IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer" or "Plaintiffs"), for their Complaint against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc., 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 filing by Macleods Pharmaceuticals Ltd. of Abbreviated New Drug Application ("ANDA") No. 205988 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of STAXYN® prior to the expiration of U.S. Patent No. 8,613,950 ("the '950 patent").

THE PARTIES

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 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.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981.

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

6. Upon information and belief, Macleods Pharmaceuticals is in the business of manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, upon information and belief, Macleods Pharmaceuticals, directly or through one or more agents (including but not limited to Macleods Pharma USA, Inc.), 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. Upon information and belief, as a part of these ANDAs, Macleods Pharmaceuticals, directly or through one or more agents, files certifications of the type described in Sections 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA") 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.

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

8. Upon information and belief, Macleods USA is a wholly-owned subsidiary of Macleods Pharmaceuticals and is controlled and dominated by Macleods Pharmaceuticals. Upon information and belief, Macleods USA markets, distributes, sells and/or offers for sale generic drugs throughout the United States and in Delaware at the direction of, under the control of, and for the direct benefit of Macleods Pharmaceuticals.

9. Upon information and belief, Macleods USA assisted in the preparation and submission of ANDA No. 205988 for Macleods Pharmaceuticals's 10 mg vardenafil hydrochloride orally disintegrating tablets ("Macleods's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Macleods Pharmaceuticals.

10. Upon information and belief, Macleods Pharmaceuticals 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 pharmaceutical products throughout the United States, including in Delaware, of generic pharmaceuticals, including the infringing Macleods's ANDA Product at issue.

11. Upon information and belief, following any FDA approval of ANDA No. 205988, Macleods Pharmaceuticals and Macleods USA will act in concert to market, distribute, offer for sale, and sell Macleods's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Macleods" or "Defendants." Upon information and belief, following any FDA approval of ANDA No.

205988, Macleods knows and intends that its ANDA Product will be marketed, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Macleods USA because, *inter alia*, Macleods USA is a corporation formed under the laws of the State of Delaware.

14. In addition, this Court has personal jurisdiction over Macleods USA because, upon information and belief, Macleods USA has registered to do business in the State of Delaware and has appointed a registered agent in Delaware, (Incorp Services, Inc., 1201 Orange St., Ste. 600, One Commerce Center, Wilmington, Delaware 19899) to accept service of process. Macleods USA has thus consented to jurisdiction in Delaware.

15. Macleods Pharmaceuticals is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, (1) Macleods Pharmaceuticals is in the business of manufacturing drug products which it markets, distributes, offers for sale and sells, either itself or through one or more of its agents (including Macleods USA), throughout the United States, including in Delaware, derives substantial revenue from services or things used or consumed in the State of Delaware, and transacts business with companies located and/or headquartered in Delaware; (2) Macleods Pharmaceuticals 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's ANDA Product in the United States, including in Delaware; and (3) Macleods USA, acting as Macleods Pharmaceuticals' agent and/or alter ego, will market, distribute, offer for sale, and/or sell Macleods's ANDA Product in the United States, including in

Delaware, upon approval of ANDA No. 205988, and will derive substantial revenue from the use or consumption of Macleods's ANDA Product in the State of Delaware.

16. Upon information and belief, Macleods USA is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in Delaware, and relies on contributions from Macleods Pharmaceuticals.

17. On information and belief, Macleods USA, acting as the agent of Macleods Pharmaceuticals, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Macleods Pharmaceuticals or for which Macleods Pharmaceuticals is the named applicant on approved ANDAs. Upon information and belief, Macleods USA and/or Macleods Pharmaceuticals are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are nearer than arm's length.

18. On information and belief, Macleods Pharmaceuticals earns revenue from the marketing, distribution, offer for sale, and/or sale in Delaware by Macleods USA of generic pharmaceutical products that are manufactured by Macleods Pharmaceuticals or for which Macleods Pharmaceuticals is the named applicant on approved ANDAs. On information and belief, various products for which Macleods Pharmaceuticals is the named applicant on approved ANDAs are available at retail pharmacies in Delaware. On information and belief, Macleods Pharmaceuticals and Macleods USA will market, distribute, offer for sale, and/or sell within the United States, including in Delaware, Macleods's ANDA Product if FDA approval is granted. If ANDA No. 205988 is approved, the generic product charged with infringing the '950 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.

19. On information and belief, Macleods Pharmaceuticals and Macleods USA participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 205988 (the ANDA at issue in this litigation) for Macleods's ANDA Product.

20. In addition, upon information and belief, this Court has personal jurisdiction over Defendants because the Notice Letter (defined below) was sent to Plaintiff Bayer HealthCare Pharmaceuticals Inc and Bayer Healthcare LLC. That has led and/or will lead to foreseeable harm and injury to one or more Plaintiffs in Delaware. Macleods Pharmaceuticals and Macleods USA have been litigants in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Bayer HealthCare Pharmaceuticals Inc., a Delaware corporation, and Bayer Healthcare LLC, a Delaware limited liability company, that Macleods would be sued in Delaware for patent infringement.

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

22. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

23. STAXYN® (active ingredient vardenafil hydrochloride) is a selective inhibitor of cyclic guanosine monophosphate-specific phosphodiesterase type 5. STAXYN® is indicated for the treatment of erectile dysfunction.

24. United States Patent No. 8,613,950, entitled "Pharmaceutical Forms with Improved Pharmacokinetic Properties," was duly and legally issued on December 24, 2013. The '950 patent is attached as Exhibit A to this complaint.

25. Bayer Intellectual Property GmbH is the assignee of the '950 patent.

26. Bayer Pharma AG holds an exclusive license under the '950 patent.

27. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 200179 for STAXYN®, which has been approved by the FDA. Pursuant to 21 U.S.C. § 355, the '950 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with STAXYN®.

28. One or more claims of the '950 patent, incorporated by reference herein, cover STAXYN®.

29. By letter dated April 21, 2015 (the "Notice Letter"), Macleods Pharmaceuticals notified Bayer HealthCare Pharmaceuticals Inc. and Bayer Healthcare LLC that Macleods Pharmaceuticals had submitted to the FDA ANDA No. 205988 for Macleods's ANDA Product. This product is a generic version of STAXYN®.

30. The purpose of ANDA No. 205988 was to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of Macleods's ANDA Product prior to the expiration of the '950 patent.

31. In the Notice Letter, Macleods Pharmaceuticals stated that, in connection with its ANDA No. 205988, Macleods Pharmaceuticals had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), with respect to the '950 patent. Upon information and belief, Macleods Pharmaceuticals submitted a Paragraph IV Certification in connection with ANDA No. 205988 asserting that the '950 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Macleods's ANDA Product.

32. In the Notice Letter, Macleods Pharmaceuticals described Macleods's ANDA Product as vardenafil hydrochloride orally disintegrating tablets.

33. On information and belief, in ANDA No. 205988, Macleods Pharmaceuticals seeks approval to market and sell the Macleods's ANDA Product to treat erectile dysfunction.

34. Macleods Pharmaceuticals had knowledge of the '950 patent prior to its filing of a Paragraph IV Certification for the '950 patent in connection with ANDA No. 205988.

35. On information and belief, Macleods intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's ANDA Product immediately and imminently upon approval of ANDA No. 205988, *i.e.*, prior to the expiration date of the '950 patent.

36. In the Notice Letter, Macleods included an Offer of Confidential Access to portions of its ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

37. Plaintiffs attempted to negotiate the terms of Macleods's Offer of Confidential Access, proposing reasonable confidentiality terms and seeking access to documents and samples beyond Macleods's ANDA that are relevant to infringement of the '950 patent. Macleods rejected Plaintiffs' offers, and the parties have been unable to reach an agreement on confidential access to internal Macleods information.

38. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

CLAIM FOR PATENT INFRINGEMENT – '950 PATENT

39. Plaintiffs incorporate each of the preceding paragraphs 1-38 as if fully set forth herein.

40. Macleods's submission of ANDA No. 205988 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Macleods's ANDA Product prior to the expiration of the '950 patent infringed the '950 patent under 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, Macleods's ANDA Product is covered by one or more claims of the '950 patent.

42. Upon information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's ANDA Product immediately and imminently upon approval of ANDA No. 205988.

43. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's ANDA Product prior to the expiration of the '950 patent would infringe one or more claims of the '950 patent.

44. Upon information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 205988.

45. Upon information and belief, use of Macleods's ANDA Product in accordance with and as directed by Macleods's proposed labeling for that product would infringe one or more claims of the '950 patent.

46. Upon information and belief, Macleods plans and intends to, and will, actively induce infringement of the '950 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. The foregoing actions by Macleods constitute and/or will constitute infringement of the '950 patent and active inducement of infringement of the '950 patent.

48. Unless Macleods is enjoined from infringing the '950 patent and/or actively inducing infringement of the '950 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that judgment be entered in favor of Plaintiffs and against Macleods and requests the following relief:

A. A judgment that Macleods has infringed the '950 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's ANDA Product, or any product that infringes the '950 patent, be not earlier than the expiration date of the '950 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's ANDA Product, or any product that infringes the '950 patent, or the inducement of any of the foregoing, prior to the expiration date of the '950 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

D. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Macleods's ANDA Product, or any product that infringes the '950 patent, prior to the expiration date of the '950 patent, will infringe and actively induce infringement by others of the '950 patent;

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

F. An award of Plaintiffs' costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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