IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,

Defendants.

Civil Action No.: _____

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer AG (Bayer AG and BIP 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, Ltd. and Dr. Reddy's Laboratories, Inc. 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 generic versions of Plaintiffs' XARELTO® products prior to the expiration of, *inter alia*, U.S. Patent No. 9,539,218.

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, 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.

Dr. Reddy's Laboratories

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, Telenangana 50034, India.

6. Upon 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 and has its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

7. Upon information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

8. Upon 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, upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. act in concert to file 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. Upon information and belief, as part of these ANDAs, Dr. Reddy's Inc., acting on behalf of Dr. Reddy's Ltd., 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. Upon 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 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Dr. Reddy's ANDA Products").

10. Upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. are agents of one another, 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 New Jersey, and including with respect to Dr. Reddy's ANDA Products at issue.

11. Upon information and belief, following any FDA approval of ANDA No. 208534, Dr. Reddy's Ltd. and Dr. Reddy's Inc. will act in concert to market, distribute, offer for sale, and sell Dr. Reddy's ANDA Products throughout the United States and within New Jersey. These entities—Dr. Reddy's Ltd. and Dr. Reddy's Inc.—are hereafter collectively referred to as "Dr. Reddy's."

12. Upon information and belief, following any FDA approval of ANDA No. 208534, Dr. Reddy's knows and intends that Dr. Reddy's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States, including in New Jersey.

JURISDICTION

13. Plaintiffs incorporate each of the preceding paragraphs as if each 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 Dr. Reddy's Ltd. and Dr. Reddy's Inc. because, among other things, upon information and belief: (1) Dr. Reddy's Ltd. and Dr. Reddy's Inc. acted in concert to file an ANDA 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 Products in the United States, including in New Jersey; and (2) Dr. Reddy's Ltd. and Dr. Reddy's Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Dr. Reddy's ANDA Products in the United States, including in New Jersey, upon approval of ANDA No. 208534, and will derive substantial revenue from the use or consumption of Dr. Reddy's ANDA Products in the State of New Jersey. Upon information and belief, if ANDA No. 208534 is approved, the generic Dr. Reddy's products charged with infringing the '218 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

16. If Dr. Reddy's Ltd. connections with New Jersey are found to be insufficient to confer personal jurisdiction, then, upon 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 New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2). Relatedly, Dr. Reddy's Ltd. in the Dr. Reddy's Notice Letter (defined below) provided an agent for service "[p]ursuant to 21 C.F.R. 314.95(c)(9)," which applies "[i]f the applicant does not reside or have a place of business in the United States."

17. This court also has personal jurisdiction over Dr. Reddy's Inc. because, upon information and belief, Dr. Reddy's Inc. is incorporated in New Jersey, has its principal place of business in New Jersey, and has a registered agent for service of process in this judicial district.

18. Upon information and belief, Dr. Reddy's Ltd. and Dr. Reddy's Inc. have consented to jurisdiction in New Jersey in a prior case arising out of the filing of an ANDA.

VENUE

19. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

20. 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.

21. 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 a corporation organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

22. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery; and (vi) in combination with aspirin, to reduce 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). XARELTO® is available as tablets in 2.5 mg, 10 mg, 15 mg, and 20 mg dosage strengths.

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

The '218 Patent

24. U.S. Patent No. 9,539,218 ("the '218 patent"), entitled "Prevention and Treatment of Thromboembolic Disorders," was duly and legally issued on January 10, 2017. The '218 patent is attached as Exhibit A.

25. As set forth in greater detail in the '218 patent, the claims of the '218 patent, incorporated by reference herein, cover certain methods involving rivaroxaban. For example, claim 1 recites, "A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic

disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke."

26. BIP is the assignee of the '218 patent.

27. Bayer AG is an exclusive licensee under the '218 patent.

28. Janssen is an exclusive sublicensee under the '218 patent.

29. Pursuant to 21 U.S.C. § 355, the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with XARELTO® tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

Infringement by Dr. Reddy's

30. By letter dated June 30, 2020, Dr. Reddy's notified BIP and Janssen, among others, that Dr. Reddy's had submitted to the FDA ANDA No. 208534 for Dr. Reddy's ANDA Products. These products are generic versions of XARELTO®.

31. In the Dr. Reddy's Notice Letter, Dr. Reddy's stated that Dr. Reddy's ANDA Products contain rivaroxaban.

32. Upon information and belief, Dr. Reddy's Ltd. is the holder of DMF 28121 for rivaroxaban.

33. In the Dr. Reddy's Notice Letter, Dr. Reddy's stated that the dosage form of Dr. Reddy's ANDA Products is tablets. Upon information and belief, the dosage form of Dr. Reddy's ANDA Products satisfies the "rapid-release tablet" requirement of claim 1 of the '218 patent.

34. In the Dr. Reddy's Notice Letter, Dr. Reddy's did not contest infringement of any claim of the '218 patent.

35. Upon information and belief, the proposed labeling for Dr. Reddy's ANDA Products directs the use of Dr. Reddy's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT); (iii) for the treatment of pulmonary embolism (PE); (iv) for the reduction in the risk of recurrence DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months; and (v) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. Upon information and belief, the proposed labeling for Dr. Reddy's ANDA Products further directs the use of Dr. Reddy's ANDA Products in a manner that satisfies the "no more than once daily for at least five consecutive days" requirement of claim 1 of the '218 patent.

36. Upon information and belief, the manufacture, use (including in accordance with and as directed by Dr. Reddy's proposed labeling for Dr. Reddy's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Products will infringe at least claim 1 of the '218 patent.

37. In the Dr. Reddy's Notice Letter, Dr. Reddy's indicated that, in connection with its ANDA No. 208534, Dr. Reddy's had filed a Paragraph IV Certification with respect to the '218 patent.

38. The purpose of ANDA No. 208534 was to obtain approval under the Food Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or sale of Dr. Reddy's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

39. Dr. Reddy's intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208534, *i.e.*, prior to the expiration of the '218 patent.

40. Dr. Reddy's has knowledge of the claims of the '218 patent. Notwithstanding this knowledge, Dr. Reddy's has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208534. Upon information and belief, by such activities, Dr. Reddy's specifically intends infringement of the '218 patent.

41. Upon information and belief, Dr. Reddy's plans and intends to, and will, actively induce infringement of the '218 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

42. Upon information and belief, Dr. Reddy's knows that Dr. Reddy's ANDA Products are especially made or adapted for use in infringing the '218 patent, and that Dr. Reddy's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Dr. Reddy's plans and intends to, and will, contribute to infringement of the'218 patent immediately and imminently upon approval of ANDA No. 208534.

43. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

44. An actual case or controversy exists between Plaintiffs and Dr. Reddy's with respect to infringement of the '218 patent.

45. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Dr. Reddy's Notice Letter.

COUNT I
(Infringement of the '218 Patent)

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

47. 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 Products was an act of infringement of the '218 patent under 35 U.S.C. § 271(e)(2).

48. Upon information and belief, Dr. Reddy's has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Dr. Reddy's ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

49. Dr. Reddy's intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dr. Reddy's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208534, *i.e.*, prior to the expiration of the '218 patent.

50. The foregoing actions by Dr. Reddy's constitute and/or will constitute infringement of the '218 patent, active inducement of infringement of the '218 patent, and/or contribution to the infringement by others of the '218 patent.

51. Unless Dr. Reddy's is enjoined from infringing the '218 patent, actively inducing infringement of the '218 patent, and contributing to the infringement by others of the '218 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Dr. Reddy's has infringed the '218 patent;

(b) A judgment 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 Products, or any product or compound the use of which infringes the '218 patent, be no earlier than the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction 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 Products, or any product or compound the use of which infringes the '218 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '218 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

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

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

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

Dated: August 12, 2020

/s/ Keith J. Miller

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned, attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon the information available to me, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, except for *Bayer Intellectual Property GmbH, et al. v. Taro Pharmaceuticals, et al.*, 1:17-cv-00462 (D. Del.) and *Bayer Intellectual Property GmbH, et al. v. InvaGen Pharmaceuticals Inc.*, 1:17-cv-00812 (D. Del.); and *Bayer Intellectual Property GmbH, et al. v. Unichem Inc. et al.*, 2:20-cv-05439 (D. N.J.).

Dated: August 12, 2020

By: */s/ Keith J. Miller*
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