IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG, 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' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' TRADJENTA® (linagliptin) tablets prior to the expiration of United States Patent Nos. 8,673,927, 8,853,156, and 9,173,859.

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. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

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

7. 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.

8. 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.

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

10. 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.

11. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit ANDA No. 213602 (the "Macleods ANDA") for Macleods Ltd.'s 5 mg linagliptin tablets (the "Macleods ANDA Product").

12. On information and belief, Macleods Ltd. acted in concert with Macleods Pharma to prepare and submit the Macleods ANDA for the Macleods ANDA Product, 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 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

13. 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).

14. 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.

PERSONAL JURISDICTION OVER MACLEODS LTD.

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

16. 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.

17. 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 Product to residents of this State upon approval of ANDA No. 213602, 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.

18. 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.*, *Boehringer Ingelheim Pharm. Inc. v. Macleods Pharm. Ltd.*, C.A. No. 18-1764-CFC (D. Del.); *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, C.A. No. 18-91-LPS (D. Del.).

19. 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

20. Plaintiffs reallege paragraphs 1-19 as if fully set forth herein.

21. 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.

22. 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's ANDA Product 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.

23. 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.*, *Boehringer Ingelheim Pharm. Inc. v. Macleods Pharm. Ltd.*, C.A. No. 18-1764-CFC (D. Del.); *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, C.A. No. 18-91-LPS (D. Del.).

BACKGROUND

U.S. PATENT NO. 8,673,927

24. On March 18, 2014, the U.S. Patent & Trademark Office ("PTO") duly and legally issued United States Patent No. 8,673,927 (the "'927 patent") entitled "Uses of DPP-IV

Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '927 patent is attached as Exhibit 1.

25. On October 15, 2018, the court entered an order in *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Co.*, C.A. No. 15-5982-PGS (consolidated) (D.N.J.), in which the court held certain claims of the '927 patent invalid due to obviousness and obvious-type double patenting.

26. On November 5, 2018, Plaintiffs filed a notice of appeal from the court's October 15, 2018 order and final judgment of invalidity.

U.S. PATENT NO. 8,853,156

27. On October 7, 2014, the PTO duly and legally issued United States Patent No. 8,853,156 (the "'156 patent") entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy" to inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. A true and correct copy of the '156 patent is attached as Exhibit 2.

28. On December 8, 2016, the court entered an order in *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Co.*, C.A. No. 15-5982-PGS (consolidated) (D.N.J.), in which the court held certain claims of the '156 patent invalid as directed to patent ineligible subject matter.

29. On November 5, 2018, Plaintiffs filed a notice of appeal from the court's December 8, 2016 order.

U.S. PATENT NO. 9,173,859

30. On November 3, 2015, the PTO duly and legally issued United States Patent No. 9,173,859 (the "'859 patent") entitled "Uses of DPP-IV Inhibitors" to inventors Klaus Dugi, Frank Himmelsbach, and Michael Mark. A true and correct copy of the '859 patent is attached as Exhibit 3.

31. On October 15, 2018, the court entered an order in *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Co.*, C.A. No. 15-5982-PGS (consolidated) (D.N.J.), in which the court held certain claims of the '859 patent invalid due to obviousness and obvious-type double patenting.

32. On November 5, 2018, Plaintiffs filed a notice of appeal from the court's October 15, 2018 order and final judgment of invalidity.

TRADJENTA®

33. BIPI is the holder of New Drug Application ("NDA") No. 201280 (the "TRADJENTA® NDA") for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

34. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '927, '156, and '859 patents are listed in the "Orange Book" with respect to TRADJENTA®.

35. The '927, '156, and '859 patents cover the TRADJENTA® product and/or the use thereof.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '927 PATENT

36. Plaintiffs reallege paragraphs 1-35 as if fully set forth herein.

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

38. Macleods has represented that the Macleods ANDA refers to and relies upon the TRADJENTA® NDA and contains data that, according to Macleods, demonstrate the bioavailability or bioequivalence of the Macleods ANDA Product to TRADJENTA®.

39. Plaintiffs received a letter from Macleods on or about August 8, 2019 stating that Macleods had included certifications in the Macleods ANDA, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '927, '156, and '859 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Macleods ANDA Product (the "Macleods Paragraph IV Certification"). Macleods intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Macleods ANDA Product prior to the expiration of the '927, '156, and '859 patents.

40. Macleods has infringed at least one claim of the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Macleods ANDA, by which Macleods seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Macleods ANDA Product prior to the expiration of the '927 patent.

41. 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 Product in the event that the FDA approves the Macleods ANDA. Accordingly, an actual and immediate controversy exists regarding Macleods's infringement of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

42. Macleods's manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods ANDA Product into the United States during the term of the '927 patent would further infringe at least one claim of the '927 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

43. On information and belief, the Macleods ANDA Product, 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 '927 patent either literally or under the doctrine of equivalents.

44. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '927 patent; Macleods knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

45. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product would contributorily infringe at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

46. On information and belief, Macleods had knowledge of the '927 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

47. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product by Macleods would actively induce infringement of at least one of the claims of the '927 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe the claims of the '927 patent and in the Macleods Paragraph IV Certification, Macleods did not deny that the Macleods ANDA Product will infringe the claims of the '927 patent.

49. Plaintiffs will be substantially and irreparably harmed if Macleods is not enjoined from infringing the '927 patent.

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

COUNT II — INFRINGEMENT OF THE '156 PATENT

51. Plaintiffs reallege paragraphs 1-50 as if fully set forth herein.

52. Macleods has infringed at least one claim of the '156 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Macleods ANDA, by which Macleods seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Macleods ANDA Product prior to the expiration of the '156 patent.

53. 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 Product in the event that the FDA approves the Macleods ANDA. Accordingly, an actual and immediate controversy exists regarding Macleods's infringement of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

54. Macleods's manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods ANDA Product into the United States during the term of the '156 patent would further infringe at least one claim of the '156 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

55. On information and belief, the Macleods ANDA Product, 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 '156 patent either literally or under the doctrine of equivalents.

56. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '156 patent; Macleods knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

57. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product would contributorily infringe at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

58. On information and belief, Macleods had knowledge of the '156 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

59. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product by Macleods would actively induce infringement of at least one of the claims of the '156 patent, either literally or under the doctrine of equivalents.

60. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe the claims of the '156 patent and in the Macleods Paragraph IV Certification, Macleods did not deny that the Macleods ANDA Product will infringe the claims of the '156 patent.

61. Plaintiffs will be substantially and irreparably harmed if Macleods is not enjoined from infringing the '156 patent.

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

COUNT III — INFRINGEMENT OF THE '859 PATENT

63. Plaintiffs reallege paragraphs 1-62 as if fully set forth herein.

64. Macleods has infringed at least one claim of the '859 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Macleods ANDA, by which Macleods seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Macleods ANDA Product prior to the expiration of the '859 patent.

65. 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 Product in the event that the FDA approves the Macleods ANDA. Accordingly, an actual and immediate controversy exists regarding Macleods's infringement of the '859 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

66. Macleods's manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods ANDA Product into the United States during the term of the '859 patent would further infringe at least one claim of the '859 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

67. On information and belief, the Macleods ANDA Product, 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 '859 patent either literally or under the doctrine of equivalents.

68. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '859 patent; Macleods knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents; and its ANDA Product is not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

69. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product would contributorily infringe at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

70. On information and belief, Macleods had knowledge of the '859 patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that

they will aid and abet another's direct infringement of at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

71. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product by Macleods would actively induce infringement of at least one of the claims of the '859 patent, either literally or under the doctrine of equivalents.

72. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe the claims of the '859 patent and in the Macleods Paragraph IV Certification, Macleods did not deny that the Macleods ANDA Product will infringe the claims of the '859 patent.

73. Plaintiffs will be substantially and irreparably harmed if Macleods is not enjoined from infringing the '859 patent.

74. 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 '927, '156, and '859 patents by submitting the Macleods ANDA;

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 '927, '156, and '859 patents, and (ii) seeking, obtaining or maintaining approval of its ANDA until the expiration of the '927, '156, and '859 patents 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 the Macleods ANDA 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 '927, '156, and '859 patents, including any extensions;

e. That Boehringer be awarded monetary relief if Macleods commercially uses, offers to sell, or sells its proposed generic version of TRADJENTA® or any other product that infringes or induces or contributes to the infringement of the '927, '156, and '859 patents, 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

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