IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM CORPORATION,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Corporation, by their undersigned attorneys, for their Complaint against Defendants, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc., hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiffs' JARDIANCE® (empagliflozin) tablets, GLYXAMBI® (empagliflozin/linagliptin) tablets and/or SYNJARDY® (empagliflozin/metformin) tablets prior to the expiration of United States Patent No. 10,258,637.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

5. BIPI, BII, and BIC are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Macleods Pharmaceuticals Ltd. ("Macleods Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (east), Mumbai, India 400059.

7. On information and belief, Macleods Ltd. controls and directs a wholly owned subsidiary in the United States named Macleods Pharma USA, Inc. ("Macleods Pharma"). Macleods Pharma is a Delaware corporation having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

8. Macleods Ltd. and Macleods Pharma are collectively referred to hereinafter as "Macleods."

9. On information and belief, Macleods is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of Delaware, through its own actions and through the actions of its agents and subsidiaries, including Macleods Pharma, from which Macleods Ltd. derives a substantial portion of its revenue.

10. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit ANDA No. 212372 (the "Macleods empagliflozin ANDA") for Macleods Ltd.'s 10 mg and 25 mg empagliflozin tablets ("Macleods empagliflozin products").

11. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit ANDA No. 212375 (the "Macleods empagliflozin/linagliptin ANDA") for Macleods Ltd.'s 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets ("Macleods empagliflozin/linagliptin products").

12. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit ANDA No. 212373 (the "Macleods empagliflozin/metformin ANDA") for Macleods Ltd.'s 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g empagliflozin and metformin hydrochloride tablets ("Macleods empagliflozin/metformin products").

13. The Macleods empagliflozin products, Macleods empagliflozin/linagliptin products, and Macleods empagliflozin/metformin products are collectively referred to hereinafter as the "Macleods ANDA Products."

14. The Macleods empagliflozin ANDA, the Macleods empagliflozin/linagliptin ANDA, and the Macleods empagliflozin/metformin ANDA are collectively referred to hereinafter as the "Macleods ANDAs."

15. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit the Macleods ANDAs for the Macleods ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of Macleods Ltd. Following FDA approval of the Macleods empagliflozin ANDA, the Macleods empagliflozin/linagliptin ANDA, and the Macleods empagliflozin/metformin ANDA, Macleods Ltd. will manufacture and supply the approved generic product to Macleods Pharma, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Macleods Ltd.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

17. Venue is proper in this Court because, among other things, Macleods Pharma is incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). Macleods Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, Macleods has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. *See, e.g.*, *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, C.A. No. 18-91-LPS (D. Del.).

PERSONAL JURISDICTION OVER MACLEODS LTD.

18. Plaintiffs reallege paragraphs 1-17 as if fully set forth herein.

19. On information and belief, Macleods Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

20. This Court has personal jurisdiction over Macleods Ltd. because, *inter alia*, Macleods Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute Macleods Ltd. infringing ANDA Products to residents of this State upon approval of ANDA No. 212372, ANDA No. 212375, or ANDA No. 212373, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through Macleods Pharma, which is a Delaware corporation; and (4) wholly owns Macleods Pharma, which is a Delaware corporation.

21. On information and belief, Macleods Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, C.A. No. 18-91-LPS (D. Del.).

22. Alternatively, to the extent the above facts do not establish personal jurisdiction over Macleods Ltd., this Court may exercise jurisdiction over Macleods Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Macleods Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and

(c) Macleods Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Macleods Ltd. satisfies due process.

PERSONAL JURISDICTION OVER MACLEODS PHARMA

23. Plaintiffs reallege paragraphs 1-22 as if fully set forth herein.

24. On information and belief, Macleods Pharma develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

25. This Court has personal jurisdiction over Macleods Pharma because, *inter alia*, Macleods Pharma, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Macleods' ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

26. On information and belief, Macleods Pharma has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g.*, *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, C.A. No. 18-91-LPS (D. Del.).

BACKGROUND

U.S. PATENT NO. 10,258,637

27. On April 16, 2019, the USPTO duly and legally issued United States Patent No. 10,258,637 ("the '637 patent") entitled "Pharmaceutical Composition, Method for Treating and

Uses Thereof" to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. A true and correct copy of the '637 patent is attached as Exhibit 1. The '637 patent is assigned to BII. BIC and BIPI are licensees of the '637 patent.

JARDIANCE®

28. BIPI is the holder of New Drug Application ("NDA") No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

29. JARDIANCE® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Exclusivity until August 1, 2019.

30. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '637 patent is among the patents listed in the Orange Book with respect to JARDIANCE®.

31. The '637 patent covers the JARDIANCE® product and its use.

GLYXAMBI®

32. BIPI is the holder of New Drug Application ("NDA") No. 206073 for empagliflozin/linagliptin, for oral use, in 10 mg/5 mg and 25 mg/5 mg dosages, which is sold under the trade name GLYXAMBI®.

33. GLYXAMBI® is listed in Orange Book as having New Chemical Exclusivity until August 1, 2019.

34. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '637 patent is among the patents listed in the Orange Book with respect to GLYXAMBI®.

35. The ’637 patent covers the GLYXAMBI® product and its use.

SYNJARDY®

36. BIPI is the holder of New Drug Application (“NDA”) No. 206111 for empagliflozin and metformin hydrochloride, for oral use, in 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, and 12.5 mg/1 g dosages, which is sold under the trade name SYNJARDY®.

37. SYNJARDY® is listed in Orange Book as having New Chemical Exclusivity until August 1, 2019.

38. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’637 patent is among the patents listed in the Orange Book with respect to SYNJARDY®.

39. The ’637 patent covers the SYNJARDY® product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I —INFRINGEMENT OF THE ’637 PATENT

40. Plaintiffs reallege paragraphs 1-39 as if fully set forth herein.

41. On information and belief, Macleods submitted the Macleods ANDAs to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Macleods ANDA Products.

42. Macleods has represented that the Macleods ANDAs refer to and rely upon the JARDIANCE® NDA, the GLYXAMBI® NDA, and the SYNJARDY® NDA and contain data that, according to Macleods, demonstrate the bioavailability or bioequivalence of the Macleods ANDA Products to JARDIANCE®, GLYXAMBI®, and SYNJARDY®.

43. Plaintiffs received letters from Macleods on or about September 13, 2019 stating that Macleods had included certifications in the Macleods empagliflozin ANDA, the Macleods empagliflozin/linagliptin ANDA, and the Macleods empagliflozin/metformin ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '637 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Macleods empagliflozin products, the Macleods empagliflozin/linagliptin products, and the Macleods empagliflozin/metformin products (the "Macleods Empagliflozin/Linagliptin Paragraph IV Certification," "Macleods Empagliflozin Paragraph IV Certification," and "Macleods Empagliflozin/Metformin Paragraph IV Certification," respectively). Macleods intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Macleods empagliflozin products, the Macleods empagliflozin/linagliptin products, and the Macleods empagliflozin/metofmrin products prior to the expiration of the '637 patent.

44. The Macleods Empagliflozin Paragraph IV Certification, the Macleods Empagliflozin/Linagliptin Paragraph IV Certification, and the Macleods Empagliflozin/Metformin Paragraph IV Certification are collectively referred to herein as the "Macleods Paragraph IV Certifications."

45. Macleods has infringed at least one claim of the '637 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Macleods ANDAs, by which Macleods seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Macleods ANDA Products prior to the expiration of the '637 patent.

46. Macleods has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Macleods ANDA Products in the event that

the FDA approves the Macleods ANDAs. Accordingly, an actual and immediate controversy exists regarding Macleods' infringement of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

47. Macleods' manufacture, use, offer to sell, or sale of the Macleods ANDA Products in the United States or importation of the Macleods ANDA Products into the United States during the term of the '637 patent would further infringe at least one claim of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

48. On information and belief, the Macleods ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '637 patent either literally or under the doctrine of equivalents.

49. On information and belief, the use of the Macleods ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Macleods knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

50. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Products would contributorily infringe at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

51. On information and belief, Macleods had knowledge of the '637 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

52. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Products by Macleods would actively induce infringement of at least one of the claims of the '637 patent, either literally or under the doctrine of equivalents.

53. On information and belief, Macleods does not deny that the Macleods ANDA Products will infringe the claims of the '637 patent and in the Macleods Paragraph IV Certifications, Macleods did not deny that the Macleods ANDA Products will infringe the claims of the '637 patent.

54. Plaintiffs will be substantially and irreparably harmed if Macleods is not enjoined from infringing the '637 patent.

55. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Macleods and for the following relief:

a. A Judgment be entered that Macleods has infringed at least one claim of the '637 patent by submitting the Macleods ANDAs;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Macleods, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '637 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '637 patent or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Macleods' ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '637 patent, including any extensions;

e. That Boehringer be awarded monetary relief if Macleods commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, GLYXAMBI®, SYNJARDY® or any other product that infringes or induces or contributes to the infringement of the '637 patent, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian P. Egan

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
began@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Leora Ben-Ami
Jeanna M. Wacker
Christopher T. Jagoe
Mira A. Mulvaney
Sam Kwon
Ashley Ross
Justin Bova
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679

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