IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
CIPLA LTD. and CIPLA USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer AG (Bayer AG and Bayer Pharma AG are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by Cipla Ltd. of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' 2.5 mg XARELTO® product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Defendants

5. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, with a place of business LBS Marg, Chandan Nagar, Vikhroli West, Mumbai, Maharashtra 400079, India.

6. On information and belief, Defendant Cipla USA Inc. ("Cipla USA") is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 10 Independence Blvd., Suite 300, Warren, New Jersey, 07059.

7. On information and belief, Cipla USA is a wholly-owned subsidiary of Cipla Ltd., and is controlled and/or dominated by Cipla Ltd.

8. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic versions of branded pharmaceutical drug products for the U.S. market. As a part of this business, on

information and belief, Cipla Ltd., acting in concert with Cipla USA, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Cipla Ltd, acting in concert with Cipla USA, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, and consistent with their practice with respect to other generic products, Cipla Ltd. and Cipla USA acted in concert to prepare and submit ANDA No. 218768 for Cipla's 2.5 mg rivaroxaban tablets ("Cipla's ANDA Product").

10. On information and belief, Cipla Ltd. and Cipla USA are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Cipla's ANDA Product at issue.

11. On information and belief, following any FDA approval of ANDA No. 218768, Cipla Ltd. and Cipla USA will market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within Delaware. These two entities—Cipla Ltd. and Cipla USA—are hereafter collectively referred to as "Cipla."

12. On information and belief, following any FDA approval of ANDA No. 218768, Cipla knows and intends that its ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over each of Cipla Ltd. and Cipla USA.

16. Cipla Ltd. is subject to personal jurisdiction in Delaware, because, among other things, Cipla Ltd., itself and through its wholly owned subsidiary Cipla USA, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Ltd., itself and through its wholly-owned subsidiary Cipla USA, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, on information and belief, Cipla Ltd. derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Cipla Ltd. and/or for which Cipla Ltd. is the named applicant on approved ANDAs. On information and belief, various products for which Cipla Ltd. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

17. In addition, Cipla Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Cipla USA and therefore the activities of Cipla USA in this jurisdiction are attributed to Cipla Ltd.

18. This Court has personal jurisdiction over Cipla USA because, among other things, Cipla USA is a corporation formed under the laws of the State of Delaware, has registered to do business in the State of Delaware, and has appointed a registered agent in Delaware (Incorp Services Inc., 919 North Market Street, Suite 950, Wilmington, Delaware 19801) to accept service of process. Cipla USA has thus consented to jurisdiction in Delaware. In addition, on information and belief, Cipla USA develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

19. In addition, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA because, among other things, on information and belief: (1) Cipla Ltd., acting in concert with Cipla USA, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in Delaware; and (2) Cipla Ltd. and Cipla USA, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Cipla's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 218768, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in the State of Delaware. On information and belief, if ANDA No. 218768 is approved, the generic Cipla product charged with infringing the '310 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in

Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

20. Further, this Court has personal jurisdiction over Cipla because Cipla Ltd. and Cipla USA regularly engage in patent litigation concerning FDA approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See e.g.*, *Novo Nordisk Inc. et al. v. Orbicular Pharmaceutical Technologies Pvt. Ltd.*, C.A. No. 22-cv-856-CFC, D.I. 164 (D. Del. July 7, 2023); *Actelion Pharmaceuticals US, Inc. et al. v. Alembic Pharmaceuticals Ltd. et al.*, C.A. No. 22-cv-1450-GBW, D.I. 35 (D. Del. June 15, 2023); *Acerta Pharma B.V. et al. v. Cipla Ltd.*, C.A. No. 22-cv-162-GBW, D.I. 24, (D. Del. April 18, 2022); *Cipla Ltd. v. Boehringer Ingelheim Pharmaceuticals Inc., et al.*, C.A. No. 22-cv-300-MN, D.I. 12 (D. Del. Mar. 14, 2022) (Cipla Ltd. only).

21. Alternatively, if Cipla Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Cipla Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Cipla Ltd. in Delaware is consistent with the United States Constitution and laws. See Fed. R. Civ. P. 4(k)(2).

VENUE

22. Venue is proper in this district for Cipla Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla Ltd. is a company organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district for Cipla USA pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla USA is incorporated in Delaware and Cipla USA is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

24. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor. The 2.5 mg tablet strength of XARELTO® is indicated for administration orally twice daily, in combination with aspirin (75-100 mg) once daily, (i) to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in adult patients with coronary artery disease (CAD); and (ii) to reduce the risk of major thrombotic vascular events (MI, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in adult patients with peripheral artery disease (PAD), including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD.

25. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

26. The ’310 patent, entitled “Reducing the Risk of Cardiovascular Events,” was duly and legally issued on November 10, 2020. The ’310 patent is attached as Exhibit A.

27. As set forth in greater detail in the ’310 patent, the claims of the ’310 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, independent claim 1 recites, “A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are clinically proven effective in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial

disease, wherein rivaroxaban is administered in an amount of 2.5 mg twice daily and aspirin is administered in an amount of 75-100 mg daily."

28. Bayer Pharma AG is the assignee of the '310 patent.

29. Bayer AG is an exclusive licensee under the '310 patent.

30. Janssen is an exclusive sublicensee under the '310 patent.

31. Pursuant to 21 U.S.C. § 355, the '310 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with the 2.5 mg strength of XARELTO®.

COUNT I: INFRINGEMENT OF THE '310 PATENT

32. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

33. By letter dated September 5, 2023 ("Cipla's Notice Letter"), Cipla notified, *inter alia*, Janssen that Cipla had submitted to the FDA ANDA No. 218768 for Cipla's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

34. In Cipla's Notice Letter, Cipla indicated that, in connection with its ANDA No. 218768, Cipla had filed, *inter alia*, a Paragraph IV Certification with respect to the '310 patent.

35. In Cipla's Notice Letter, Cipla stated that Cipla's ANDA Product contains rivaroxaban.

36. On information and belief, the proposed labeling for Cipla's ANDA Product directs a method of reducing the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI), and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD). On information and belief, the proposed labeling for Cipla's ANDA Product further directs the administration of Cipla's ANDA Product and aspirin in amounts

that are clinically proven effective in reducing the risk of MI, stroke or CV death in a human patient with CAD and/or PAD, wherein Cipla's ANDA Product will be administered twice daily and aspirin is administered in an amount of 75-100 mg daily.

37. The purpose of ANDA No. 218768 was, *inter alia*, to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Cipla's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

38. Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218768, *i.e.*, prior to the expiration of the '310 patent.

39. On information and belief, the manufacture, use (including in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product will infringe at least claim 1 of the '310 patent.

40. Cipla has knowledge of the claims of the '310 patent. Notwithstanding this knowledge, Cipla has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 218768. On information and belief, by such activities, Cipla specifically intends to infringe the '310 patent.

41. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '310 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

42. On information and belief, Cipla knows that Cipla's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Cipla's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. Cipla's ANDA Product is a material part of the claimed invention. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '310 patent immediately and imminently upon approval of ANDA No. 218768.

43. Cipla's submission of ANDA No. 218768 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Cipla's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

44. On information and belief, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

45. Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling prior to the expiration of the '310 patent.

46. The foregoing actions by Cipla constitute and/or will constitute infringement of the '310 patent, active inducement of infringement of the '310 patent, and/or contribution to the infringement by others of the '310 patent.

47. Unless Cipla is enjoined from infringing the '310 patent, actively inducing infringement of the '310 patent, and contributing to the infringement by others of the '310 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

48. This action is being commenced before the expiration of forty-five days from the date Bayer and Janssen received Cipla's Notice Letter.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '310 PATENT

49. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

50. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Cipla on the other regarding Cipla's liability for infringement and active inducement of infringement of the '310 patent.

51. An actual case or controversy exists between Plaintiffs and Cipla with respect to Cipla's liability for infringement of the '310 patent.

52. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Cipla's ANDA Product will infringe and induce the infringement of the '310 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Cipla has infringed the '310 patent;

(b) A judgment ordering that the effective date of any FDA approval for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's ANDA Product, or any product or compound the use of which infringes the '310 patent, be no earlier than the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Cipla, and all persons acting in concert with Cipla, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the use of which infringes the

'310 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '310 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Cipla's ANDA Product prior to the expiration of the '310 patent will infringe and induce the infringement of the '310 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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