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

ANDA with intent to commercially manufacture, use, offer for sale, sell, market, distribute, and/or import its ANDA Product in the State of North Carolina, including in this District.

21. This Court also has personal jurisdiction over each Defendant because each of the Defendants' affiliations with the State of North Carolina, including by virtue of Accord's incorporation in North Carolina and having a principle place of business in Durham, North Carolina, are so continuous and systematic as to render each Defendant essentially at home in this forum.

22. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

23. Venue is proper in this Court because, among other things, Accord is *inter alia* incorporated and has its principle place of business in the State of North Carolina, and therefore "resides" in this judicial district and has a regular and established place of business in this District. 28 U.S.C. § 1400(b). Intas Pharmaceuticals Ltd. is a foreign corporation not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT AND RYDAPT®

24. On July 5, 2011, the U.S. Patent and Trademark Office duly and legally issued the '031 Patent, entitled "Staurosporine Derivatives as Inhibitors of FLT3 Receptor Tyrosine Kinase Activity." A true and correct copy of the '031 Patent is attached hereto as **Exhibit A**.

25. The ’031 Patent is wholly owned by Novartis and Dana-Farber, who therefore have the right to sue for and obtain equitable relief and damages for infringement of the ’031 Patent.

26. Novartis is the holder of New Drug Application (“NDA”) No. 217342 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of RYDAPT® (Midostaurin) Capsules, 25 mg. RYDAPT® is a kinase inhibitor indicated for the treatment of adult patients with acute myeloid leukemia that is FLT3 mutation-positive, in combination with chemotherapy. RYDAPT® has been approved by the FDA for such indication.

27. Methods of using RYDAPT® to treat patients with FLT3 mutation-positive acute myeloid leukemia as indicated and prescribed in its approved label are covered by one or more claims of the ’031 Patent.

28. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’031 Patent in connection with RYDAPT®.

COUNT 1: INFRINGEMENT BY ACCORD OF THE ’031 PATENT

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

30. Accord, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Accord’s ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as RYDAPT®, and will be bioequivalent to RYDAPT®.

31. Accord's ANDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its ANDA Product, prior to the expiration of the '031 Patent constitutes infringement of one or more of the claims of the '031 Patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, Accord intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA Product with its proposed labeling immediately and imminently upon approval of its ANDA.

33. Upon information and belief, Accord's ANDA Product's proposed labeling will be substantially identical to at least the portions of the RYDAPT® label relating to the treatment of acute myeloid leukemia, and the RYDAPT® label discloses all elements of at least claim 1 of the '031 Patent. Thus, upon information and belief, Accord's ANDA Product labeling will disclose all elements of at least claim 1 of the '031 Patent.

34. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Accord's ANDA Product would infringe one or more claims of the '031 Patent.

35. Upon information and belief, use of Accord's ANDA Product in accordance with and as directed by its proposed labeling for each ANDA Product constitutes and/or will constitute infringement of one or more claims of the '031 Patent; active inducement of the infringement of the '031 Patent; and contribution to the infringement of the '031 Patent under 35 U.S.C. §§271(a)-(c).

36. Upon information and belief, Accord acted without a reasonable basis for believing that it would not be liable for infringing the ’031 Patent, active inducement of infringement of the ’031 Patent, and/or contribution to the infringement by others of the ’031 Patent.

37. If Accord’s infringement of the ’031 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis and Dana-Farber pray that this Court grant the following relief:

1. A judgment that one or more claims of the ’031 Patent is not invalid, is enforceable, and is infringed by Accord’s ANDA submissions, and that Accord’s making, using, offering to sell, or selling in the United States, or importing into the United States of its ANDA Product will infringe the ’031 Patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Accord’s ANDA shall be a date not earlier than the expiration date of the ’031 Patent, including any extensions and/or additional periods of exclusivity.

3. An order permanently enjoining Accord, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or in concert with Accord, from making, using, offering to sell, or selling in the United States, or importing into the United States its ANDA Product, until after the expiration date of the ’031 Patent, including any extensions and/or additional periods of exclusivity.

4. Damages, including monetary and other relief, to Plaintiffs if Accord engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its ANDA Product, prior to the expiration date of the '031 Patent, including any extensions and/or additional periods of exclusivity.

5. Plaintiffs' costs and expenses in this action.

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

This the 7th day of June, 2022

s/ Andrew S. Chamberlin

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