

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

EAGLE PHARMACEUTICALS, INC.,

Plaintiff,

v.

ACCORD HEALTHCARE INC., ACCORD
HEALTHCARE LTD., and INTAS
PHARMACEUTICALS LTD.,

Defendants.

C.A. No. _____

COMPLAINT

Plaintiff Eagle Pharmaceuticals, Inc. (“Eagle”), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission of New Drug Application (“NDA”) No. 216987 (“Accord’s NDA”) by Defendants Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd. (collectively, “Accord”) to the United States Food and Drug Administration (“FDA”) that includes a certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV Certification”) that Accord is requesting approval from FDA of its NDA to manufacture and sell its proposed product, which relies on data from bioavailability and/or bioequivalence studies contained in Eagle’s FDA-approved NDA No. 205580 for BELRAPZO®, 100 mg/4 mL (25 mg/mL) Bendamustine Hydrochloride Injection product, prior to the expiration of Eagle’s U.S. Patent Nos. 8,609,707 (“the ’707 patent”); 9,265,831 (“the ’831 patent”); 9,572,796 (“the ’796 patent”); 9,572,797 (“the ’797 patent”); 10,010,533 (“the ’533 patent”); and 11,103,483 (“the ’483 patent”) (collectively, “the Patents-in-Suit”).

PARTIES

2. Plaintiff Eagle is a corporation organized and existing under the laws of Delaware, with its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677.

3. On information and belief, Defendant Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703. On information and belief, Accord Healthcare Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs throughout the United States, including Delaware.

4. On information and belief, Defendant Accord Healthcare Ltd. is a corporation organized and existing under the laws of the Republic of India, with a place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad, Gujarat 380 054, Republic of India. On information and belief, Accord Healthcare Ltd. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products, including through various affiliates, including Accord Healthcare Inc., throughout the United States, including Delaware.

5. On information and belief, Defendant Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Republic of India, with a place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, Gujarat 380 009, Republic of India. On information and belief, Intas Pharmaceuticals Ltd. is in the business of, among other things, manufacturing and selling generic versions of pharmaceutical drug products, including through various operating subsidiaries, including Accord Healthcare Inc. and Accord Healthcare Ltd., throughout the United States, including Delaware.

6. On information and belief, Accord Healthcare Inc. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd. and the U.S. agent for Intas Pharmaceuticals Ltd.

7. On information and belief, Accord Healthcare Ltd. is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

8. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. acted in concert to prepare and submit Accord's NDA to FDA.

9. On information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare Ltd. actively encouraged, recommended, and promoted that Accord Healthcare Inc. prepare and submit Accord's NDA to FDA and knew that the filing of Accord's NDA would infringe the Patents-in-Suit, including because Intas Pharmaceuticals Ltd. and Accord Healthcare Ltd. knew that Accord's NDA would include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) with respect to the Patents-in-Suit.

10. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. know and intend that upon approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will manufacture a Bendamustine Hydrochloride Injection product, 100 mg/4 mL (25 mg/mL) in a multi-dose vial ("Accord's NDA Product"); and Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will directly or indirectly market, sell, and distribute Accord's NDA Product throughout the United States, including Delaware. On information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Accord's NDA Product, and enter into agreements that are nearer than arm's length. On information and belief,

Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. participated, assisted, and cooperated in carrying out the acts complained about herein.

11. On information and belief, following any FDA approval of Accord's NDA, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and Accord Healthcare Ltd. will act in concert to distribute and sell Accord's NDA Product throughout the United States, including within Delaware.

JURISDICTION

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

13. 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 Accord Healthcare Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd.

14. This Court has personal jurisdiction over Accord because, among other things, Accord Healthcare Inc., itself and through its parent Intas Pharmaceuticals Ltd. and affiliate Accord Healthcare Ltd., has purposefully availed itself of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. On information and belief, Accord Healthcare Inc., itself and through its parent Intas Pharmaceuticals Ltd. and affiliate Accord Healthcare Ltd., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware, and/or has engaged in systematic and continuous business contacts within Delaware.

15. In addition, this Court has personal jurisdiction over Accord Healthcare Inc. because, on information and belief, Accord Healthcare Inc., Intas Pharmaceuticals Ltd., and

Accord Healthcare Ltd. are alter egos of each other. Therefore, Intas Pharmaceuticals Ltd.'s and Accord Healthcare Ltd.'s activities in Delaware are attributable to Accord Healthcare Inc.

16. This Court has personal jurisdiction over Intas Pharmaceuticals Ltd. 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. On information and belief, Intas Pharmaceuticals Ltd., itself and through its subsidiaries Accord Healthcare Inc. and Accord Healthcare Ltd., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

17. In addition, this Court has personal jurisdiction over Intas Pharmaceuticals Ltd. because, on information and belief, Intas Pharmaceuticals Ltd. directs and controls Accord Healthcare Inc. and Accord Healthcare Ltd.; and Accord Healthcare Inc., Intas Pharmaceuticals Ltd., Accord Healthcare Ltd., are alter egos of each other. Therefore, Accord Healthcare Inc.'s and Accord Healthcare Ltd.'s activities in Delaware are attributable to Intas Pharmaceuticals Ltd.

18. This Court has personal jurisdiction over Accord Healthcare Ltd. 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. On information and belief, Accord Healthcare Ltd., itself and through its affiliate Accord Healthcare Ltd. and parent Intas Pharmaceuticals Inc., develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

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