IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG and JANSSEN PHARMACEUTICALS, INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC., | ) | |
| Defendants. | ) | |

**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 Macleods Pharmaceuticals Limited 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 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.

### Defendants

5. On information and belief, Defendant Macleods Pharmaceuticals Limited ("MPL") is a corporation organized and existing under the laws of India, with a place of business at Atlanta Arcade, Marol Church Road, Andheri (East) Mumbai, 400059, India.

6. On information and belief, Defendant Macleods Pharma USA, Inc. ("Macleods USA") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

7. On information and belief, Macleods USA is a wholly-owned subsidiary of MPL, and is controlled and dominated by MPL.

8. On information and belief, MPL 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, MPL, acting in concert with Macleods 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, MPL, acting in concert with Macleods 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, MPL and Macleods USA acted in concert to prepare and submit ANDA No. 213114 for MPL's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Macleods' ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of MPL.

10. On information and belief, MPL and Macleods 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 Macleods' ANDA Products at issue.

11. On information and belief, following any FDA approval of ANDA No. 213114, MPL and Macleods USA will act in concert to market, distribute, offer for sale, and sell Macleods' ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Macleods."

12. On information and belief, following any FDA approval of ANDA No. 213114, Macleods knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

## JURISDICTION AND VENUE

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 Macleods USA because, among other things, Macleods 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. Macleods USA has thus consented to jurisdiction in Delaware.

16. In addition, this Court has personal jurisdiction over MPL and Macleods USA because, among other things, on information and belief: (1) MPL, acting in concert with Macleods 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 Macleods' ANDA Products in the United States, including in Delaware; and (2) MPL and Macleods USA, acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Macleods' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 213114, and will derive substantial revenue from the use or consumption of Macleods' ANDA Products in the State of Delaware. On information and belief, if ANDA No.

213114 is approved, the generic Macleods products charged with infringing the '218 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.

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

18. MPL and Macleods USA have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and have filed counterclaims in such cases.

19. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) because Macleods USA is incorporated in Delaware, and pursuant to 28 U.S.C. § 1391(c)(3) because MPL is a defendant not resident in the United States.

## FACTUAL BACKGROUND

20. 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.

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

22. 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.

23. 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."

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

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

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

27. 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®.

**Infringement by Macleods**

28. By letter dated March 28, 2019 (the “Macleods Notice Letter”), Macleods notified BIP and Janssen, among others, that Macleods had submitted to the FDA ANDA No. 213114 for Macleods’ ANDA Products. These products are generic versions of XARELTO®.

29. In the Macleods Notice Letter, Macleods stated that Macleods’ ANDA Products contain rivaroxaban.

30. In the Macleods Notice Letter, Macleods stated that the dosage form of Macleod’s ANDA Products is tablets. On information and belief, the dosage form of Macleods’ ANDA Products satisfies the “rapid-release tablet” requirement of claim 1 of the ’218 patent.

31. On information and belief, the proposed labeling for Macleods’ ANDA Products directs the use of Macleods’ 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. On information and belief, the proposed labeling for Macleods’ ANDA Products further directs the use of Macleods’ 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.

32. In the Notice Letter, Macleods did not substantively contest infringement of any claim of the ’218 patent.

33. On information and belief, the manufacture, use (including in accordance with and as directed by Macleods’ proposed labeling for Macleods’ ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Macleods’ ANDA Products will infringe at least claim 1 of the ’218 patent.

34. In the Macleods Notice Letter, Macleods indicated that, in connection with its ANDA No. 213114, Macleods had filed Paragraph IV Certifications with respect to the ’218 patent.

35. The purpose of ANDA No. 213114 was 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 Macleods’ ANDA Products with their proposed labeling prior to the expiration of the ’218 patent.

36. Macleods intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods’ ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213114, *i.e.*, prior to the expiration of the ’218 patent.

37. Macleods has knowledge of the claims of the ’218 patent. Notwithstanding this knowledge, Macleods has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods’ ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213114. On information and belief, by such activities, Macleods specifically intends to infringe the ’218 patent.

38. On information and belief, Macleods 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.

39. On information and belief, Macleods knows that Macleods’ ANDA Products are especially made or adapted for use in infringing the ’218 patent, and that Macleods’ ANDA Products are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the ’218 patent immediately and imminently upon approval of ANDA No. 213114.

40. The foregoing actions by Macleods 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.

41. An actual case or controversy exists between Plaintiffs and Macleods with respect to infringement of the ’218 patent.

42. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Macleods Notice Letter.

**CLAIM FOR RELIEF**
**(Infringement of the ’218 Patent)**

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

44. Macleods’ submission of ANDA No. 213114 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Macleods’ ANDA Products was an act of infringement of the ’218 patent under 35 U.S.C. § 271(e)(2).

45. On information and belief, Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import

Macleods' ANDA Products with their proposed labeling prior to the expiration of the '218 patent.

46. Macleods intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 213114, *i.e.*, prior to the expiration of the '218 patent.

47. The foregoing actions by Macleods 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.

48. Unless Macleods 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 Macleods has infringed the '218 patent;

(b) A judgment ordering that the effective date of any FDA approval for Macleods to make, use, offer for sale, sell, market, distribute, or import Macleods' 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 Macleods, and all persons acting in concert with Macleods, from making, using, selling, offering for sale, marketing, distributing, or importing Macleods' 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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