IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, Plaintiffs, v. EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., 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. Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc.

4. On information and belief, Eugia Pharma Specialities Ltd. is a corporation organized and existing under the laws of India, having a place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, India, 500038. On information and belief, Eugia Pharma Specialities Ltd. is a subsidiary of Aurobindo Pharma Ltd.

5. On information and belief, Eugia Pharma Specialities Ltd. is sometimes described as Eugia Pharma "Specialities" Ltd. and sometimes as Eugia Pharma "Specialties" Ltd., including, for example in Answers filed in the following cases: *Pfizer Inc. et al. v. Eugia Pharma Specialties Ltd.*, *et al.*, C.A. No. 20-01528-CFC, D.I. 7 (D. Del.) ("Eugia Pharma Specialities Ltd."); *Amgen Inc. et al. v. Eugia Pharma Specialties Ltd., et al.*, C.A. No. 22-00227-MN, D.I. 11 (D. Del.) ("Eugia Pharma Specialties Limited"); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, C.A. No. 22-03186-EP-LDW, D.I. 24 (D.N.J.) ("Eugia Pharma Specialities Limited (a.k.a. Eugia Pharma Specialties Limited)").

6. On information and belief, Eugia US LLC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520 and a Delaware Registered Agent at 251

Little Falls Drive, Wilmington, Delaware 19808. On information and belief, Eugia US LLC is a subsidiary of Aurobindo Pharma Ltd.

7. On information and belief, Aurobindo Pharma Ltd. is a company organized and existing under the laws of India, with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

8. On information and belief, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520 and a Delaware Registered Agent at 251 Little Falls Drive, Wilmington, Delaware 19808. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

9. On information and belief, Eugia Pharma Specialities 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. On information and belief, Eugia US LLC 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.

11. On information and belief, Aurobindo Pharma 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.

12. On information and belief, Aurobindo Pharma 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.

13. By a letter dated May 15, 2025 ("Eugia Notice Letter"), Eugia Pharma Specialities Ltd. notified Novartis that (i) Eugia Pharma Specialities Ltd. had submitted to the FDA ANDA No. 220516 for Nilotinib Capsules, 50 mg, 150 mg, and 200 mg ("Eugia ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia 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. 220516 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.

14. Eugia Pharma Specialities Ltd. has committed an act of infringement in this judicial district by filing ANDA No. 220516 with the intent to make, use, sell, offer for sale, and/or import the Eugia 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.

15. On information and belief, Eugia US LLC acted in concert with and/or under the direction of Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd. and/or Aurobindo Pharma USA, Inc. in the preparation and submission of ANDA No. 220516, and, if the ANDA is approved, will act in concert with and/or under the direction of Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd. and/or Aurobindo Pharma USA, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

16. On information and belief, Aurobindo Pharma Ltd. acted in concert with and/or directed Eugia Pharma Specialities Ltd., Eugia US LLC, and/or Aurobindo Pharma USA, Inc. in

the preparation and submission of ANDA No. 220516, and, if the ANDA is approved, will act in concert with and/or direct Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

17. On information and belief, Aurobindo Pharma USA, Inc. acted in concert with and/or under the direction of Eugia Pharma Specialities Ltd., Eugia US LLC, and/or Aurobindo Pharma Ltd. in the preparation and submission of ANDA No. 220516, and, if the ANDA is approved, will act in concert with and/or under the direction of Eugia Pharma Specialities Ltd., Eugia US LLC, and/or Aurobindo Pharma Ltd. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia ANDA Products in or into the United States, including Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

18. Eugia Pharma Specialities Ltd., by itself, or, on information and belief, together with Eugia US LLC and/or Aurobindo Pharma Ltd. and/or Aurobindo Pharma USA, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Eugia ANDA Products, that will be purposefully directed at Delaware and elsewhere.

19. On information and belief, Eugia Pharma Specialities 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 Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma 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.

20. On information and belief, Eugia US LLC 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 Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma 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.

21. On information and belief, Aurobindo Pharma 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 Eugia Pharma Specialities Ltd., Eugia US LLC, and Aurobindo Pharma 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.

22. On information and belief, Aurobindo Pharma 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 Eugia Pharma Specialities Ltd., Eugia US LLC, and Aurobindo Pharma 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.

23. Eugia Pharma Specialities Ltd., Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. have availed themselves 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.*, *Taiho Pharm. Co., Ltd. et al. v. Eugia Pharma Specialities Ltd. et al.*, C.A. No. 23-01193-CFC (D. Del.), *Amgen Inc. et al. v. Aurobindo Pharma Limited et al.*, C.A. No. 22-227-MN (D. Del.); A*stellas Pharma Inc. et al. v. Eugia Pharma Specialities Ltd. et al*., C.A. No. 18-757-GMS (D. Del.).

24. Eugia Pharma Specialities Ltd., the entity identified in the Eugia Notice Letter as having submitted ANDA No. 220516, has agreed not to challenge personal jurisdiction and venue in the District of Delaware for actions concerning ANDA No. 220516.

JURISDICTION AND VENUE

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

26. This Court has personal jurisdiction over Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. because each such Defendant's affiliations with the State of Delaware, including Eugia US LLC's and Aurobindo Pharma USA, Inc.'s incorporation in Delaware, and Eugia Pharma Specialities Ltd.'s and Aurobindo Pharma Ltd.'s ownership of and/or actions in concert with Eugia US LLC and/or Aurobindo Pharma USA, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

27. This Court also has personal jurisdiction over Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. 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. 220516 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 NPC, a Delaware corporation.

28. This Court also has personal jurisdiction over Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 220516, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 220516 that will be purposefully directed at Delaware, including the marketing of the Eugia ANDA Products in Delaware, prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

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 Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc.

30. Venue is proper in this Court because Eugia US LLC and Aurobindo Pharma USA, Inc. are incorporated in the State of Delaware and therefore reside in this judicial district, and because Eugia Pharma Specialities Ltd. and Aurobindo Pharma Ltd. are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

31. Eugia Pharma Specialities Ltd., the entity identified in the Eugia Notice Letter as having submitted ANDA No. 220516, has agreed not to challenge personal jurisdiction and venue in the District of Delaware for actions concerning ANDA No. 220516.

THE PATENTS-IN-SUIT AND TASIGNA®

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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

40. Novartis incorporates paragraphs 1–39 as if fully set forth herein.

41. On information and belief, Eugia Pharma Specialities Ltd., by itself or in concert with Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc., submitted to the FDA ANDA No. 220516 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 Eugia ANDA Products prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents.

42. This action was commenced within the 45-day period following Novartis's receipt of the Eugia Notice Letter.

43. 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 Eugia ANDA Products in or into the United States prior to the expiration of the '904, '756, '537, '363, '760, and '029 patents, Eugia Pharma Specialities Ltd., and on information and

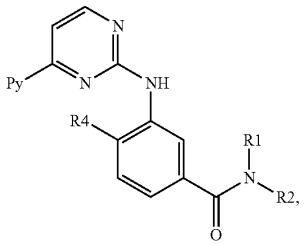
belief, Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. have committed an act of infringement under 35 U.S.C. § 271(e)(2).

44. On information and belief, when Eugia filed ANDA No. 220516, Eugia 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.

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

46. On information and belief, the Eugia 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 Eugia 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. 12 of the '363 patent. On information and belief, the Eugia 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

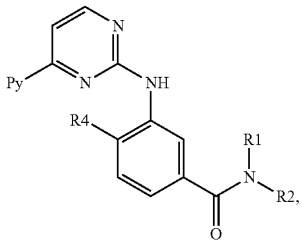
(b) Py denotes 5-pyrimidyl, R_1 is hydrogen, R_2 is [[(3S)-3-(dimethylamino)-1-pyrrolidinyl]methyl]-3-(trifluoromethyl)phenyl and R_4 is methyl;

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 Eugia 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 Eugia ANDA Products are approved, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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.

47. On information and belief, if the Eugia ANDA Products are approved, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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 Eugia ANDA Products are approved, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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. 12 of the '363 patent. On information and belief, if the Eugia ANDA Products are approved, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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;

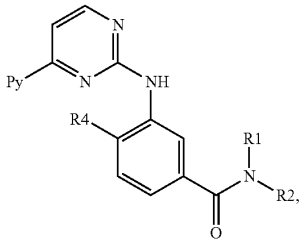
or

(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 Eugia 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 Eugia 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. 12 of the ’363 patent. On information and belief, if the Eugia 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 Eugia ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following the approved instructions in the Eugia ANDA Products will directly infringe one or more claims of the ’537, ’363, and ’029 patents. On information and belief, if the Eugia ANDA Products are approved, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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 Eugia 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.

48. Novartis will be substantially and irreparably damaged by Eugia Pharma Specialities Ltd.'s, Eugia US LLC's, Aurobindo Pharma Ltd.'s, and/or Aurobindo Pharma USA, Inc.'s infringement of the '904, '756, '537, '363, '760, and '029 patents.

49. 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. 220516 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 Eugia ANDA Products and any act committed by Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. 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).

50. On information and belief, Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and/or Aurobindo Pharma USA, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia ANDA Products, including seeking approval of those products under ANDA No. 220516.

51. There is a substantial and immediate controversy between Novartis and Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. 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 Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. 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:

52. Judgment that Defendants Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. have infringed one or more claims of the '904, '756, '537, '363, '760, and '029 patents by filing ANDA No. 220516;

53. A permanent injunction restraining and enjoining Defendants Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. 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 Eugia 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;

54. An order that the effective date of any approval of ANDA No. 220516 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;

55. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Eugia 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;

56. Damages or other monetary relief from Defendants Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma Ltd., and Aurobindo Pharma USA, Inc. for the infringement, inducement of infringement, and/or contributory infringement of the '904, '756, '537, '363, '760, and '029 patents in the event Defendants sell the Eugia ANDA Products in the United States;

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

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

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

Dated: June 27, 2025

MCCARTER & ENGLISH, LLP

By: /s/ Daniel M. Silver
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiff
Novartis Pharmaceuticals Corporation
and Novartis AG

OF COUNSEL:

Nicholas N. Kallas
Christina Schwarz
VENABLE LLP
151 West 42nd Street
New York, New York 10036
(212) 307-5500
nkallas@venable.com
cschwarz@venable.com