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.	)	
MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS 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, MSN Laboratories Private Ltd., and MSN Pharmaceuticals 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® XR (empagliflozin/metformin extended release) tablets prior to the expiration of United States Patent Nos. 8,551,957 and/or 9,949,998.

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 MSN Laboratories Private Ltd. ("MSN Ltd.") is a company organized and existing under the laws of India, having a principal place of business at Plot #C-24, Industrial Estate, Sanathnagar Hyderabad-18 Telangana, India.

7. On information and belief, MSN Ltd. controls and directs a wholly owned subsidiary in the United States named MSN Pharmaceuticals Inc. ("MSN Pharma"). MSN Pharma is a Delaware corporation having a principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey 08837.

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

9. On information and belief, MSN Ltd. 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 MSN Pharma, from which MSN Ltd. derives a substantial portion of its revenue.

10. On information and belief, MSN Pharma acted in concert with MSN Ltd. to prepare and submit ANDA No. 212358 (the "MSN Empagliflozin ANDA") for MSN Ltd.'s 10 mg and 25 mg empagliflozin tablets ("MSN Empagliflozin Products").

11. On information and belief, MSN Pharma acted in concert with MSN Ltd. to prepare and submit ANDA No. 212359 (the "MSN Empagliflozin/Linagliptin ANDA") for MSN Ltd.'s 10 mg/5 mg and 25 mg/5 mg Empagliflozin/Linagliptin tablets ("MSN Empagliflozin/Linagliptin Products").

12. On information and belief, MSN Pharma acted in concert with MSN Ltd. to prepare and submit ANDA No. 212362 (the "MSN XR ANDA") for MSN Ltd.'s 5 mg/500 mg, 5 mg/1 g, 12.5 mg/500 mg, 10 mg/1g, 12.5 mg/1 g and 25 mg/1 g empagliflozin and metformin hydrochloride extended release tablets ("MSN XR Products").

13. The MSN Empagliflozin Products, MSN Empagliflozin/Linagliptin Products, and MSN XR Products are collectively referred to hereinafter as the "MSN ANDA Products."

14. The MSN Empagliflozin ANDA, the MSN Empagliflozin/Linagliptin ANDA, and the MSN XR ANDA are collectively referred to hereinafter as the "MSN ANDAs."

15. On information and belief, MSN Pharma acted in concert with MSN Ltd. to prepare and submit the MSN ANDAs for the MSN ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of MSN Ltd. Following FDA approval of the MSN Empagliflozin ANDA, the MSN Empagliflozin/Linagliptin ANDA, and/or the MSN XR ANDA, MSN Ltd. will manufacture and supply the approved generic products to

MSN 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 MSN 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, MSN 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). MSN 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, MSN has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. *See, e.g.*, *Millenium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd. et al*, 1:16-cv-01255.

PERSONAL JURISDICTION OVER MSN LTD.

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

19. On information and belief, MSN 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 MSN Ltd. because, *inter alia*, MSN 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 infringing MSN ANDA Products to residents of this State upon approval of ANDA No. 212358, ANDA No. 212359, or/or ANDA No. 212362, 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 MSN Pharma, which is a Delaware corporation; and (4) wholly owns MSN Pharma, which is a Delaware corporation.

21. On information and belief, MSN Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and MSN Ltd. has filed counterclaims in such cases. *See, e.g.*, *Millenium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd. et al*, 1:16-cv-01255.

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

PERSONAL JURISDICTION OVER MSN PHARMA

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

24. On information and belief, MSN 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 MSN Pharma because, *inter alia*, MSN Pharma, on information and belief: (1) is incorporated under the laws of the State of Delaware;

(2) intends to market, sell, or distribute MSN ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

26. On information and belief, MSN Pharma has not contested jurisdiction in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *Millenium Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd. et al*, 1:16-cv-01255 (D. Del.).

BACKGROUND

U.S. PATENT NO. 8,551,957

27. On October 8, 2013, the USPTO duly and legally issued United States Patent No. 8,551,957 ("the '957 patent") entitled "Pharmaceutical Composition Comprising a Glucopyranosyl-Substituted Benzene Derivate" to inventors Klaus Dugi, Michael Mark, Leo Thomas and Frank Himmelsbach. A true and correct copy of the '957 patent is attached as Exhibit 1. The '957 patent is assigned to BII. BIC and BIPI are licensees of the '957 patent.

U.S. PATENT NO. 9,949,998

28. On April 24, 2018, the USPTO duly and legally issued United States Patent No. 9,949,998 ("the '998 patent") entitled "Pharmaceutical Composition, Methods 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 '998 patent is attached as Exhibit 2. The '998 patent is assigned to BII. BIC and BIPI are licensees of the '998 patent.

JARDIANCE®

29. 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®.

30. 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.

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '998 patent is among the patents listed in the Orange Book with respect to JARDIANCE®.

32. The '998 patent covers the JARDIANCE® product and its use.

GLYXAMBI®

33. 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®.

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

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '957 and '998 patents are among the patents listed in the Orange Book with respect to GLYXAMBI®.

36. The '957 and '998 patents cover the GLYXAMBI® product and its use.

SYNJARDY® XR

37. BIPI is the holder of New Drug Application ("NDA") No. 208658 for empagliflozin and metformin hydrochloride, extended release, 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® XR.

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

39. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '998 patent is among the patents listed in the Orange Book with respect to SYNJARDY® XR.

40. The '998 patent covers the SYNJARDY® XR product and its use.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '998 PATENT

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

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

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

44. Plaintiffs received a letter from MSN on or about October 3, 2018 stating that MSN had included a certification in the MSN Empagliflozin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '998 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the MSN Empagliflozin Products (the "MSN Empagliflozin Paragraph IV Certification"). MSN intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the MSN Empagliflozin Products prior to the expiration of the '998 patent.

45. Plaintiffs received a letter from MSN on or about October 3, 2018 stating that MSN had included a certification in the MSN Empagliflozin/Linagliptin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the ’957 and ’998 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the MSN Empagliflozin/Linagliptin Products (the “MSN Empagliflozin/Linagliptin Paragraph IV Certification”). MSN intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the MSN Empagliflozin/Linagliptin Products prior to the expiration of the ’957 and ’998 patents.

46. Plaintiffs received a letter from MSN on or about October 3, 2018 stating that MSN had included a certification in the MSN XR ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the ’998 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the MSN XR Products (the “MSN XR Paragraph IV Certification”). MSN intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the MSN XR Products prior to the expiration of the ’998 patent.

47. The MSN Empagliflozin Paragraph IV Certification, MSN Empagliflozin/Metformin Paragraph IV Certification, MSN Empagliflozin/Linagliptin Paragraph IV Certification, and MSN XR Paragraph IV Certification are collectively referred herein as the “MSN Paragraph IV Certifications.”

48. MSN has infringed at least one claim of the ’998 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the MSN ANDAs, by which MSN seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the MSN ANDA Products prior to the expiration of the ’998 patent.

49. MSN has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the MSN ANDA Products in the event that the FDA approves the MSN ANDAs. Accordingly, an actual and immediate controversy exists regarding MSN's infringement of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

50. MSN's manufacture, use, offer to sell, or sale of the MSN ANDA Products in the United States or importation of the MSN ANDA Products into the United States during the term of the '998 patent would further infringe at least one claim of the '998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

51. On information and belief, the MSN 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 '998 patent either literally or under the doctrine of equivalents.

52. On information and belief, the use of the MSN ANDA Products constitutes a material part of at least one of the claims of the '998 patent; MSN knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '998 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.

53. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products would contributorily infringe at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

54. On information and belief, MSN had knowledge of the '998 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 '998 patent, either literally or under the doctrine of equivalents.

55. On information and belief, the offering to sell, sale, and/or importation of the MSN ANDA Products by MSN would actively induce infringement of at least one of the claims of the '998 patent, either literally or under the doctrine of equivalents.

56. On information and belief, MSN does not deny that the MSN ANDA Products will infringe the claims of the '998 patent. In the MSN Paragraph IV Certifications, MSN did not deny that the MSN ANDA Products will infringe the claims of the '998 patent.

57. Plaintiffs will be substantially and irreparably harmed if MSN is not enjoined from infringing the '998 patent.

58. 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 '957 PATENT

59. Plaintiffs reallege paragraphs 1-58 as if fully set forth herein.

60. MSN has infringed at least one claim of the '957 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the MSN Empagliflozin/Linagliptin ANDA, by which MSN seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the MSN Empagliflozin/Linagliptin Products prior to the expiration of the '957 patent.

61. MSN has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the MSN Empagliflozin/Linagliptin Products in the event that the FDA approves the MSN Empagliflozin/Linagliptin ANDA. Accordingly, an actual

and immediate controversy exists regarding MSN's infringement of the '957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

62. MSN's manufacture, use, offer to sell, or sale of the MSN Empagliflozin/Linagliptin Products in the United States or importation of the MSN Empagliflozin/Linagliptin Products into the United States during the term of the '957 patent would further infringe at least one claim of the '957 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

63. On information and belief, the MSN Empagliflozin/Linagliptin 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 '957 patent either literally or under the doctrine of equivalents.

64. On information and belief, the use of the MSN Empagliflozin/Linagliptin Products constitutes a material part of at least one of the claims of the '957 patent; MSN knows that its Empagliflozin/Linagliptin Products are especially made or adapted for use in infringing at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents; and its Empagliflozin/Linagliptin Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

65. On information and belief, the offering to sell, sale, and/or importation of the MSN Empagliflozin/Linagliptin Products would contributorily infringe at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

66. On information and belief, MSN had knowledge of the '957 patent and, by its promotional activities and package inserts for its Empagliflozin/Linagliptin Products, knows or

should know that they will aid and abet another's direct infringement of at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

67. On information and belief, the offering to sell, sale, and/or importation of the MSN Empagliflozin/Linagliptin Products by MSN would actively induce infringement of at least one of the claims of the '957 patent, either literally or under the doctrine of equivalents.

68. On information and belief, MSN does not deny that the MSN Empagliflozin/Linagliptin Products will infringe the claims of the '957 patent. In the MSN Empagliflozin/Linagliptin Paragraph IV Certification, MSN did not deny that the MSN Empagliflozin/Linagliptin Products will infringe the claims of the '957 patent.

69. Plaintiffs will be substantially and irreparably harmed if MSN is not enjoined from infringing the '957 patent.

70. 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 MSN and for the following relief:

a. A Judgment be entered that MSN has infringed at least one claim of the '957 and/or '998 patents by submitting the MSN 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 MSN, 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 '957 and/or '998 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '957 and/or '998 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 MSN's 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 '957 and '998 patents, including any extensions;

e. That Boehringer be awarded monetary relief if MSN commercially uses, offers to sell, or sells its respective proposed generic versions of JARDIANCE®, GLYXAMBI®, SYNJARDY® XR, or any other product that infringes or induces or contributes to the infringement of the '957 and/or '998 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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