IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED and ABBVIE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Allergan Pharmaceuticals International Limited and AbbVie Inc. (collectively, "Plaintiffs") file this complaint for patent infringement against Defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods") under 35 U.S.C. §§ 271(e)(2), (b), and (c). This patent action concerns the pharmaceutical drug product Savella® and U.S. Patent No. 7,994,220 (the "'220 patent"). Plaintiffs hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular, under 35 U.S.C. § 271. This action arises from Macleods' submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiffs' SAVELLA®, prior to the expiration of the '220 patent. SAVELLA® (milnacipran hydrochloride) tablets are approved in the U.S. for the management of fibromyalgia under New Drug Application ("NDA") No. 022256.

THE PARTIES

2. Plaintiff Allergan Pharmaceuticals International Limited ("APIL") is a company organized and existing under the laws of the Republic of Ireland having offices at Clonshaugh Business & Technology Park, Dublin 17, Ireland.

3. APIL is the assignee and owner of the '220 patent.

4. Plaintiff AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1 North Waukegan Road, North Chicago, IL 60064.

5. AbbVie holds NDA No. 022256 for SAVELLA®.

6. Upon information and belief, Defendant Macleods Pharmaceuticals Ltd. ("MPL") is a corporation organized and existing under the laws of India, with a place of business at 304 Atlanta Arcade, Marol Church Rd., Andheri (East), Mumbai, 400059, India.

7. Upon 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 103 College Road East, Second Floor, Princeton, New Jersey 08540.

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

9. On information and belief, MPL is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic versions of branded pharmaceutical products for the U.S. market. 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,

Macleods USA is the United States regulatory agent for MPL. 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 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.

10. Upon information and belief, Macleods USA is a generic pharmaceutical company in the business of marketing, researching, and developing generic drug products. Upon information and belief, Macleods USA directly and through its affiliates markets and sells drug products in the state of Delaware and throughout the United States.

11. Upon information and belief, MPL and Macleods USA filed Macleods' ANDA No. 210944 seeking FDA approval for milnacipran hydrochloride tablets, 12.5 mg, 25 mg, 50 mg, and 100 mg strengths ("Macleods ANDA Products"), with reference to AbbVie's NDA No. 022256 for SAVELLA®. Upon information and belief, MPL and Macleods USA acted collaboratively in the preparation of ANDA No. 210944 and continue to act collaboratively in pursuing FDA approval of ANDA No. 210944 and seeking to market the Macleods ANDA Products. Upon information and belief, MPL and Macleods USA intend to commercially manufacture, market, offer for sale, and/or sell the Macleods ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 210944.

JURISDICTION AND VENUE

12. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Macleods USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Upon information and belief, Macleods USA is a corporation organized and existing under the laws of the State of Delaware and has appointed a registered agent in the State of Delaware to accept service of process. Macleods USA is registered to do business as a domestic corporation in the State of Delaware (File Number 5062107). Macleods USA has therefore purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here.

14. This Court has personal jurisdiction over MPL because, on information and belief, it has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Macleods' ANDA Products in the State of Delaware upon approval of ANDA No. 210944.

15. This Court has personal jurisdiction over Macleods because of its regular transaction and/or solicitation of business in the State of Delaware. Upon information and belief, Macleods is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. By continuously placing its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, Macleods has engaged in the regular conduct of business within this judicial district.

16. This Court also has personal jurisdiction over Macleods because, *inter alia*, this action arises from activities of Macleods directed toward the State of Delaware. More specifically, Macleods is subject to personal jurisdiction in this district because, *inter alia*, Macleods has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against Plaintiffs, including AbbVie Inc., which is a Delaware corporation.

17. Macleods' filing of its ANDA No. 210944 with a Paragraph IV certification regarding U.S. Patent No. 7,994,220 has a substantial connection with this district because it reliably and non-speculatively predicts activities by Macleods in this district.

18. For these reasons, this Court has personal jurisdiction over Macleods. This Court also has personal jurisdiction over Macleods because it has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g.*, *ZS Pharma, Inc., v. Macleods Pharms. Ltd.,* No. 23-1190-JLH, D.I. 15 (D. Del. Dec. 19, 2023).

19. Upon information and belief, venue is proper in this Court under 28 U.S.C. § 1391(b) and (c) as to MPL, because it is incorporated in India and may be sued in any judicial district in the United States.

20. Upon information and belief, venue is proper in this Court under 28 U.S.C. § 1400(b) as to Macleods USA, because it is a corporation organized and existing under the laws of the State of Delaware.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '220 Patent Under 35 U.S.C. § 271(e)(2))

21. Plaintiffs reallege and incorporate by reference paragraphs 1-20.

22. The ’220 patent, titled “Milnacipran for the Long-Term Treatment of Fibromyalgia Syndrome,” was duly and legally issued to inventors Srinivas G. Rao, Michael Gendreau, and Jay D. Kranzler by the PTO on August 9, 2011. The ’220 patent is assigned to APIL and expires on September 19, 2029. This expiration date includes a 1089-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the ’220 patent is attached as Exhibit A. A true and correct copy of the Issue Notification reflecting the patent term adjustment is attached as Exhibit B.

23. New Drug Application NDA No. 022256 is directed to the use of SAVELLA® in the management of fibromyalgia. The FDA approved NDA No. 022256 on January 14, 2009. The ’220 patent is listed in the Orange Book for NDA No. 022256. AbbVie Inc. is the holder of NDA No. 022256.

24. Upon information and belief, Macleods filed, or caused to be filed, ANDA No. 210944 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation of milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States before the expiration of the ’220 patent.

25. Upon information and belief, ANDA No. 210944 contains a Paragraph IV certification alleging that all the claims of the ’220 patent are invalid or will not be infringed by the manufacture, use, or sale of the Macleods’ ANDA Products.

26. Macleods sent, or caused to be sent, the Macleods Notice Letter notifying Plaintiffs that Macleods had submitted ANDA No. 210944 and purporting to provide information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Macleods Notice Letter alleges that claims 1-7 of the ’220

patent are invalid or will not be infringed by the manufacture, use, or sale of the Macleods' ANDA Products.

27. Upon information and belief, Macleods seeks approval of an indication for the Macleods' ANDA Products that is claimed in the '220 patent.

28. Under 35 U.S.C. § 271(e)(2)(A), Macleods infringed one or more claims of the '220 patent in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '220 patent—the Macleods' ANDA Products, the use of which would directly infringe one or more claims of the '220 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the '220 patent, by users of the Macleods' ANDA Products.

29. Upon information and belief, Macleods has knowledge of the '220 patent and filed ANDA No. 210944 seeking authorization to commercially manufacture, use, offer for sale, and sell the Macleods' ANDA Products in the United States. Upon information and belief, if the FDA approves ANDA No. 210944, physicians, health care providers, and/or patients will use the Macleods' ANDA Products in accordance with the instructions and/or label provided by Macleods and will directly infringe, literally and/or through the doctrine of equivalents one or more claims of the '220 patent.

30. Upon information and belief, Macleods knows and intends that physicians, health care providers, and/or patients will use the Macleods' ANDA Products in accordance with the instructions and/or label provided by Macleods, and will therefore induce infringement of one or more of the claims of the '220 patent with the requisite intent.

31. Upon information and belief, if the FDA approves ANDA No. 210944, Macleods will sell or offer to sell the Macleods' ANDA Products specifically labeled for use in practicing

one or more of the method claims of the '220 patent, wherein the Macleods' ANDA Products are a material part of the method claimed, wherein Macleods knows that physicians will prescribe and patients will use the Macleods' ANDA Products in practicing one or more of the methods claimed in the '220 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Macleods will thus contribute to the infringement of the '220 patent.

32. Plaintiffs will be substantially and irreparably harmed by Macleods' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '220 Patent Under 35 U.S.C. § 271(b) and/or (c))

33. Plaintiffs reallege and incorporate by reference paragraphs 1-32.

34. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. Upon information and belief, Macleods, upon the manufacture, sale, offer for sale, or use within the United States, or importation into the United States, of Macleods' generic milnacipran product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '220 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

36. Upon information and belief, Macleods has knowledge of the '220 patent and has filed ANDA No. 210944 seeking authorization to commercially manufacture, use, offer for sale, and sell the Macleods' ANDA Products in the United States. Upon information and belief, if the

FDA approves ANDA No. 210944, physicians, health care providers, and/or patients will use the Macleods' ANDA Products in accordance with the instructions and/or label provided by Macleods and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '220 patent, under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

37. Upon information and belief, Macleods knows and intends that physicians, health care providers, and/or patients will use the Macleods' ANDA Products in accordance with the instructions and/or label provided by the '220 patent with the requisite intent under 35 U.S.C. § 271(b).

38. Upon information and belief, if the FDA approves ANDA No. 210944, Macleods will sell or offer to sell the Macleods' ANDA Products specifically labeled for use in practicing one or more claims of the '220 patent, wherein the Macleods' ANDA Products are a material part of the invention claimed in the '220 patent, wherein Macleods knows that physicians will prescribe and patients will use the Macleods' ANDA Products for practicing one or more claims in the '220 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Macleods will thus contribute to the infringement of the '220 patent under 35 U.S.C. § 271(c).

39. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Macleods as to liability for Macleods' infringement of the '220 patent claims. Macleods' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Macleods' threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

a) declare that, under 35 U.S.C. § 271(e)(2)(A), Macleods infringed United States Patent No. 7,994,220 by submitting ANDA No. 210944 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Macleods' generic milnacipran product prior to the expiration of said patent;

b) declare that Macleods' commercial manufacture, use or sale, or offer for sale in, or importation into the United States of the Macleods' ANDA Products prior to the expiration of United States Patent No. 7,994,220 would constitute infringement of said patent under 35 U.S.C. § 271(b) and/or (c);

c) order that the effective date of any FDA approval of the Macleods' ANDA Products shall be no earlier than the expiration date of United States Patent No. 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

d) enjoin Macleods, and all persons acting in concert with Macleods, from seeking, obtaining, or maintaining final approval of ANDA No. 210944 until the expiration of United States Patent No. 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

e) enjoin Macleods and all persons acting in concert with Macleods, from commercially manufacturing, using, offering for sale, or selling the Macleods' ANDA Products within the United States, or importing the Macleods' ANDA Products into the United States, until the expiration of United States Patent No. 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

f) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

g) award damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Macleods engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Macleods ANDA Products, or induces or contributes to such conduct, prior to the expiration United States Patent No. 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

h) award costs and expenses in this action; and

h) grant Plaintiffs such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

July 19, 2024