’842 patent are valid.

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

66. Plaintiffs incorporate each of the preceding paragraphs 1–65 as if fully set forth herein.

67. On October 14, 2014, the USPTO duly and lawfully issued the ’562 patent, entitled “Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer.” A copy of the ’562 patent is attached hereto as Exhibit C.

68. Plaintiff The University of Sheffield is the assignee of the ’562 patent. Plaintiffs

The University of Sheffield, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, and MSD International Business GmbH collectively possess all exclusive rights and interests in the ’562 patent.

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

70. Methods of using LYNPARZA® are covered by Claim 1 of the ’562 patent, and the ’562 patent has been listed in connection with LYNPARZA® in the FDA’s Orange Book.

71. 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 ’562 patent was an act of infringement of the ’562 patent under 35 U.S.C. § 271(e)(2)(A).

72. On information and belief, the use of Natco’s ANDA Product in accordance with and as directed by Natco’s proposed labeling for that product would infringe Claim 1 of the ’562 patent.

73. On information and belief, Natco plans and intends to, and will, actively induce infringement of the ’562 patent and that Natco’s ANDA Product and its proposed labeling is not suitable for substantial non-infringing use. On information and belief, Natco plans and intends to, and will, contribute to infringement of the ’562 patent after approval of Natco’s ANDA.

74. The foregoing actions by Natco constitute and/or will constitute infringement of the ’562 patent, active inducement of infringement of the ’562 patent, and contribution to the infringement by others of the ’562 patent.

75. On information and belief, Natco has acted with full knowledge of the ’562 patent and without a reasonable basis for believing that it would not be liable for the infringing of the

’562 patent, and contributing to the infringement by others of the ’562 patent.

76. In Natco’s Notice Letter, Natco did not contest infringement of Claim 1 of the ’562 patent on any basis other than the alleged invalidity of that claim.

77. Unless Natco is enjoined from infringing the ’562 patent, actively inducing the infringement of the ’562 patent, and contributing to the infringement by others of the ’562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

Count VI Declaratory Judgment of the ’562 Patent

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

79. 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 ’562 patent.

80. 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 ’562 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’562 patent, and that the claims of the ’562 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Natco’s submission to the FDA of Natco’s ANDA;

B. A judgment that the Patents-in-Suit are valid and enforceable;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval 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 Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity.

D. 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 Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

E. 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 latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

F. 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 Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce

infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

G. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

H. An award of Plaintiffs' costs and expenses in this action; and

I. Such further and other relief as this Court may deem just and proper.

Dated: February 10, 2023

Respectfully submitted,

/s/ Charles H. Chevalier

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