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**
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,	)	
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 Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") 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 Dr. Reddy'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, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., acting in concert, prepared and submitted ANDA No. 208534 for Dr. Reddy's 2.5 mg rivaroxaban tablets ("Dr. Reddy'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. 208534 on May 14, 2025. On information and belief, following that approval, Dr. Reddy's began to import into the United States, and/or use, sell, and/or offer to sell in the United States, Dr. Reddy's ANDA Product prior to the expiration of the '310 patent. *See, e.g.*, Ex. B, Dr. Reddy's, "Medication Guide: Rivaroxaban Tablets" (last visited August 14, 2025), https://tinyurl.com/45v7vf8j.

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 Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

8. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") is a corporation organized under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

9. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd., and is controlled and/or dominated by Dr. Reddy's Ltd.

10. On information and belief, Dr. Reddy's Ltd. 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, Dr. Reddy's Ltd. and Dr. Reddy's Inc., acting in concert, file ANDAs with the FDA seeking approval to engage in, and 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.

11. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to prepare and submit ANDA No. 208534 for Dr. Reddy's ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Dr. Reddy's Ltd. Dr. Reddy's has admitted in pending patent litigation concerning infringement of the '310 patent that Dr. Reddy's prepared and filed Dr. Reddy's ANDA No. 208534 for the matters described therein. *See Bayer Pharma AG et al. v. Dr. Reddy's Laby's, Inc. et al.*, C.A. No. 21-cv-732-RGA (D. Del. Sept. 22, 2021), D.I. 16, ¶ 9.

12. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. 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 Dr. Reddy's ANDA Product at issue.

13. On information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. have received FDA approval for ANDA No. 208534 and have acted in concert to import, market, distribute, offer for sale, and/or sell Dr. Reddy's ANDA Product throughout the United States, including in Delaware. *See, e.g.*, Ex. B, Dr. Reddy's, "Medication Guide: Rivaroxaban Tablets" (last visited August 14, 2025), https://tinyurl.com/45v7vf8j.

14. On information and belief, Dr. Reddy's knows and intends that Dr. Reddy'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 Dr. Reddy's Ltd. and Dr. Reddy's Inc.

18. This Court has personal jurisdiction over Dr. Reddy's Ltd. and Dr. Reddy's Inc. because, among other things, on information and belief: (1) Dr. Reddy's Ltd. and Dr. Reddy's

Inc. acted in concert to file ANDA No. 208534 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy's ANDA Product in the United States, including in Delaware; and (2) Dr. Reddy's ANDA Product has been approved by the FDA, and now Dr. Reddy's Ltd. and Dr. Reddy's Inc., acting in concert and/or as agents of one another, have imported, marketed, distributed, offered for sale, and/or sold Dr. Reddy's ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use and/or consumption of Dr. Reddy's ANDA Product in the State of Delaware.

19. In addition, on information and belief, Dr. Reddy'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.

20. In addition, Dr. Reddy's Ltd. and Dr. Reddy's Inc. regularly engage in patent litigation concerning FDA approved branded drug products in this district, they 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 Pharma AG et al. v. Dr. Reddy's Laby's Inc. et al.*, C.A. No. 23-cv-410-RGA (D. Del. Aug. 15, 2023), D.I. 10, ¶ 15; *Anacor Pharm., Inc. et al. v. Dr. Reddy's Laby's Ltd.*, C.A. No. 21-cv-1349-CFC (D. Del. Nov. 19, 2021), D.I. 11, ¶ 30; *Bayer Pharma AG et al. v. Dr. Reddy's Laby's Inc. et al.*, C.A. No. 21-cv-732-RGA (D. Del. Sept. 22, 2021), D.I. 16, ¶ 15; *Intercept Pharms., Inc. et al. v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 21-cv-34-MN (D. Del. Feb. 5, 2021), D.I. 10, ¶ 15.

21. Alternatively, if Dr. Reddy's Ltd.'s connections with Delaware, including its connections with Dr. Reddy's Inc., are found to be insufficient to confer personal jurisdiction, then on information and belief, Dr. Reddy's Ltd. is not subject to jurisdiction in any state's courts

of general jurisdiction, and exercising jurisdiction over Dr. Reddy's 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 Dr. Reddy's Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Dr. Reddy's Ltd. is a private limited 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 Dr. Reddy's Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Dr. Reddy's Inc. is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and, on information and belief, is subject to venue in this judicial district and/or will consent to venue in this district for the purpose of this case. *See Bayer Pharma AG et al. v. Dr. Reddy's Laby's Inc. et al.*, C.A. No. 23-cv-410-RGA (D. Del. Aug. 15, 2023), D.I. 10, ¶ 18; *Anacor Pharms., Inc. et al. v. Dr. Reddy's Lab'ys Ltd.*, C.A. No. 21-cv-1349-CFC (D. Del. Nov. 19, 2021), D.I. 11, ¶ 39; *Bayer Pharma AG et al. v. Dr. Reddy's Lab'ys Inc. et al.*, C.A. No. 21-cv-732-RGA (D. Del. Sept. 22, 2021), D.I. 16, ¶ 18; *Intercept Pharms., Inc. et al. v. Dr. Reddy's Laby's, Inc. et al.*, C.A. No. 21-cv-35-MN (D. Del. Feb. 5, 2021), D.I. 10, ¶ 24.

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 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.

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 April 14, 2021 ("Dr. Reddy's First Notice Letter"), Dr. Reddy's notified, *inter alia*, Plaintiffs that Dr. Reddy's Inc., on behalf of Dr. Reddy's Ltd., had submitted to the FDA ANDA No. 208534 for Dr. Reddy's ANDA Product. This product is a generic version of the 2.5 mg strength of XARELTO®.

34. In Dr. Reddy's First Notice Letter, Dr. Reddy's indicated that, in connection with its ANDA No. 208534, Dr. Reddy's had filed, *inter alia*, a Paragraph IV Certification with respect to the '310 patent.

35. In Dr. Reddy's First Notice Letter, Dr. Reddy's stated that Dr. Reddy's ANDA Product contains rivaroxaban.

36. After receiving Dr. Reddy's First Notice Letter, Bayer and Janssen sued Dr. Reddy's Ltd. and Dr. Reddy's Inc. for infringement of the '310 patent on May 24, 2021, in this district.

37. The pending '310 patent action against Dr. Reddy's 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. Del. Oct. 27, 2021), D.I. 22, ¶ 1 ("Consolidated Infringement Action").

38. In the Consolidated Infringement Action, Dr. Reddy's stipulated that the use of Dr. Reddy's ANDA Product in accordance with its labeling infringes each of claims 1–4 of the '310 patent. *See* Consolidated Infringement Action, D.I. 133.

39. 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.).

40. By letter dated March 15, 2023 ("Dr. Reddy's Second Notice Letter"), Dr. Reddy's notified Bayer and Janssen that it was "filing a patent certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the C.F.R. in support of its previously filed Abbreviated New Drug Application ('ANDA') No. 208534 with respect to rivaroxaban tablets, 2.5 mg." Dr. Reddy's Second Notice Letter indicated that Dr. Reddy's was seeking approval from the FDA to engage in the commercial manufacture, use or sale of Dr. Reddy's ANDA Product prior to the expiration of the '310 patent. Dr. Reddy's Second Notice Letter also indicated that it was "provid[ing] an updated paragraph IV certification to FDA to address the newly listed codes" that were added to the '310 patent in connection with the 2.5 mg strength of XARELTO®.

41. After receiving Dr. Reddy's Second Notice Letter, Bayer and Janssen sued Dr. Reddy's Ltd. and Dr. Reddy's Inc. for infringement of the '310 patent on April 13, 2023, in this district. That action has been coordinated with the Consolidated Infringement Action and is also stayed pending resolution of the appeal in *Mylan Pharmaceuticals Inc. et al. v. Bayer Pharma AG*, IPR2022-00517 (PTAB); *see Bayer Pharma AG et al. v. Dr. Reddy's Laby's, Inc.*, C.A. No. 23-cv-410-RGA (Sept. 8, 2023), D.I. 14.

42. On information and belief, Dr. Reddy's ANDA Product received final approval from the FDA on May 14, 2025. *See* Ex. C, U.S. Food & Drug Admin., Drugs@FDA: FDA-Approved Drugs (last visited August 12, 2025), https://tinyurl.com/25bthmba.

43. On information and belief, since the approval of Dr. Reddy's ANDA Product, Dr. Reddy's 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. *See* Ex. B, Dr. Reddy's, "Medication Guide: Rivaroxaban Tablets" (last visited August 14, 2025), https://tinyurl.com/45v7vf8j.

44. On information and belief, the approved labeling for Dr. Reddy's ANDA Product recommends, instructs, and/or encourages health care professionals to utilize the product in accordance with said approved labeling. *See* Ex. B, Dr. Reddy's, "Medication Guide: Rivaroxaban Tablets" (last visited August 14, 2025), https://tinyurl.com/45v7vf8j. The Medication Guide for Dr. Reddy'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, the Medication Guide for Dr. Reddy's ANDA Product further directs the administration of Dr. Reddy'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 Dr. Reddy's ANDA Product is administered twice daily and aspirin is administered once daily in an amount of 75-100 mg daily. *Id.*

45. On information and belief, Dr. Reddy's knows that Dr. Reddy's ANDA Product with its proposed labeling is especially made or adapted for use in infringing the '310 patent, and that Dr. Reddy's ANDA Product with its proposed labeling is not suitable for substantial noninfringing use. Dr. Reddy's ANDA Product is a material part of the claimed invention. On information and belief, since the FDA approved ANDA No. 208534, Dr. Reddy's 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 Dr. Reddy'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 Dr. Reddy's 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, Dr. Reddy's submission of ANDA No. 208534 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Dr. Reddy's ANDA Product was an act of infringement of the '310 patent under 35 U.S.C. § 271(e)(2).

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

49. Dr. Reddy's infringement, inducement of infringement, and/or contribution to infringement is willful. On information and belief, Dr. Reddy's is aware of the '310 patent at least because Dr. Reddy's is involved in related litigation concerning Dr. Reddy's infringement of the '310 patent. *See Bayer Pharma AG et al. v. Dr. Reddy's Lab'ys Inc. et al.*, C.A. No. 23-cv-410-RGA (D. Del.); *Bayer Pharma AG et al. v. Dr. Reddy's Lab'ys Inc. et al.*, C.A. No. 21-cv-732-RGA (D. Del.).

50. Unless Dr. Reddy's 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 Dr. Reddy'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 Dr. Reddy's on the other regarding Dr. Reddy'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 Dr. Reddy's with respect to Dr. Reddy'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 Dr. Reddy'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 Dr. Reddy's 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 Dr. Reddy's to make, use, offer for sale, sell, market, distribute, or import Dr. Reddy'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 Dr. Reddy's, and all persons acting in concert with Dr. Reddy's, from making,

using, selling, offering for sale, marketing, distributing, or importing Dr. Reddy'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 Dr. Reddy'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 Dr. Reddy'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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August 19, 2025