IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and DANA-FARBER CANCER INSTITUTE, INC., Plaintiffs, v. LOTUS PHARMACEUTICAL CO., LTD. and TEVA PHARMACEUTICAL DEVELOPMENT, INC., Defendants.	Civil Action No. _____

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 an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Lotus Pharmaceutical Co., Ltd. ("Lotus") and Teva Pharmaceuticals Development, Inc. ("Teva") (collectively, "Defendants"). This action relates to Abbreviated New Drug Applications ("ANDAs") filed by Defendants with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, offer for sale, or sale of their respective generic versions of Novartis's RYDAPT® Capsules, 25 mg, prior to the expiration of U.S. Patent Nos. 7,973,031 (the "'031 Patent"), 8,222,244 (the "'244 Patent"), and 8,575,146 (the "'146 Patent") (collectively, "Asserted Patents").

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 and ’244 Patents. Novartis owns all rights in the ’146 Patent.

B. The Generic Defendants

7. Upon information and belief, Defendant Teva Pharmaceutical Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

8. Upon information and belief, Teva Pharmaceutical Development, 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.

9. Teva Pharmaceutical Development, Inc. is referred to hereafter as "Teva" unless otherwise noted.

10. Upon information and belief, Defendant Lotus Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Taiwan, having a principal place of business at 17F, No. 277, Song Ren Road, Xin Yi District, Taipei City 110, Taiwan.

11. Upon information and belief, Lotus Pharmaceutical Co., Ltd. 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.

12. Lotus Pharmaceutical Co., Ltd. is referred to hereafter as "Lotus" unless otherwise noted.

DEFENDANTS' INFRINGING ACTS

A. Teva

13. By a letter dated June 14, 2021, Teva notified Plaintiffs that Teva had submitted to the FDA ANDA No. 216076 for a generic version of RYDAPT® ("Teva'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 Teva's ANDA Product prior to the expiration of the '031 and '146 Patents.

14. In its Notice Letter, Teva notified Plaintiffs that, as a part of its ANDA, Teva 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 and '146 Patents asserting that the '031 and '146

Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of Teva's ANDA Product.

15. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 216076, Teva will make, use, offer to sell, and/or sell Teva's ANDA Product throughout the United States, and/or import such generic drug product into the United States, including in this judicial district.

16. Teva has committed an act of infringement in this judicial district by filing ANDA No. 216076 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 216076 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

17. Teva 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. 216076 upon approval.

18. Teva 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.*, *Biogen Inc. et al. v. Teva Pharm. Development Inc.*, C.A. No. 21-389 (D. Del.)

B. Lotus

19. By a letter dated June 24, 2021, Lotus notified Plaintiffs that Lotus had submitted to the FDA ANDA No. 215834 for a generic version of RYDAPT® ("Lotus's ANDA Product"), seeking approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Lotus's ANDA Product prior to the expiration of the '031, '244, and '146 Patents.

20. In its Notice Letter, Lotus notified Plaintiffs that, as a part of its ANDA, Lotus 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, '244, and '146 Patents asserting that the '031, '244, and '146 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, and sale of Lotus's ANDA Product.

21. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 215834, Lotus will make, use, offer to sell, and/or sell Lotus's ANDA Product throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

22. Lotus has committed an act of infringement in this judicial district by filing ANDA No. 215834 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 215834 in this judicial district, an act of infringement that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

23. Lotus 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. 215834 upon approval.

24. Lotus has availed itself of the legal protections of the State of Delaware by, among other things, filing suit in the United States District Court for the District of Delaware. *See e.g.*, *Lotus Pharm. Co., Ltd. v. GlaxoSmithKline LLC et al.*, 16-377 (D. Del.).

JURISDICTION AND VENUE

25. 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).

26. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing each ANDA that has led to foreseeable harm and injury to Novartis, a Delaware corporation.

27. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware are so continuous and systematic as to render each Defendant essentially at home in this forum.

28. This Court also has personal jurisdiction over each Defendant because each 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 their subsidiaries and/or admitting jurisdiction and filing lawsuits and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

29. 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.

30. Venue is proper in this Court because, among other things, each Defendant 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). Those defendants that are foreign corporations not residing in any United States judicial district may be sued in any judicial district. 28 U.S.C. §

1391(c)(3). Moreover, each of the Defendants have litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

THE PATENTS-IN-SUIT AND RYDAPT®

31. 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**.

32. 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.

33. On July 17, 2012, the U.S. Patent and Trademark Office duly and legally issued the '244 Patent, entitled "Staurosporine Derivatives as Inhibitors of FLT3 Receptor Tyrosine Kinase Activity." A true and correct copy of the '244 Patent is attached hereto as **Exhibit B**.

34. The '244 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 '244 Patent.

35. 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 C**.

36. 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.

37. 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, as well for the treatment of adult patients with aggressive systemic mastocytosis,

systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia. RYDAPT® has been approved by the FDA for both indications.

38. Methods of using RYDAPT® to treat patients as indicated and prescribed in its approved label are covered by one or more claims of the '031, '244, and/or '146 Patents.

39. The FDA's official publication of approved drugs (the "Orange Book") lists the '031, '244, and '146 Patents in connection with RYDAPT®.

COUNT I: INFRINGEMENT BY LOTUS OF THE '031 PATENT

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

41. Lotus, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Lotus'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®.

42. Lotus'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).

43. Upon information and belief, Lotus 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.

44. Upon information and belief, Lotus's ANDA Product's proposed labeling will be substantially identical to the RYDAPT® label, and the RYDAPT® label discloses all elements of at least claim 1 of the '031 Patent. Thus, upon information and belief, Lotus's ANDA Product labeling will disclose all elements of at least claim 1 of the '031 Patent.

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

46. Upon information and belief, use of Lotus's ANDA Product to treat patients with FLT3 mutation-positive acute myeloid leukemia 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).

47. Upon information and belief, Lotus 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.

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

COUNT II: INFRINGEMENT BY LOTUS OF THE '244 PATENT

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

50. Lotus, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Lotus'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®.

51. Lotus'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 '244 Patent constitutes infringement of one or more of the claims of the '244 Patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, Lotus intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA

Product with the respective proposed labeling immediately and imminently upon approval of its ANDA.

53. Upon information and belief, Lotus's ANDA Product's proposed labeling will be substantially identical to the RYDAPT® label, and the RYDAPT® label discloses all elements of at least claim 1 of the '244 Patent. Thus, upon information and belief, Lotus's ANDA Product labeling will disclose all elements of at least claim 1 of the '244 Patent.

54. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Lotus's ANDA Product would infringe one or more claims of the '244 Patent.

55. Upon information and belief, use of Lotus's ANDA Product to treat patients with FLT3 mutation-positive acute myeloid leukemia in accordance with and as directed by its proposed labeling for the ANDA Product constitutes and/or will constitute infringement of one or more claims of the '244 Patent; active inducement of the infringement of the '244 Patent; and contribution to the infringement of the '244 Patent under 35 U.S.C. §§271(a)-(c).

56. Upon information and belief, Lotus acted without a reasonable basis for believing that it would not be liable for infringing the '244 Patent, active inducement of infringement of the '244 Patent, and/or contribution to the infringement by others of the '244 Patent.

57. If Lotus's infringement of the '244 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT BY LOTUS OF THE '146 PATENT

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

59. Lotus, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Lotus'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®.

60. Lotus'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).

61. Upon information and belief, Lotus 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.

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

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

64. Upon information and belief, use of Lotus's ANDA Product to treat patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia 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 the infringement of the '146 Patent; and contribution to the infringement of the '146 Patent under 35 U.S.C. §§271(a)-(c).

65. Upon information and belief, Lotus 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.

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

COUNT IV: INFRINGEMENT BY TEVA OF THE '031 PATENT

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

68. Teva, by filing its ANDA, has necessarily represented to the FDA that, upon approval, Teva'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®.

69. Teva'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).

70. Upon information and belief, Teva 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.

71. Upon information and belief, Teva's ANDA Product's proposed labeling will be substantially identical to the RYDAPT® label, and the RYDAPT® label discloses all elements of at least claim 1 of the '031 Patent. Thus, upon information and belief, Teva's ANDA Product labeling will disclose all elements of at least claim 1 of the '031 Patent.

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

73. Upon information and belief, use of Teva's ANDA Product to treat patients with FLT3 mutation-positive acute myeloid leukemia 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).

74. Upon information and belief, Teva 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.

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

COUNT V: INFRINGEMENT BY TEVA OF THE ’146 PATENT

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

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

78. Teva’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).

79. Upon information and belief, Teva 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.

80. Upon information and belief, Teva’s ANDA Product’s proposed labeling will be substantially identical to the RYDAPT® label, and the RYDAPT® label discloses all elements of at least claim 1 of the ’146 Patent. Thus, upon information and belief, Teva’s ANDA Product labeling will disclose all elements of at least claim 1 of the ’146 Patent.

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

82. Upon information and belief, use of Teva's ANDA Product to treat patients with aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia 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 the infringement of the '146 Patent; and contribution to the infringement of the '146 Patent under 35 U.S.C. §§271(a)-(c).

83. Upon information and belief, Teva 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.

84. If Teva's infringement of the '146 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 Lotus's and Teva's ANDA submissions, and that Lotus's and Teva's making, using, offering to sell, or selling in the United States, or importing into the United States of their respective ANDA Products 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 Lotus's and Teva's ANDAs shall be a date not earlier than the expiration date of the '031 Patent, including any extensions and/or additional periods of exclusivity.

3. A judgment that one or more claims of the '146 Patent is not invalid, is enforceable, and is infringed by Lotus's and Teva's ANDA submissions, and that Lotus's, and Teva's making,

using, offering to sell, or selling in the United States, or importing into the United States of their respective ANDA Products will infringe the ’146 Patent.

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

5. A judgment that one or more claims of the ’244 Patent is not invalid, is enforceable, and is infringed by Lotus’s ANDA submissions, and that Lotus’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 ’244 Patent.

6. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Lotus’s ANDA shall be a date not earlier than the expiration date of the ’244 Patent, including any extensions and/or additional periods of exclusivity.

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

8. Damages, including monetary and other relief, to Plaintiffs if any Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its ANDA Product, prior to the latest expiration date of the patents asserted against each Defendant, including any extensions and/or additional periods of exclusivity.

9. Plaintiffs’ costs and expenses in this action.

10. 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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