IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, Plaintiffs, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("NPC") and Novartis AG (collectively, "Novartis"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by the above-named Defendants seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of nilotinib hydrochloride capsules, generic versions of Novartis's Tasigna® capsules, 50 mg, 150 mg, and 200 mg, prior to the expiration of U.S. Patent Nos. 8,163,904 ("the '904 patent"), 8,293,756 ("the '756 patent"), 8,389,537 ("the '537 patent"), 8,415,363 ("the '363 patent"), 8,501,760 ("the '760 patent"), and 9,061,029 ("the '029 patent").

THE PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Novartis AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

B. Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (ANDA No. 219134)

4. On information and belief, Teva Pharmaceuticals, 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, #3, Parsippany, New Jersey 07054. On information and belief, Teva Pharmaceuticals, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

5. On information and belief, Teva Pharmaceuticals USA, 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, #3, Parsippany, New Jersey 07054. On information and belief, Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

6. On information and belief, Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 124 Dvora HaNevi'a St. Tel Aviv 6944020, Israel.

7. On information and belief, Teva Pharmaceuticals, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

8. On information and belief, Teva Pharmaceuticals USA, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

9. On information and belief, Teva Pharmaceutical Industries Ltd. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

10. By a letter dated February 20, 2024 ("Teva Notice Letter"), Teva Pharmaceuticals, Inc. notified Novartis that (i) Teva Pharmaceuticals, Inc. had submitted to the FDA ANDA No. 219134 for nilotinib hydrochloride capsules, 50 mg, 150 mg, and 200 mg ("Teva ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents, and that (ii) ANDA No. 219134 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '904, '756, '537, '363, '760, and '029 patents.

11. Teva Pharmaceuticals, Inc. has committed an act of infringement in this judicial district by filing ANDA No. 219134 with the intent to make, use, sell, offer for sale, and/or import the Teva ANDA Products in or into this judicial district, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents, an act of infringement that has led and will lead to foreseeable harm and injury to NPC, a Delaware corporation.

12. On information and belief, Teva Pharmaceuticals USA, Inc. acted in concert with and/or under the direction of Teva Pharmaceuticals, Inc. in the preparation and submission of ANDA No. 219134, and, if the ANDA is approved, will act in concert with and/or under the direction of Teva Pharmaceuticals, Inc., to engage in the commercial manufacture, use, sale,

offer for sale, and/or importation of the Teva ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

13. On information and belief, Teva Pharmaceutical Industries Ltd. acted in concert with and/or directed Teva Pharmaceuticals, Inc. and/or Teva Pharmaceuticals USA, Inc. in the preparation and submission of ANDA No. 219134, and, if the ANDA is approved, will act in concert with and/or direct Teva Pharmaceuticals, Inc. and/or Teva Pharmaceuticals USA, Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

14. Teva Pharmaceuticals, Inc., by itself, or together with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Teva ANDA Products, that will be purposefully directed at Delaware and elsewhere.

15. On information and belief, Teva Pharmaceuticals USA, Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Teva Pharmaceuticals, Inc. and Teva Pharmaceutical Industries Ltd.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

16. On information and belief, Teva Pharmaceutical Industries Ltd. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling

drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

17. Teva Pharmaceutical Industries Ltd. 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.*, *Amicus Therapeutics US, LLC et al. v. Teva Pharm. USA, Inc. et al.*, C.A. No. 22-1462 (D. Del.); *Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Labs, Ltd. et al.*, C.A. No. 16-1267 (D. Del.).

JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction over Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. because each such Defendant's affiliations with the State of Delaware, including Teva Pharmaceuticals, Inc.'s and Teva Pharmaceuticals USA, Inc.'s incorporation in Delaware, and Teva Pharmaceutical Industries Ltd.'s ownership of and actions in concert with Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

20. This Court also has personal jurisdiction over Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and

submitting ANDA No. 219134 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

21. This Court also has personal jurisdiction over Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 219134, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 219134 that will be purposefully directed at Delaware, including the marketing of the Teva ANDA Products in Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

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 Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd.

23. Venue is proper in this Court because Teva Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. are incorporated in the State of Delaware and therefore reside in this judicial district, and because Teva Pharmaceutical Industries Ltd. is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

THE PATENTS-IN-SUIT AND TASIGNA®

24. Novartis AG is the owner of the '904 patent, titled "Salts of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide." The '904 patent was duly and legally issued on April 24, 2012. A true and correct copy of the '904 patent is attached hereto as Exhibit A.

25. Novartis AG is the owner of the ’756 patent, titled “Pharmaceutical compositions comprising nilotinib hydrochloride monohydrate.” The ’756 patent was duly and legally issued on October 23, 2012. A true and correct copy of the ’756 patent is attached hereto as Exhibit B.

26. Novartis AG is the owner of the ’537 patent, titled “Salts of 4-methyl N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide.” The ’537 patent was duly and legally issued on March 5, 2013. A true and correct copy of the ’537 patent is attached hereto as Exhibit C.

27. Novartis AG is the owner of the ’363 patent, titled “Crystalline forms of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide.” The ’363 patent was duly and legally issued on April 9, 2013. A true and correct copy of the ’363 patent is attached hereto as Exhibit D.

28. Novartis AG is the owner of the ’760 patent, titled “Pharmaceutical compositions comprising nilotinib or its salt.” The ’760 patent was duly and legally issued on August 6, 2013. A true and correct copy of the ’760 patent is attached hereto as Exhibit E.

29. Novartis AG is the owner of the ’029 patent, titled “Method of treating proliferative disorders and other pathological conditions mediated by Bcr-Abl, c-Kit, DDR1, DDR2 or PDGF-R kinase activity.” The ’029 patent was duly and legally issued on June 23, 2015. A true and correct copy of the ’029 patent is attached hereto as Exhibit F.

30. NPC is the holder of New Drug Application (“NDA”) No. 022068 by which the FDA granted approval for the commercial manufacture, marketing, sale, and use of TASIGNA® (nilotinib hydrochloride) capsules, 50 mg, 150 mg, and 200 mg. TASIGNA® currently is indicated for the treatment of: adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)

in chronic phase; adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib; and pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

31. NPC has the exclusive right to sell TASIGNA® in the United States, including under the ’904, ’756, ’537, ’363, ’760, and ’029 patents.

INFRINGEMENT OF THE PATENTS-IN-SUIT

32. Novartis incorporates paragraphs 1–31 as if fully set forth herein.

33. On information and belief, Teva Pharmaceuticals, Inc., by itself or in concert with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., submitted to the FDA ANDA No. 219134 under the provisions of 21 U.S.C.§ 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products prior to the expiration of the ’904, ’756, ’537, ’363, ’760, and ’029 patents.

34. This action was commenced within the 45-day period following Novartis’s receipt of the Teva Notice Letter.

35. By filing their ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products in or into the United States prior to the expiration of the ’904, ’756, ’537, ’363, ’760, and ’029 patents, Teva Pharmaceuticals, Inc., and on information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have committed an act of infringement under 35 U.S.C. § 271(e)(2).

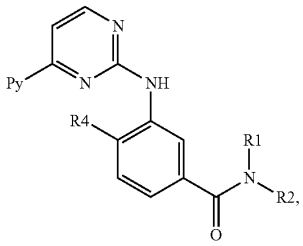
36. On information and belief, when Teva filed ANDA No. 219134, Teva was aware of the ’904, ’756, ’537, ’363, ’760, and ’029 patents and that the filing of the ANDA with the

request for its approval prior to the expiration of the ’904, ’756, ’537, ’363, ’760, and ’029 patents was an act of infringement of those patents.

37. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products in or into the United States will infringe one or more claims of the ’904, ’756, ’537, ’363, ’760, and ’029 patents.

38. On information and belief, the Teva ANDA Products will contain instructions for treating chronic myelogenous leukemia comprising the step of administering to a subject in need thereof, a therapeutically effective amount of a salt, 4-methyl—N—[3-(4-methyl-imidazol-1-yl-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzeneamide monohydrochloride monohydrate. On information and belief, the Teva ANDA Products will contain instructions for treating chronic myelogenous leukemia comprising the step of administering to a subject in need thereof, a therapeutically effective amount of either (1) crystalline form B of the hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide as a monohydrate characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.4°, 12.0°, 12.3°, 14.6°, 14.8°, 15.7°, 17.6°, 19.2°, 19.5,° 20.5°, 22.0°, 23.4°, 23.9°, 25.0°, 25.5°, 25.9°, 27.0° (2θ degrees) as shown in FIG. 8 of the ’363 patent or (2) crystalline form B′ of the anhydrous hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide, characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.5°, 12.0°, 13.9°, 14.3°, 15.4°, 17.6°, 18.6°, 20.3°, 21.7°, 22.5°, 23.2°, 24.7°, 24.9°, 25.2°, 26.0°, 26.6°, 27.5°, 28.2°, 29.2° and 30.0° (2θ degrees) as shown in FIG. 9 of the ’363 patent. On information and belief, the Teva ANDA Products will contain instructions for a method of

treating a proliferative disorder wherein the proliferative disorder or other pathological condition is selected from melanoma, breast cancer, cancer of the colon, lung cancer, cancer of the prostate or Kaposi's sarcoma, gastrointestinal stromal tumors (GIST), acute myeloid leukemia (AML), leukemia which responds to an inhibition of the Abl tyrosine kinase activity, mesothelioma, systemic mastocytosis, hypereosinophilic syndrome (HES), fibrosis, rheumatoid arthritis, polyarthritis, scleroderma, lupus erythematosus, graft-versus host diseases, neurofibromatosis, pulmonary hypertension, Alzheimer's disease, seminomas and dysgerminomas and psoriasis comprising oral administration of an effective dose of a pyrimidylaminobenzamide of formula (I):



wherein

(a) Py denotes 3-pyridyl,

R_1 represents hydrogen, lower alkyl, lower alkoxy-lower alkyl, acyloxy-lower alkyl, carboxy-lower alkyl, lower alkoxycarbonyl-lower alkyl, or phenyl-lower alkyl;

R_2 represents hydrogen, lower alkyl, optionally substituted by one or more identical or different radicals R_3, cycloalkyl, benzcycloalkyl, heterocyclyl, an aryl group, or a mono- or bicyclic heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; and

R_3 represents hydroxy, lower alkoxy, acyloxy, carboxy, lower alkoxycarbonyl, carbamoyl, N-mono- or N,N-di-substituted carbamoyl, amino, mono- or di-substituted amino, cycloalkyl,

heterocyclyl, an aryl group, or a mono- or bi-cyclic heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; or

R_1 and R_2, together, represent alkylene with 4, 5 or 6 carbon atoms optionally mono- or di-substituted by lower alkyl, cycloalkyl, heterocyclyl, phenyl, hydroxy, lower alkoxy, amino, mono- or di-substituted amino, oxo, pyridyl, pyrazinyl or pyrimidinyl; benzalkylene with 4 or 5 carbon atoms; oxaalkylene with 1 oxygen and 3 or 4 carbon atoms; or azaalkylene with 1 nitrogen and 3 or 4 carbon atoms, wherein nitrogen is unsubstituted or substituted by lower alkyl, phenyl-lower alkyl, lower alkoxycarbonyl-lower alkyl, carboxy-lower alkyl, carbamoyl-lower alkyl, N-mono- or N,N-di-substituted carbamoyl-lower alkyl, cycloalkyl, lower alkoxycarbonyl, carboxy, phenyl, substituted phenyl, pyridinyl, pyrimidinyl or pyrazinyl;

R_4 represents hydrogen, lower alkyl or halogen;

or

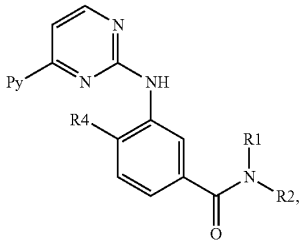
(b) Py denotes 5-pyrimidyl, R_1 is hydrogen, R_2 is [[(3S)-3-(dimethylamino)-1-pyrrolidinyl]methyl]-3-(trifluoromethyl)phenyl and R_4 is methyl;

or a pharmaceutically acceptable salt thereof, and, optionally, pharmaceutically acceptable carriers, dispersed in a fruit preparation, to a human patient in need thereof. On information and belief, if the Teva ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’537, ’363, and ’029 patents. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. will actively encourage, recommend, or promote this infringement with

knowledge of the ’537, ’363, and ’029 patents, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’537, ’363, and ’029 patents.

39. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which must be specifically labeled for treating chronic myelogenous leukemia comprising the step of administering to a subject in need thereof, a therapeutically effective amount of a salt, 4-methyl––N–[3-(4-methyl-imidazol-1-yl-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzeneamide monohydrochloride monohydrate. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which must be specifically labeled for treating chronic myelogenous leukemia comprising the step of administering to a subject in need thereof, a therapeutically effective amount of either (1) crystalline form B of the hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide as a monohydrate characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.4°, 12.0°, 12.3°, 14.6°, 14.8°, 15.7°, 17.6°, 19.2°, 19.5,° 20.5°, 22.0°, 23.4°, 23.9°, 25.0°, 25.5°, 25.9°, 27.0° (2θ degrees) as shown in FIG. 8 of the ’363 patent or (2) crystalline form B′ of the anhydrous hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide, characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.5°, 12.0°, 13.9°, 14.3°, 15.4°, 17.6°, 18.6°, 20.3°, 21.7°, 22.5°, 23.2°, 24.7°, 24.9°, 25.2°, 26.0°, 26.6°, 27.5°, 28.2°, 29.2° and 30.0° (2θ

degrees) as shown in FIG. 9 of the ’363 patent. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which must be specifically labeled for a method of treating a proliferative disorder wherein the proliferative disorder or other pathological condition is selected from melanoma, breast cancer, cancer of the colon, lung cancer, cancer of the prostate or Kaposi's sarcoma, gastrointestinal stromal tumors (GIST), acute myeloid leukemia (AML), leukemia which responds to an inhibition of the Abl tyrosine kinase activity, mesothelioma, systemic mastocytosis, hypereosinophilic syndrome (HES), fibrosis, rheumatoid arthritis, polyarthritis, scleroderma, lupus erythematosus, graft-versus host diseases, neurofibromatosis, pulmonary hypertension, Alzheimer's disease, seminomas and dysgerminomas and psoriasis comprising oral administration of an effective dose of a pyrimidylaminobenzamide of formula (I):



wherein

(a) Py denotes 3-pyridyl,

R_1 represents hydrogen, lower alkyl, lower alkoxy-lower alkyl, acyloxy-lower alkyl, carboxy-lower alkyl, lower alkoxycarbonyl-lower alkyl, or phenyl-lower alkyl;

R_2 represents hydrogen, lower alkyl, optionally substituted by one or more identical or different radicals R_3, cycloalkyl, benzcycloalkyl, heterocyclyl, an aryl group, or a mono- or bicyclic

heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; and

R_3 represents hydroxy, lower alkoxy, acyloxy, carboxy, lower alkoxycarbonyl, carbamoyl, N-mono- or N,N-di-substituted carbamoyl, amino, mono- or di-substituted amino, cycloalkyl, heterocyclyl, an aryl group, or a mono- or bi-cyclic heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; or

R_1 and R_2, together, represent alkylene with 4, 5 or 6 carbon atoms optionally mono- or di-substituted by lower alkyl, cycloalkyl, heterocyclyl, phenyl, hydroxy, lower alkoxy, amino, mono- or di-substituted amino, oxo, pyridyl, pyrazinyl or pyrimidinyl; benzalkylene with 4 or 5 carbon atoms; oxaalkylene with 1 oxygen and 3 or 4 carbon atoms; or azaalkylene with 1 nitrogen and 3 or 4 carbon atoms, wherein nitrogen is unsubstituted or substituted by lower alkyl, phenyl-lower alkyl, lower alkoxycarbonyl-lower alkyl, carboxy-lower alkyl, carbamoyl-lower alkyl, N-mono- or N,N-di-substituted carbamoyl-lower alkyl, cycloalkyl, lower alkoxycarbonyl, carboxy, phenyl, substituted phenyl, pyridinyl, pyrimidinyl or pyrazinyl;

R_4 represents hydrogen, lower alkyl or halogen;

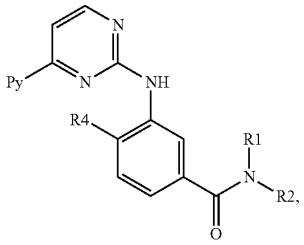
or

(b) Py denotes 5-pyrimidyl, R_1 is hydrogen, R_2 is [[(3S)-3-(dimethylamino)-1-pyrrolidinyl]methyl]-3-(trifluoromethyl)phenyl and R_4 is methyl;

or a pharmaceutically acceptable salt thereof, and, optionally, pharmaceutically acceptable carriers, dispersed in a fruit preparation, to a human patient in need thereof. On information and belief, if the Teva ANDA Products are approved, those products will constitute a material part of a method of treating chronic myelogenous leukemia comprising the step of administering to a

subject in need thereof, a therapeutically effective amount of a salt, 4-methyl–N–[3-(4-methyl-imidazol-1-yl-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzeneamide monohydrochloride monohydrate. On information and belief, if the Teva ANDA Products are approved, those products will constitute a material part of a method of treating chronic myelogenous leukemia comprising the step of administering to a subject in need thereof, a therapeutically effective amount of either (1) crystalline form B of the hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide as a monohydrate characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.4°, 12.0°, 12.3°, 14.6°, 14.8°, 15.7°, 17.6°, 19.2°, 19.5,° 20.5°, 22.0°, 23.4°, 23.9°, 25.0°, 25.5°, 25.9°, 27.0° (2θ degrees) as shown in FIG. 8 of the ’363 patent or (2) crystalline form B′ of the anhydrous hydrochloride salt of 4-methyl-N-[3-(4-methyl-imidazol-1-yl)-5-trifluoromethyl-phenyl]-3-(4-pyridin-3-yl-pyrimidin-2-ylamino)-benzamide, characterized by an x-ray powder diffraction pattern having at least one maxima selected from about 7.2°, 9.2°, 11.5°, 12.0°, 13.9°, 14.3°, 15.4°, 17.6°, 18.6°, 20.3°, 21.7°, 22.5°, 23.2°, 24.7°, 24.9°, 25.2°, 26.0°, 26.6°, 27.5°, 28.2°, 29.2° and 30.0° (2θ degrees) as shown in FIG. 9 of the ’363 patent. On information and belief, if the Teva ANDA Products are approved, those products will constitute a material part of a method of treating a proliferative disorder wherein the proliferative disorder or other pathological condition is selected from melanoma, breast cancer, cancer of the colon, lung cancer, cancer of the prostate or Kaposi's sarcoma, gastrointestinal stromal tumors (GIST), acute myeloid leukemia (AML), leukemia which responds to an inhibition of the Abl tyrosine kinase activity, mesothelioma, systemic mastocytosis, hypereosinophilic syndrome (HES), fibrosis, rheumatoid arthritis, polyarthritis, scleroderma, lupus erythematosus, graft-versus host diseases, neurofibromatosis,

pulmonary hypertension, Alzheimer's disease, seminomas and dysgerminomas and psoriasis comprising oral administration of an effective dose of a pyrimidylaminobenzamide of formula (I):



wherein

(a) Py denotes 3-pyridyl,

R_1 represents hydrogen, lower alkyl, lower alkoxy-lower alkyl, acyloxy-lower alkyl, carboxy-lower alkyl, lower alkoxycarbonyl-lower alkyl, or phenyl-lower alkyl;

R_2 represents hydrogen, lower alkyl, optionally substituted by one or more identical or different radicals R_3, cycloalkyl, benzcycloalkyl, heterocyclyl, an aryl group, or a mono- or bicyclic heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; and

R_3 represents hydroxy, lower alkoxy, acyloxy, carboxy, lower alkoxycarbonyl, carbamoyl, N-mono- or N,N-di-substituted carbamoyl, amino, mono- or di-substituted amino, cycloalkyl, heterocyclyl, an aryl group, or a mono- or bi-cyclic heteroaryl group comprising 0-, 1-, 2- or 3-ring nitrogen atoms and 0 or 1 oxygen atom and 0 or 1 sulfur atom, which groups in each case are unsubstituted or mono- or poly-substituted; or

R_1 and R_2, together, represent alkylene with 4, 5 or 6 carbon atoms optionally mono- or di-substituted by lower alkyl, cycloalkyl, heterocyclyl, phenyl, hydroxy, lower alkoxy, amino, mono- or di-substituted amino, oxo, pyridyl, pyrazinyl or pyrimidinyl; benzalkylene with 4 or 5

carbon atoms; oxaalkylene with 1 oxygen and 3 or 4 carbon atoms; or azaalkylene with 1 nitrogen and 3 or 4 carbon atoms, wherein nitrogen is unsubstituted or substituted by lower alkyl, phenyl-lower alkyl, lower alkoxycarbonyl-lower alkyl, carboxy-lower alkyl, carbamoyl-lower alkyl, N-mono- or N,N-di-substituted carbamoyl-lower alkyl, cycloalkyl, lower alkoxycarbonyl, carboxy, phenyl, substituted phenyl, pyridinyl, pyrimidinyl or pyrazinyl;

R_4 represents hydrogen, lower alkyl or halogen;

or

(b) Py denotes 5-pyrimidyl, R_1 is hydrogen, R_2 is [[(3S)-3-(dimethylamino)-1-pyrrolidinyl]methyl]-3-(trifluoromethyl)phenyl and R_4 is methyl;

or a pharmaceutically acceptable salt thereof, and, optionally, pharmaceutically acceptable carriers, dispersed in a fruit preparation, to a human patient in need thereof. On information and belief, if the Teva ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Teva ANDA Products will directly infringe one or more claims of the ’537, ’363, and ’029 patents. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. will contributorily infringe one or more claims of the ’537, ’363, and ’029 patents and will do so with knowledge of the ’537, ’363, and ’029 patents, and that the Teva ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’537, ’363, and ’029 patents and are not suitable for substantial non-infringing use.

40. Novartis will be substantially and irreparably damaged by Teva Pharmaceuticals, Inc.’s, Teva Pharmaceuticals USA, Inc.’s and/or Teva Pharmaceutical Industries Ltd.’s infringement of the ’904, ’756, ’537, ’363, ’760, and ’029 patents.

41. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 219134 be a date that is no earlier than February 23, 2029, the expiration of the '904 patent's pediatric exclusivity, March 25, 2028, the expiration of the '756 patent's pediatric exclusivity, January 18, 2027, the expiration of the '537, '363, and '760 patents' pediatric exclusivity, October 7, 2032, the expiration of the '029 patent's pediatric exclusivity, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Teva ANDA Products and any act committed by Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd. with respect to the subject matter claimed in the '904, '756, '537, '363, '760, and '029 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

42. On information and belief, Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products, including seeking approval of those products under ANDA No. 219134.

43. There is a substantial and immediate controversy between Novartis and Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. concerning the '904, '756, '537, '363, '760, and '029 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. will directly infringe, induce infringement of, and/or contributorily infringe, one or more claims of the '904, '756, '537, '363, '760, and '029 patents.

PRAYER FOR RELIEF

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

44. Judgment that Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. have infringed one or more claims of the '904, '756, '537, '363, '760, and '029 patents by filing ANDA No. 219134;

45. A permanent injunction restraining and enjoining Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Teva ANDA Products prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents, inclusive of any extensions and additional periods of exclusivity;

46. An order that the effective date of any approval of ANDA No. 219134 be a date that is not earlier than the expiration date of the '904, '756, '537, '363, '760, and '029 patents, inclusive of any extensions and additional periods of exclusivity;

47. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe, one or more claims of the '904, '756, '537, '363, '760, and '029 patents;

48. Damages or other monetary relief from Defendants Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. for the infringement, inducement of infringement, and/or contributory infringement, of the '904, '756, '537, '363, '760, and '029 patents in the event Teva sells its ANDA Products in the United States;

49. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

50. Novartis's costs and expenses in this action; and

51. Such other and further relief as the Court may deem just and proper.

Dated: April 4, 2024

MCCARTER & ENGLISH, LLP

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