IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	**JURY TRIAL DEMANDED**
APOTEX INC. and APOTEX CORP.,	)	
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 Apotex Inc. and Apotex Corp. (collectively, "Apotex") 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"). This action further relates to Apotex's unauthorized importation into the United States, and use, sale, and/or offer for sale of products in the United States, that infringe at least one claim of the '310 patent. The '310 patent is attached as Exhibit A.

2. On information and belief, Apotex Inc. and Apotex Corp., acting in concert, prepared and submitted ANDA No. 217810 for Apotex's 2.5 mg rivaroxaban tablets ("Apotex's ANDA Product"), 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 the '310 patent.

3. On information and belief, the FDA granted approval to the product that is the subject of ANDA No. 217810 on May 2, 2025. On information and belief, following that approval, Apotex began to import into the United States, and/or use, sell, and/or offer to sell in the United States, Apotex's ANDA Product prior to the expiration of the '310 patent. *See, e.g.*, Ex. B, Apotex, "Rivaroxaban Tablets" (last visited May 28, 2025), https://tinyurl.com/yve853h5.

THE PARTIES

Plaintiffs

4. 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.

5. 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.

6. 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

7. On information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Apotex Corp.

8. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

10. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Apotex Inc., acting in concert with Apotex Corp., files ANDAs with FDA seeking approval to engage in, and engages 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.

11. On information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 217810 for Apotex's ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Apotex Inc.

12. On information and belief, Apotex Inc. and Apotex Corp. 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 Apotex's ANDA Product at issue.

13. On information and belief, Apotex Inc. and Apotex Corp. have received FDA approval for ANDA No. 217810 and have acted in concert to import, market, distribute, offer for sale, and/or sell Apotex's ANDA Product throughout the United States, including in Delaware. *See, e.g.*, Ex. B, Apotex, "Rivaroxaban Tablets" (last visited May 28, 2025), https://tinyurl.com/yve853h5.

14. On information and belief, Apotex knows and intends that Apotex's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

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

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Declaratory judgment relief is authorized under 28 U.S.C. §§ 2201 and 2202.

17. This Court has personal jurisdiction over each of Apotex Inc. and Apotex Corp.

18. This Court has personal jurisdiction over Apotex Inc. because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., has purposely

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, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., 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. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

19. This Court has personal jurisdiction over Apotex Corp. because, among other things, Apotex Corp. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Apotex Corp. is a corporation formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed registered agents in Delaware (United Corporate Services, Inc., 800 North State Street, Suite 304, Dover, DE) to accept service of process. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Apotex Corp. 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.

20. In addition, on information and belief, Apotex Corp., acting as an agent of Apotex Inc., markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the

United States generic pharmaceutical products that are manufactured by Apotex Inc. or for which Apotex is the named applicant on approved ANDAs.

21. In addition, this Court has personal jurisdiction over Apotex Inc. and Apotex Corp. because, among other things, on information and belief: (1) Apotex Inc. and Apotex Corp. acted in concert to file ANDA No. 217810 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product in the United States, including in Delaware; and (2) Apotex's ANDA Product has been approved by the FDA, and now Apotex Inc. and Apotex Corp., acting in concert and/or as agents of one another, have imported, marketed, distributed, offered for sale, and/or sold Apotex's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use and/or consumption of Apotex's ANDA Product in the State of Delaware.

22. On information and belief, Apotex's ANDA Product, which is charged with infringing the '310 patent, has been prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

23. Apotex Inc. and Apotex Corp. regularly engage in patent litigation concerning FDA approved branded drug products in this district, have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and/or they have filed counterclaims in such cases. *See, e.g.*, *Bayer Intellectual Property GmbH et al. v. Apotex Inc. et al.*, Case No. 23-327-RGA, D.I. 11 (D. Del. June 30, 2023); *Bayer Pharma AG et al. v. Apotex Inc. et al.*, Case No. 22-1596-RGA, D.I. 11 (D. Del. Mar. 7, 2023); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Case No. 21-1429-WCB, D.I. 14 (D. Del. Mar. 1, 2022); *Bial-Portela*

& CA S.A. v. Apotex Inc. et al., Case No. 21-187-CFC, D.I. 6 (D. Del. Mar. 3, 2021); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Case No. 20-749-RGA, D.I. 7 (D. Del. June 26, 2020).

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

VENUE

25. Venue is proper in this district for Apotex Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Inc. is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

26. Venue is proper in this district for Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

27. 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 death, myocardial infarction, and stroke) in adult patients with coronary artery disease (CAD); and (ii) to reduce the risk of major thrombotic vascular events (myocardial infarction, 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.

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

29. 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.

30. 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."

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

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

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

34. 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

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

36. By letter dated October 31, 2022 ("Apotex's Notice Letter"), Apotex notified, *inter alia*, Plaintiffs that Apotex Inc. and Apotex Corp., acting in concert, had submitted to the FDA ANDA No. 217810 for Apotex's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

37. In Apotex's Notice Letter, Apotex indicated that, in connection with its ANDA No. 217810, Apotex had filed a Paragraph IV Certification with respect to the '310 patent.

38. In Apotex's Notice Letter, Apotex stated that Apotex's ANDA Product contains rivaroxaban.

39. After receiving Apotex's Notice Letter, Bayer and Janssen sued Apotex Inc. and Apotex Corp. for infringement of the '310 patent on December 14, 2022, in this district. In that pending '310 patent action, Apotex stipulated that the use of Apotex's ANDA Product in accordance with its labeling infringes each of claims 1–4 of the '310 patent. *See Bayer Pharma AG et al. v. Apotex Inc. et al.*, Case No. 22-1596-RGA, D.I. 19 (D. Del. June 20, 2023).

40. The pending '310 patent action against Apotex was consolidated before this Court for all purposes, including trial, in *Bayer Pharma AG et al. v. Lupin Limited et al.*, Case No. 21-314-RGA, D.I. 147 ¶ 1 (D. Del. June 20, 2023) ("Consolidated Infringement Action").

41. The Consolidated Infringement Action is currently stayed pending final resolution of any appeal in *Mylan Pharmaceuticals Inc. et al. v. Bayer Pharma AG*, IPR2022-00517 (PTAB), *see Bayer Pharma Aktiengesellschaft v. Mylan Pharms. Inc.*, No. 2023-2434 (Fed. Cir.).

42. On information and belief, Apotex's ANDA Product received final approval from the FDA on May 2, 2025. *See* Ex. C, U.S. Food & Drug Admin., Drugs@FDA: FDA-Approved Drugs, https://tinyurl.com/279rvbjp (last visited May 28, 2025).

43. On information and belief, since the approval of Apotex's ANDA Product, Apotex has been importing that product into the United States, using that product in the United States, offering to sell that product in the United States, and selling that product in the United States. Apotex's ANDA Product is prominently listed as a product for sale by Apotex on Apotex's website. *See* Ex. B, Apotex, "Rivaroxaban Tablets" (last visited May 28, 2025), https://tinyurl.com/yve853h5.

44. On information and belief, the approved labeling for Apotex's ANDA Product recommends, instructs, and/or encourages health care professionals to utilize the product in accordance with said approved labeling. *See* Ex. D, https://tinyurl.com/ypxtf5na (last visited May 28, 2025). Section 2 of the approved labeling for Apotex'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). *Id.* On information and belief, Section 2 of the approved labeling for Apotex's ANDA Product further directs the administration of Apotex'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 Apotex's ANDA Product is administered twice daily and aspirin is administered in an amount of 75-100 mg daily. *Id.*

45. On information and belief, Apotex knows that Apotex's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Apotex's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. Apotex's ANDA Product is a material part of the claimed invention. On information and belief, since the FDA approved ANDA No. 217810, Apotex has contributed, and plans and intends to continue to contribute, to infringement of the '310 patent.

46. On information and belief, the use, sale, offer for sale, and/or importation of Apotex's ANDA Product in conjunction with its labeling infringes one or more claims, including at least claim 1, of the '310 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, and/or Apotex induces and/or contributes to the infringement of one or more claims, including at least claim 1, of the '310 patent under 35 U.S.C. § 271(b) and/or (c).

47. In addition, Apotex's submission of ANDA No. 217810 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

48. Apotex has actively induced, and will continue to actively induce, infringement of at least claim 1 of the '310 patent by way of selling Apotex's ANDA Product and/or by way of the substance of its approved labeling and/or by way of its marketing of Apotex's ANDA Product.

49. Apotex's infringement, inducement of infringement, and/or contribution to infringement is willful. On information and belief, Apotex is aware of the '310 patent at least because Apotex is involved in related litigation concerning Apotex's infringement of the '310 patent. *See Bayer Pharma AG et al. v. Apotex Inc. et al.*, Case No. 22-1596-RGA, D.I. 1 (D. Del. Dec. 14, 2022); *Bayer Pharma AG et al. v. Lupin Limited et al.*, Case No. 21-314-RGA, D.I. 147 (D. Del. June 20, 2023).

50. Unless Apotex 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.

51. Plaintiffs have suffered, and will continue to suffer, monetary damages, including but not limited to lost profits, as a result of Apotex's infringement of the '310 patent.

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

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

53. 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 Apotex on the other regarding Apotex's liability for infringement, active inducement of, and/or contribution to the infringement of the '310 patent.

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

55. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Product infringes, induces, and/or contributes to the infringement of the '310 patent under 35 U.S.C. § 271(a), (b), and/or (c).

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Apotex has infringed, induced infringement of, and/or contributed to the infringement of, the '310 patent;

(b) A judgment pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex'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 permanent injunction pursuant to, *inter alia*, 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex'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 Apotex's ANDA Product prior to the expiration of the '310 patent infringes and/or actively induces infringement of and/or contributes to the infringement by others of the '310 patent;

(e) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs for Apotex's past infringement, inducement of infringement, and/or contributory infringement, and any continuing or future infringement, inducement of infringement, and/or contributory infringement, of the '310 patent up until the date such judgment is entered, including pre- and post-judgment interest, costs, and disbursements as justified pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284;

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

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

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

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