

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
CIVIL ACTION NO. 1:22-cv-00431**

NOVARTIS PHARMACEUTICALS
CORPORATION and DANA-FARBER
CANCER INSTITUTE, INC.,

Plaintiffs,

v.

ACCORD HEALTHCARE INC., AND
INTAS PHARMACEUTICAL LTD.,

Defendants.

COMPLAINT

Novartis Pharmaceuticals Corporation (“Novartis”) and Dana-Farber Cancer Institute, Inc. (“Dana-Farber”) (collectively, “Plaintiffs”) by their attorneys hereby allege as follows:

NATURE OF THE ACTION

1. This is a Hatch-Waxman action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Intas Pharmaceuticals Ltd. and Accord Healthcare Inc. This action relates to Abbreviated New Drug Application (“ANDA”) No. 217342 filed by Accord with the U.S. Food and Drug Administration (“FDA”) for approval to engage in the commercial manufacture, use, offer for sale, or sale of a generic version of Novartis’s RYDAPT® Capsules, 25 mg, prior to the expiration of U.S. Patent No. 7,973,031 (the “’031 Patent” or “Asserted Patent”).

PARTIES

A. Plaintiffs

2. Plaintiff Novartis 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. Novartis is engaged in the business of creating, developing, and bringing to market revolutionary drug therapies to benefit patients against serious diseases, including treatments for leukemia and mastocytosis. RYDAPT® is one such treatment option. Novartis markets and sells RYDAPT® in this judicial district and throughout the United States.

4. Plaintiff Dana-Farber is a non-profit corporation organized and existing under the laws of the State of Massachusetts, having a principal place of business at 450 Brookline Avenue, Boston, Massachusetts 02215.

5. Dana-Farber is a world-renowned center for patient care, research and education. Dana-Farber helps to advance this mission through, among other things, licensing intellectual property which helps to fund innovative research and treatment for cancer and other patients who have sought treatment in their hospital and other facilities.

6. Novartis and Dana-Farber own all rights in the '031 Patent.

B. Defendants

7. Upon information and belief, Defendant Intas Pharmaceuticals Ltd. is a corporation organizing and existing under the laws of India, having a principal place of

business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad 380009, Gujarat, India.

8. Upon information and belief, Defendant Accord Healthcare Inc. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

9. Upon information and belief, Intas Pharmaceuticals Ltd. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Accord Healthcare Inc. is a wholly-owned subsidiary of Intas Pharmaceuticals Ltd. and is controlled and/or dominated by Intas Pharmaceutical Ltd. Upon information and belief, Accord Healthcare Inc. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Accord Healthcare Inc.

10. Upon information and belief, Accord Healthcare Inc. is the commercial arm of Intas Pharmaceuticals Ltd. Upon information and belief, Accord Healthcare Inc. and Intas Pharmaceuticals Ltd. together provide full integration in functional areas such as active pharmaceutical ingredient and finished dosage form manufacturing, research and development, clinical program management, and the economies of scale in worldwide distribution.

11. Intas Pharmaceuticals Ltd. and Accord Healthcare Inc. are collectively referred to hereafter as “Accord” unless otherwise noted.

DEFENDANTS’ INFRINGING ACTS

12. By a letter dated April 26, 2022, Accord notified Plaintiffs that Accord had submitted to the FDA ANDA No. 217342 for a generic version of RYDAPT® (Accord’s “ANDA Product”), seeking approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord’s ANDA Product prior to the expiration of the ’031 Patent.

13. In its Notice Letter, Accord notified Plaintiffs that, as a part of its ANDA, Accord had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’031 Patent asserting that the ’031 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of Accord’s ANDA Product.

14. Upon information and belief, and consistent with their past practices, Accord acted collaboratively in the preparation and submission of ANDA No. 217342.

15. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 217342, Accord will work in concert with one another to make, use, offer to sell, and/or sell the ANDA Product throughout the United States, and/or import such generic drug product into the United States, including in this judicial district.

16. Accord has committed an act of infringement in this judicial district by filing ANDA No. 217342 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 217342 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation, and to Dana Farber.

17. Accord has extensive contacts with the State of North Carolina, is incorporated in the State of North Carolina, regularly conducts business in the State of North Carolina, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of North Carolina, and intends to sell in the State of North Carolina the generic product described in ANDA No. 217342 upon approval.

18. Accord has availed themselves of the legal protections of the State of North Carolina by, among other things, being incorporated in North Carolina.

JURISDICTION AND VENUE

19. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

20. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, induced, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in this district by filing the

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