

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS
CORPORATION and
ASTEX THERAPEUTICS, LTD.

Plaintiffs,

V.

NATCO PHARMA LIMITED, NATCO
PHARMA, INC. and NATCO PHARMA
USA LLC

Defendants.

C.A. No.: _____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation (“Novartis”) and Astex Therapeutics, Ltd. (“Astex”) (collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Natco Pharma Limited, Natco Pharma, Inc., and Natco Pharma USA LLC (collectively, “Natco” or “Defendants”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 219528 (the “Natco ANDA”) filed by Defendants with the United States Food and Drug Administration (“FDA”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 200 mg ribociclib tablets, generic versions of Novartis’s KISQALI® (ribociclib) tablets (collectively, the “ANDA Product”), prior to the expiration of U.S. Patent No. 9,868,739 (“the ’739 patent”).

PARTIES

A. Novartis Pharmaceuticals Corporation and Astex Therapeutics Ltd.

2. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

3. Plaintiff Astex Therapeutics Ltd. is a British corporation with its principal place of business at 436 Cambridge Science Park, Cambridge, CB4 0QA, United Kingdom.

4. Plaintiffs own all rights in the '739 patent.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary drug therapies to benefit patients against serious diseases, including treatments for breast cancer. KISQALI[®] and the KISQALI[®] FEMARA[®] CO-PACK (collectively “KISQALI[®] Products”) are such treatment options. Novartis markets and sells KISQALI[®] Products in this judicial district and throughout the United States.

B. Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited

6. Upon information and belief, Natco Pharma USA LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at the Company Corporation, 251 Little Falls Drive, Wilmington, Delaware 19808, and having a principal place of business at Suite C100, 300 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Natco Pharma USA LLC is a wholly owned subsidiary of Natco Pharma Limited and operates at or under its direction.

7. Upon information and belief, Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at the Business Filings Incorporated, 108 West 13th St., Wilmington, Delaware, 19801, and having a principal place of business at 241 West Roseville Road, Lancaster, Pennsylvania 17601. Upon

information and belief, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma Limited and operates at or under its discretion.

8. Upon information and belief, Natco Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Natco House Road No. 2, Banjara Hills, Hyderabad 50034, India. Upon information and belief, Natco Pharma Limited is the corporate parent of Natco Pharma USA LLC and Natco Pharma, Inc., controls Natco Pharma USA LLC and Natco Pharma, Inc. as its United States agents, and directs and distributes its generic products throughout the United States, including this district, through Natco Pharma USA LLC and Natco Pharma, Inc.

9. Upon information and belief, Defendants are a generic pharmaceutical organization that work to develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

DEFENDANTS' INFRINGING ACTS

10. In a letter dated October 30, 2024 (the "Natco Notice Letter"), Defendants notified Plaintiffs (i) that Natco Pharma Limited submitted to the FDA ANDA No. 219528, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 200 mg ribociclib tablets in or into the United States, including Delaware, prior to the expiration of the '739 patent and (ii) that ANDA No. 219528 includes a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) against the '739 patent.

11. Defendants have committed an act of infringement in this judicial district by filing the Natco ANDA with the intent to make, use, sell, offer for sale, and/or import the ANDA Product in or into this judicial district prior to the expiration of the '739 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

12. Upon information and belief, Natco Pharma Limited acted in concert with and/or

directed Natco Pharma USA LLC and/or Natco Pharma, Inc. in the preparation and submission of the Natco ANDA and, if the Natco ANDA is approved, will act in concert with and direct Natco Pharma USA LLC and/or Natco Pharma, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in or into the United States, including Delaware, prior to the expiration of the '739 patent.

13. Upon information and belief, Natco Pharma USA LLC has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Natco Pharma Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

14. Upon information and belief, Natco Pharma, Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Natco Pharma Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

15. Upon information and belief, Natco Pharma Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates; purposefully incorporated its wholly owned subsidiaries, Natco Pharma USA, LLC and Natco Pharma, Inc., in Delaware; has purposefully availed itself of the privilege of doing business in Delaware; and

derives substantial revenue from the sale of drug products in Delaware.

16. Natco Pharma Limited has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court of the District of Delaware. *See, e.g., Pharmacyclics LLC v. Zydus Worldwide DMCC*, Civ. Action No. 20-403-CFC (D. Del. 2020); *Pharmacyclics LLC v. Alvogen Pine Brook LLC*, Civ. Action No. 19-434-CFC (D. Del. 2019); *Cephalon Inc. v. Breckenridge Pharmaceutical, Inc.*, Civ. Action No. 14-671 (GMS) (D. Del. 2014).

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

18. This Court has personal jurisdiction over Natco Pharma Limited under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, Natco Pharma Limited is organized under the laws of India and the exercise of personal jurisdiction over Natco Pharma Limited in any judicial district is consistent with the United States Constitution and laws.

19. This Court has personal jurisdiction over Natco Pharma USA LLC because Natco Pharma USA LLC is a limited liability company organized and existing under Delaware law.

20. This Court has personal jurisdiction over Natco Pharma, Inc. because Natco Pharma, Inc. is a corporation organized and existing under Delaware law.

21. This Court also has personal jurisdiction over Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited because, upon information and belief, Defendants have committed or aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting the Natco ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts will lead to foreseeable harm and injury to Novartis,

a Delaware corporation.

22. Upon information and belief, the effort to seek approval for the Natco ANDA and to manufacture, import, market, and/or sell Defendants' ANDA Product upon approval has been a cooperative and joint enterprise and venture between Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited.

23. This Court also has personal jurisdiction over Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited because, upon information and belief, Defendants, upon approval of the Natco ANDA, will market, distribute, offer for sale, and/or sell Defendants' ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of Delaware.

24. This Court also has personal jurisdiction over Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited because, upon information and belief, Defendants' ANDA Product, upon approval of the Natco ANDA, will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

25. This Court also has personal jurisdiction over Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited because, upon information and belief, Defendants' affiliations with the State of Delaware, including Natco Pharma USA LLC and Natco Pharma, Inc.'s organization or incorporation in Delaware, Natco Pharma USA LLC and Natco Pharma, Inc.'s availing itself, at Natco Pharma Limited's direction, of the legal protections of the State of Delaware, and Natco Pharma Limited's ownership of and actions in concert with Natco Pharma USA LLC and Natco Pharma, Inc. are sufficiently continuous and systematic as to render

Defendants at home in this forum.

26. Upon information and belief, Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States including in this judicial district.

27. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Natco Pharma USA LLC, Natco Pharma, Inc., and Natco Pharma Limited.

28. Venue is proper in this Court because Natco Pharma USA LLC is organized under the laws of the State of Delaware and therefore resides in this judicial district, Natco Pharma, Inc. is incorporated under the laws of the State of Delaware and therefore resides in this judicial district, and Natco Pharma Limited is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3). Defendants have also previously conceded that venue is proper in Delaware for at least the cases listed above and have conceded that venue is proper in Delaware for purposes of the counterclaims filed in those cases.

THE PATENT-IN-SUIT AND KISQALI®

29. Plaintiffs are the owners of the '739 patent, titled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof." The '739 patent was duly and legally issued on January 16, 2018. A true and correct copy of the '739 patent is attached hereto as **Exhibit A**.

30. Plaintiffs are the owners of the '739 patent by virtue of assignment.

31. The '739 patent expires on November 9, 2031, excluding any pediatric exclusivity.

32. The '739 patent generally claims a method of treating cancer which responds to

inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide.

33. Claim 9 recites: The method of any one of claims 1-8 [drawn to methods of treating cancer which responds to inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide characterized by initial or post-DVS XRPD illustrated in FIG. 2, initial or post-DVS DSC illustrated in FIG. 3, initial or post-DVS TGA illustrated in FIG. 4, initial or post-DVS XRPD illustrated in FIG. 6], wherein the cancer is breast cancer, genitourinary cancer, lung cancer, gastrointestinal cancer, epidermoid cancer, melanoma, ovarian cancer, neuroblastoma, head and/or neck cancer, hyperplasias, larynx cancer, lymphatic system cancer, bone cancer, epidermas cancer, hematopoietic cancer, myeloma, thyroid follicular cancer, a tumor of mesenchymal origin, a tumor of the central or peripheral nervous system, seminoma, teratocarcinoma, xeroderma pigmentosum, and Kaposi's sarcoma.

34. KISQALI[®] contains ribociclib succinate, which is a succinate salt of ribociclib, i.e., 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethyl-amide recited in the claims of the '739 patent.

35. Novartis is the holder of New Drug Application ("NDA") No. 209092 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of KISQALI[®] (ribociclib) tablets. KISQALI[®] is currently indicated (i) in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of

recurrence; and (ii) for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with (a) an aromatase inhibitor as initial endocrine-based therapy; or (b) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

36. One or more claims of the '739 patent cover methods of use of KISQALI[®], including for example claim 9 of the '739 patent.

37. The FDA's official publication of approved drugs (the "Orange Book") lists the '739 patent in connection with KISQALI[®].

INFRINGEMENT OF THE '739 PATENT

FIRST COUNT FOR PATENT INFRINGEMENT **('739 PATENT) (ANDA No. 219528)**

38. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

39. Plaintiffs received the Natco Notice Letter dated October 30, 2024, purporting to include a Notice of Certification for ANDA No. 219528 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '739 patent.

40. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets, which comprise ribociclib succinate, a succinate salt of ribociclib, that are claimed in at least claim 9 of the '739 patent.

41. Upon information and belief, Defendants' generic products, if approved and marketed in the United States, will infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claim 9, of the '739 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

42. Ribociclib succinate is a succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide as recited in

claims 1-8 upon which claim 9 of the '739 patent depends. FDA-approved KISQALI[®] comprises ribociclib succinate, which is a CDK inhibitor approved for (i) treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and (ii) adjuvant treatment of adults with HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence. Claim 9 is drawn to a method of treating cancer which responds to inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide.

43. Upon information and belief, Defendants filed ANDA No. 219528 seeking authorization to commercially manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets in the United States. Upon information and belief, if the FDA approves ANDA No. 219528, physicians, health care providers, and/or patients will use Defendants' generic ribociclib tablets according to Defendants' provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claim 9, of the '739 patent.

44. Upon information and belief, if the FDA approves ANDA No. 219528, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants' generic ribociclib tablets according to Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including for example claim 9, of the '739 patent with the requisite intent under 35 U.S.C. § 271(b).

45. Upon information and belief, if the FDA approves ANDA No. 219528, Defendants will sell or offer to sell their generic ribociclib tablets with provided instructions and/or label in an

infringing manner, wherein Defendants' generic ribociclib tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants' generic ribociclib tablets in accordance with Defendants' provided instructions and/or label, wherein such use will directly infringe at least one claim, including for example claim 9, of the '739 patent, and wherein generic ribociclib succinate tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including for example claim 9, of the '739 patent under 35 U.S.C. § 271(c).

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including for example claim 9, of the '739 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 219528 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets before the expiration date of the '739 patent. Upon information and belief, the products described in ANDA No. 219528 would infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claim 9, of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 219528 complained of herein were done by and for the benefit of Defendants.

48. Upon information and belief, Defendants had actual knowledge of the '739 patent prior to the submission of ANDA No. 219528 to the FDA.

49. If Defendants' marketing and sale of generic ribociclib succinate tablets prior to expiration of the '739 patent and all other relevant activities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

50. This action was commenced within 45 days of Plaintiffs' receipt of the Natco

Notice Letter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

51. Judgment that Defendants Natco Pharma USA LLC, Natco Pharma, Inc. and Natco Pharma Limited have infringed one or more claims of the '739 patent by filing ANDA No. 219528;

52. A permanent injunction restraining and enjoining Defendants, and their affiliates, subsidiaries, and each of their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product until the expiration of the '739 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled, or such later date as the Court may determine;

53. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 219528 shall be a date that is not earlier than the expiration of the '739 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

54. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the '739 patent;

55. Damages or other monetary relief to Plaintiffs from Defendants for the infringement, inducement of infringement, or contributory infringement of the '739 patent if one or more Defendants engage in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product prior to the expiration date of the '739 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs

are or become entitled;

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

57. Plaintiffs' costs and expenses in this action; and

58. Such other and further relief as the Court may deem just and proper.

DATED: December 13, 2024

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