IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. LUPIN INC., Defendant.	Civil Action No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") by its attorneys hereby alleges 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 defendant Lupin Inc. ("Lupin" or "Defendant"). This action relates to Abbreviated New Drug Application ("ANDA") No. 216015 filed by Defendant 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. 8,575,146 (the "'146 Patent" or "Asserted Patent").

PARTIES

A. Plaintiff

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 owns all rights in the '146 Patent.

4. Plaintiff 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.

B. Defendant Lupin

5. Upon information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

6. Upon information and belief, Lupin Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this district.

7. Lupin Inc. is referred to hereafter as "Lupin" unless otherwise noted.

DEFENDANT'S INFRINGING ACTS

8. By a letter dated June 14, 2021, Lupin notified Plaintiff that Lupin had submitted to the FDA ANDA No. 216015 for a generic version of RYDAPT® (Lupin'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 Lupin's ANDA Product prior to the expiration of the '146 Patent.

9. In its Notice Letter, Lupin notified Plaintiff that, as a part of its ANDA, Lupin 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 '146 Patent asserting that the '146 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of Lupin's ANDA Product.

10. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 216015, Lupin will 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.

11. Lupin has committed an act of infringement in this judicial district by filing ANDA No. 216015 with the intent to make, use, offer to sell, and/or sell the ANDA Product in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

12. Lupin has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, 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 Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 216015 upon approval.

13. Lupin has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See e.g.*, *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A., et al.*, C.A. No. 20-415 (D. Del.); *Novartis Pharm. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-01979 (D. Del.); *Ferring Pharm. Inc. et al. v. Lupin Inc. et al.*, C.A. No. 19-913 (D. Del.).

JURISDICTION AND VENUE

14. 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).

15. This Court has personal jurisdiction over Lupin because, among other things, Lupin 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 Delaware corporation.

16. This Court also has personal jurisdiction over Lupin because of Lupin's affiliations with the State of Delaware, including in many instances by virtue of its incorporation in Delaware, are so continuous and systematic as to render Lupin essentially at home in this forum.

17. This Court also has personal jurisdiction over Lupin because it has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

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

19. Venue is proper in this Court because, among other things, Lupin is *inter alia* incorporated in the State of Delaware and therefore "resides" in this judicial district and/or 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). Moreover, Lupin has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

THE PATENT-IN-SUIT AND RYDAPT®

20. On November 5, 2013, the U.S. Patent and Trademark Office duly and legally issued the '146 Patent, entitled "Pharmaceutical Uses of Staurosporine Derivatives." A true and correct copy of the '146 Patent is attached hereto as **Exhibit A**.

21. The ’146 Patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the ’146 Patent.

22. 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 aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, and/or mast cell leukemia. RYDAPT® has been approved by the FDA for such indication.

23. Methods of using RYDAPT® to treat patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, and/or mast cell leukemia as indicated and prescribed in its approved label are covered by one or more claims of the ’146 Patent.

24. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’146 Patent in connection with RYDAPT®.

COUNT 1: INFRINGEMENT BY LUPIN OF THE ’146 PATENT

25. Plaintiff realleges, and incorporates in full herein, each preceding paragraph.

26. Lupin, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Lupin’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®.

27. Lupin’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 ’146 Patent constitutes infringement of one or more of the claims of the ’146 Patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon information and belief, Lupin 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.

29. Upon information and belief, Lupin's ANDA Product's proposed labeling will be substantially identical to at least the portions of the RYDAPT® label relating to the treatment of mastocytosis, and the RYDAPT® label discloses all elements of at least claim 1 of the '146 Patent. Thus, upon information and belief, Lupin's ANDA Product labeling will disclose all elements of at least claim 1 of the '146 Patent.

30. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Lupin's ANDA Product would infringe one or more claims of the '146 Patent.

31. Upon information and belief, use of Lupin'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 '146 Patent; active inducement of infringement of the '146 Patent; and contribution to the infringement of the '146 Patent under 35 U.S.C. §§271(a)-(c).

32. Upon information and belief, Lupin acted without a reasonable basis for believing that it would not be liable for infringing the '146 Patent, active inducement of infringement of the '146 Patent, and/or contribution to the infringement by others of the '146 Patent.

33. If Lupin's infringement of the '146 Patent is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more claims of the '146 Patent is not invalid, is enforceable, and is infringed by Lupin's ANDA submission, and that Lupin'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 ’146 Patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Lupin’s ANDA shall be a date not earlier than the expiration date of the ’146 Patent, including any extensions and/or additional periods of exclusivity.

3. An order permanently enjoining Lupin, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or in concert with Lupin, 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 ’146 Patent, including any extensions and/or additional periods of exclusivity.

4. Damages, including monetary and other relief, to Novartis if Lupin 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 ’146 Patent, including any extensions and/or additional periods of exclusivity.

5. Novartis’s 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 29, 2021

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