IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. CIPLA LIMITED and CIPLA 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 and declaratory judgment action arising under Title 35 of the United States Code and concerning a 505(b)(2) New Drug Application ("505(b)(2) NDA") 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 d-tartrate capsules, versions of Novartis's TASIGNA® capsules, 50 mg, 150 mg, and 200 mg, prior to the expiration of U.S. Patent No. 8,389,537 ("the '537 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. Cipla Limited and Cipla USA, Inc.

4. Upon information and belief, Cipla Limited is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

5. Upon information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey 07059. Upon information and belief, Cipla USA, Inc. is an indirect, wholly owned subsidiary of Cipla Limited. *See, e.g.*, *Acerta Pharma B.V. et al. v. Cipla Limited and Cipla USA, Inc.*, 24-587-GBW (D. Del.) (D.I. 10 at 3).

6. Upon information and belief, Cipla Limited and Cipla USA, Inc. (collectively, "Cipla") are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. Upon information and belief, the acts of Cipla Limited and Cipla USA, Inc. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

7. Upon information and belief, Cipla is a generic pharmaceutical organization that works to develop, manufacture, market, import, sell, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States, either directly or indirectly.

8. By a letter dated May 9, 2024 ("Cipla Notice Letter"), Cipla Limited notified Novartis that (i) Cipla Limited had submitted to the FDA 505(b)(2) NDA No. 218922 for nilotinib d-tartrate capsules, 50 mg, 150 mg, and 200 mg ("Cipla 505(b)(2) NDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States, including Delaware, prior to the expiration of the '537 patent, and that (ii) 505(b)(2) NDA No. 218922 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '537 patent.

9. On February 19, 2025, FDA approved 505(b)(2) NDA No. 218922.

10. Cipla Limited has committed an act of infringement in this judicial district by filing 505(b)(2) NDA No. 218922 with the intent to make, use, sell, offer for sale, and/or import the Cipla 505(b)(2) NDA Products in or into this judicial district, prior to the expiration of the '537 patent, an act of infringement that has led and will lead to foreseeable harm and injury to NPC, a Delaware corporation.

11. On information and belief, Cipla Limited acted in concert with and/or directed Cipla USA, Inc. in the preparation and submission of the Cipla 505(b)(2) NDA No. 218922, and will act in concert with and/or direct Cipla USA, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States, including Delaware, prior to the expiration of the '537 patent.

12. Cipla Limited, by itself, or together with Cipla USA, Inc., has taken the costly, significant step of applying to the FDA for approval, and has obtained such approval, to engage in future activities, including the marketing of the Cipla 505(b)(2) NDA Products, that will be purposefully directed at Delaware and elsewhere.

13. On information and belief, Cipla Limited 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 Cipla 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.

14. On information and belief, Cipla 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 Cipla Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

15. Cipla Limited has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court of the District of Delaware. *See, e.g., Acerta Pharma B.V. et al. v. Cipla Limited et al.*, C.A. No. 24-587-GBW; *Gilead Scis., Inc. v. Cipla Limited*, C.A. No. 23-1480-MN; *Hikma Pharms. USA, Inc. v. Cipla USA, Inc. and Cipla Limited*, C.A. No. 23-1157-GBW.

16. Cipla USA, Inc. has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court of the District of Delaware. *See, e.g., Acerta Pharma B.V. et al. v. Cipla Limited et al.*, C.A. No. 24-587-GBW; *Hikma Pharms. USA, Inc. v. Cipla USA, Inc. and Cipla Limited*, C.A. No. 23-1157-GBW.

JURISDICTION AND VENUE

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

18. This Court has personal jurisdiction over Cipla Limited under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Cipla Limited is organized under the laws of India and the exercise of personal jurisdiction over Cipla Limited in any judicial district is consistent with the United States Constitution and laws.

19. This Court has personal jurisdiction over Cipla USA, Inc. because Cipla USA, Inc. is a corporation organized and existing under Delaware law.

20. This Court also has personal jurisdiction over Cipla Limited and Cipla 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 505(b)(2) NDA No. 218922 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. Upon information and belief, the effort to seek approval for the 505(b)(2) NDA No. 218922 and to manufacture, import, market, and/or sell the Cipla 505(b)(2) NDA Products

upon approval has been a cooperative and joint enterprise and venture between Cipla Limited and Cipla USA, Inc.

22. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, on information and belief, each such Defendant will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under 505(b)(2) NDA No. 218922 that will be purposefully directed at Delaware, including the marketing of the Cipla 505(b)(2) NDA Products in Delaware, prior to the expiration of the '537 patent.

23. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, the Cipla 505(b)(2) NDA Products will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

24. This Court also has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, upon information and belief, Defendants' affiliations with the State of Delaware, including Cipla USA, Inc.'s organization or incorporation in Delaware, Cipla Limited and Cipla USA, Inc.'s availing themselves of the legal protections of the State of Delaware, and Cipla Limited's ownership of and actions in concert with Cipla USA, Inc. are sufficiently continuous and systematic as to render Defendants at home in this forum.

25. Upon information and belief, Cipla Limited and Cipla USA, Inc. operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the Cipla 505(b)(2) NDA Products, throughout the United States including in this judicial district.

26. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc.

27. Venue is proper in this Court because Cipla USA, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Cipla Limited 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). Cipla Limited and Cipla USA, Inc. have also previously conceded that venue is proper in Delaware for at least the cases listed above and have conceded that venue is proper in Delaware for purposes of the counterclaims filed in those cases.

THE PATENT-IN-SUIT AND TASIGNA®

28. 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 A.

29. The ’537 patent claims, *inter alia*, 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.

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 ’537 patent. NPC markets TASIGNA® in the United States.

INFRINGEMENT OF THE PATENT-IN-SUIT

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

33. On information and belief, Cipla Limited, by itself or in concert with Cipla USA, Inc., submitted to the FDA 505(b)(2) NDA No. 218922 under the provisions of 21 U.S.C. § 355(b)(2) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products prior to the expiration of the ’537 patent.

34. By filing their 505(b)(2) NDA under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States prior to the expiration of the ’537 patent, Cipla Limited and Cipla USA, Inc. have committed an act of infringement under 35 U.S.C. § 271(e)(2).

35. On information and belief, when Cipla filed 505(b)(2) NDA No. 218922, Cipla was aware of the ’537 patent and that the filing of the 505(b)(2) NDA with the request for its approval prior to the expiration of the ’537 patent was an act of infringement of that patent.

36. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States will infringe one or more claims of the ’537 patent under 35 U.S.C. § 271(a) and/or § 271(b).

37. On information and belief, the Cipla 505(b)(2) NDA Products 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, according to the claimed subject matter of the ’537 patent. On information and belief, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe (under the doctrine of equivalents) one or more claims of the ’537 patent. On information and belief Cipla Limited and/or Cipla USA, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’537 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’537 patent.

38. On information and belief, Cipla Limited and/or Cipla 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, according to the claimed subject matter of the ’537 patent.

39. Novartis will be substantially and irreparably damaged by Cipla Limited’s and/or Cipla USA, Inc.’s infringement of the ’537 patent.

40. 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 resetting the effective approval date of 505(b)(2) NDA No. 218922 to a date that is no earlier than January 18, 2027, the expiration of the ’537 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 Cipla 505(b)(2) NDA Products and any act committed by Cipla Limited and Cipla

USA, Inc. with respect to the subject matter claimed in the '537 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

41. On information and belief, Cipla Limited and Cipla USA, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products.

42. There is a substantial and immediate controversy between Novartis, Cipla Limited, and Cipla USA, Inc. concerning the '537 patent. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States will infringe one or more claims of the '537 patent under 35 U.S.C. § 271(a) and/or § 271(b), and Cipla Limited and Cipla USA, Inc. will induce direct infringement of one or more claims of the '537 patent under 35 U.S.C. § 271(b).

PRAYER FOR RELIEF

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

43. Judgment that Defendants Cipla Limited and Cipla USA, Inc. have infringed one or more claims of the '537 patent by filing 505(b)(2) NDA No. 218922;

44. A preliminary and permanent injunction restraining and enjoining Defendants Cipla Limited and Cipla 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 Cipla 505(b)(2) NDA Products prior to the expiration of the '537 patent, inclusive of any extensions and additional periods of exclusivity;

45. An order resetting the approval date of 505(b)(2) NDA No. 218922 to a date that is not earlier than the expiration date of the '537 patent, inclusive of any extensions and additional periods of exclusivity;

46. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Cipla 505(b)(2) NDA Products in or into the United States will infringe one or more claims of the '537 patent under 35 U.S.C. § 271(a) and/or § 271(b), and Cipla Limited and Cipla USA, Inc. will induce direct infringement of one or more claims of the '537 patent under 35 U.S.C. § 271(b);

47. Damages or other monetary relief from Defendants Cipla Limited and Cipla USA, Inc. for the infringement and/or inducement of infringement of the '537 patent in the United States;

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

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

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

Dated: February 21, 2025

MCCARTER & ENGLISH, LLP

/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 Plaintiffs
Novartis Pharmaceuticals Corporation and Novartis AG

Nicholas N. Kallas
Christina Schwarz
VENABLE LLP
151 W. 42nd Street, 49th Floor
New York, NY 10036
(212) 218-2100
nkallas@venable.com
cschwarz@venable.com