

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

ACERTA PHARMA B.V., ASTRAZENECA
UK LIMITED, ASTRAZENECA
PHARMACEUTICALS LP,
ASTRAZENECA AB, and MERCK SHARP
& DOHME B.V.,

Plaintiffs,

v.

NATCO PHARMA LIMITED and NATCO
PHARMA, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Acerta Pharma B.V., AstraZeneca UK Limited, AstraZeneca Pharmaceuticals LP, AstraZeneca AB (collectively “AstraZeneca”), and Merck Sharp & Dohme B.V. (“Merck”) (together hereinafter “Plaintiffs”) file this Complaint for patent infringement against Natco Pharma Limited and Natco Pharma, Inc. (collectively, “Natco”), and by their attorneys, hereby allege as follows:

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 Abbreviated New Drug New Drug Application (“ANDA”) No. 216768 (“Natco’s ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CALQUENCE® (acalabrutinib) 100 mg oral capsules prior to the expiration of U.S. Patent No. 9,290,504 (“the ’504 patent”); U.S. Patent No. 9,758,524 (“the ’524 patent”); U.S. Patent No. 10,239,883 (“the ’883 patent”); U.S. Patent No. 9,796,721 (“the

'721 patent"); U.S. Patent No. 10,167,291 ("the '291 patent"); and U.S. Patent No. 10,272,083 ("the '083 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

PARTIES

2. Plaintiff Acerta Pharma B.V. is a private limited liability company organized and existing under the laws of the Netherlands, having its principal place of business at Kloosterstraat 9, 5349 AB Oss, The Netherlands.

3. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, having its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom. AstraZeneca UK Limited is the holder of New Drug Application No. 210259 for the manufacture and sale of CALQUENCE[®] (acalabrutinib) which has been approved by the FDA.

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, having its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, Delaware, 19850.

5. Plaintiff AstraZeneca AB is a corporation organized and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

6. Plaintiff Merck Sharp & Dohme B.V. is a company organized and existing under the laws of The Netherlands, having its principal place of business at Waarderweg 39, 2031BN Haarlem, The Netherlands.

7. 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 through various operating subsidiaries, including Natco Pharma, Inc.

8. On information and belief, defendant Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 297 Mine Bank Rd., Wellsville, PA 17365-9514. 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.

9. On information and belief, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma Limited and is controlled and/or dominated by Natco Pharma Limited.

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

11. 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 Products and Natco Pharma Limited and Natco Pharma, Inc. will directly or indirectly market, sell, and distribute Natco's ANDA Products throughout the United States, including in Delaware.

12. 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 Products throughout the United States, including within Delaware.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs 1–12 as if fully set forth herein.

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

15. 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.

16. Natco Pharma Limited is subject to personal jurisdiction in Delaware because, among other things, Natco Pharma Limited, itself and through its wholly-owned subsidiary Natco Pharma Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Natco Pharma Limited itself, and through its wholly-owned subsidiary Natco Pharma, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Natco Pharma Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Natco Pharma, Inc. and therefore the activities of Natco Pharma, Inc. in this jurisdiction are attributed to Natco Pharma Limited.

17. Natco Pharma, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Natco Pharma, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs

throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

18. In addition, this Court has personal jurisdiction over Natco because, among other things, on information and belief: (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 in Delaware; 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 Delaware, and will derive substantial revenue from the use or consumption of Natco's ANDA Product in Delaware. *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 Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

19. In addition, this Court has personal jurisdiction over Natco because Natco Pharma Limited and Natco Pharma, Inc. regularly (1) engage in patent litigation concerning Natco's ANDA products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.,* Defs.' Answer, *Cephalon, Inc. v. Breckenridge Pharmaceutical, Inc. et al.*, No. 1:14-cv-00671 (D. Del. Jul. 7, 2014), D.I. 7; Natco's Answer to Second Am. Compl., *Gilead Sciences, Inc. v. Apotex, Inc. et al.*, No. 1:20-cv-00189 (D. Del. Nov. 15, 2021), D.I. 391.

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