IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION and DANA-FARBER CANCER INSTITUTE, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis") and Dana-Farber Cancer Institute, Inc. ("Dana-Farber") (collectively, "Plaintiffs") by its 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 Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"). This action relates to Abbreviated New Drug Application ("ANDA") No. 215921 filed by DRL 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. Defendant DRL

7. Upon information and belief, Defendant Dr. Reddy’s Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

8. Upon information and belief, Defendant Dr. Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, 50034, India.

9. Upon information and belief, Dr. Reddy's Laboratories, 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, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, 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 Dr. Reddy's Laboratories, Ltd.

10. Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to hereafter as "DRL" unless otherwise noted.

DEFENDANTS' INFRINGING ACTS

11. By a letter dated June 16, 2021, DRL notified Plaintiffs that DRL had submitted to the FDA ANDA No. 215921 for a generic version of RYDAPT® (DRL'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 DRL's ANDA Product prior to the expiration of the '031 Patent.

12. In its Notice Letter, DRL notified Plaintiffs that, as a part of its ANDA, DRL 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 DRL's ANDA Product.

13. Upon information and belief, and consistent with their past practices, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted collaboratively in the preparation and submission of ANDA No. 215921.

14. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 215921, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. 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.

15. DRL has committed an act of infringement in this judicial district by filing ANDA No. 215921 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 215921 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a corporation having a principal place of business in New Jersey.

16. DRL has extensive contacts with the State of New Jersey, regularly conducts business in the State of New Jersey, 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 New Jersey, and intends to sell in the State of New Jersey the generic product described in ANDA No. 215921 upon approval. Furthermore, upon information and belief, DRL is incorporated in this judicial district and has a principal, regular, and established place of business in this judicial district.

17. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have availed themselves of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting claims and counterclaims in lawsuits filed in the United States District

Court for the District of New Jersey. *See e.g.*, *Dr. Reddy's Laboratories, Inc. et al. v. AstraZeneca AB et al.*, C.A. No. 18-16057 (D.N.J.); *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 21-02111 (D.N.J.); *Merck Sharp & Dohme BV et al v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 20-02909 (D.N.J.); *Mitsubishi Tanabe Pharma Corporation et al. v. Dr. Reddy's Laboratories, Inc. et al.*, 19-18764 (D.N.J.); *Bristol-Myers Squibb Company v. Dr. Reddy's Laboratories, Ltd. et al*, C.A. No. 19-18686 (D.N.J.).

JURISDICTION AND VENUE

18. 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).

19. This Court has personal jurisdiction over DRL because, among other things, DRL has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing its ANDA that has led to foreseeable harm and injury to Novartis, a corporation having a principal place of business in New Jersey.

20. This Court also has personal jurisdiction over DRL because of its affiliations with the State of New Jersey, including in many instances by virtue of its incorporation in New Jersey or the incorporation in New Jersey of subsidiaries, are so continuous and systematic as to render DRL essentially at home in this forum.

21. This Court also has personal jurisdiction over DRL because it has frequently availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation for itself and their subsidiaries and admitting jurisdiction and filing lawsuits and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

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 DRL.

23. Venue is proper in this Court because, among other things, DRL has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). Dr. Reddy's Laboratories 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). Moreover, DRL has litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey.

THE PATENTS-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. 207997 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 DRL OF THE '031 PATENT

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

30. DRL, by filing its ANDA, has necessarily represented to the FDA that, upon approval, DRL'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. DRL'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, DRL 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, DRL'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, DRL'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 DRL's ANDA Product would infringe one or more claims of the '031 Patent.

35. Upon information and belief, use of DRL'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 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, DRL 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 DRL'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 DRL's ANDA submissions, and that DRL'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 DRL'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 DRL, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or in concert with DRL, 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 DRL 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.

Dated: July 30, 2021

McCARTER & ENGLISH, LLP

By: */s/ John E. Flaherty*
John E. Flaherty
Cynthia S. Betz
100 Mulberry Street
4 Gateway Center
Newark, NJ 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc.

OF COUNSEL:

Jane M. Love, Ph.D.
Kyanna Sabanoglu
Sung Bin Lee
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
(212) 351-4000
jlove@gibsondunn.com
ksabanoglu@gibsondunn.com
slee3@gibsondunn.com

Anne Y. Brody, Ph.D.
Ronald A. Lee
GIBSON, DUNN & CRUTCHER LLP
3161 Michelson Drive,
Irvine, CA 92612-4412 USA
(949) 451-3800
abrody@gibsondunn.com
ronaldlee@gibsondunn.com

Attorneys for Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc., by their undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions involving and/or relating to RYDAPT® and the Patent In Suit: *Novartis Pharmaceuticals Corp. v. Lupin, Inc.*, No. 21-cv-1105 (D. Del.); *Novartis Pharmaceuticals Corp., et al. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 21-cv-1106 (D. Del.); and *Novartis Pharmaceuticals Corp., et al. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 21-cv-1107 (D. Del.).

McCARTER & ENGLISH, LLP

By: */s/ John E. Flaherty*
John E. Flaherty
Cynthia S. Betz
100 Mulberry Street
4 Gateway Center
Newark, NJ 07102
(973) 622-4444
jflaherty@mccarter.com
cbetz@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc.

OF COUNSEL:

Jane M. Love, Ph.D.
Kyanna Sabanoglu
Sung Bin Lee
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
(212) 351-4000
jlove@gibsondunn.com
ksabanoglu@gibsondunn.com
slee3@gibsondunn.com

Anne Y. Brody, Ph.D.
Ronald A. Lee
GIBSON, DUNN & CRUTCHER LLP
3161 Michelson Drive,
Irvine, CA 92612-4412 USA
(949) 451-3800
abrody@gibsondunn.com
ronaldlee@gibsondunn.com

Attorneys for Novartis Pharmaceuticals Corporation and Dana-Farber Cancer Institute, Inc.