IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
IPCA LABORATORIES LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, "Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Ipca Laboratories Ltd. ("Ipca" or "Defendant"), 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 Defendant's 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' JARDIANCE® (empagliflozin) tablets prior to the expiration of United States Patent Nos. 11,090,323 and 11,833,166.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having its 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 its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

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

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

6. On information and belief, Defendant Ipca Laboratories Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 125 Kandivali Industrial Estate, Kandivali (West), Mumbai 400 067, Maharashtra, India.

7. Ipca Laboratories Ltd. is referred to hereinafter as "Ipca" or "Defendant."

8. On information and belief, Ipca 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, from which Ipca derives a substantial portion of its revenue.

9. On information and belief, Ipca prepared and submitted ANDA No. 220640 (the "Ipca ANDA") for Ipca's 10 mg and 25 mg empagliflozin tablets for oral administration (the "Ipca ANDA Products").

10. On information and belief, Ipca intends to commercially manufacture, market, offer for sale, and sell the Ipca ANDA Products throughout the United States, including in the State of Delaware, in the event the FDA approves the Ipca ANDA.

JURISDICTION AND VENUE

11. 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).

12. Venue is proper in this Court as to Ipca because, among other things, Ipca is an Indian corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER IPCA LABORATORIES LTD.

13. Plaintiffs reallege and incorporate by reference paragraphs 1–12 as if fully set forth herein.

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

15. This Court has personal jurisdiction over Ipca because, *inter alia*, Ipca, 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 Ipca's infringing ANDA Products to residents of this State upon approval of ANDA No. 220640, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through its agents.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Ipca, this Court may exercise jurisdiction over Ipca pursuant to Fed. R. Civ. P. 4(k)(2)

because: (a) Plaintiffs' claims arise under federal law; (b) Ipca would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Ipca has sufficient contacts with the United States as a whole, including, but not limited to, filing an ANDA 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 Ipca satisfies due process.

THE PATENTS-IN-SUIT

17. On August 17, 2021, the USPTO duly and legally issued United States Patent No. 11,090,323 ("the '323 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 '323 patent is attached as Exhibit A. BII and BIPI collectively own all right, title, and interest in and to the '323 patent.

18. On December 5, 2023, the USPTO duly and legally issued United States Patent No. 11,833,166 ("the '166 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 '166 patent is attached as Exhibit B. BII and BIPI collectively own all right, title, and interest in and to the '166 patent.

JARDIANCE®

19. 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®.

20. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '323 patent and '166 patent are among the patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") with respect to JARDIANCE®.

21. The '323 patent and '166 patent cover the JARDIANCE® product and its use.

ACTS GIVING RISE TO THIS ACTION

22. On information and belief, Ipca submitted the Ipca ANDA to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market the Ipca ANDA Products prior to the expiration of the Plaintiffs' patents covering JARDIANCE®.

23. Ipca has represented that the Ipca ANDA refers to and relies upon the JARDIANCE® NDA and contains data that, according to Ipca, demonstrate the bioavailability or bioequivalence of the Ipca ANDA Products to JARDIANCE®.

24. Plaintiffs received a letter from Ipca on or about August 18, 2025 (the "Ipca Letter"), stating that Ipca had included a certification in the Ipca ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '323 and '166 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Ipca ANDA Products (the "Ipca Paragraph IV Certification"). Therefore, Ipca intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Ipca ANDA Products prior to the expiration of the '323 and '166 patents.

25. On information and belief, Ipca does not dispute that the Ipca ANDA Products will infringe the claims of the'323 and '166 patents in the Ipca Letter.

26. Plaintiffs requested access to Ipca's ANDA pursuant to a proposed modified Offer of Confidential Access ("OCA").

27. Ipca refused to share its ANDA under Plaintiffs' proposed OCA terms and further refused to engage in any discussions regarding modification of the OCA terms.

28. Plaintiffs dispute all grounds for invalidity raised by Ipca in its Paragraph IV Notice Letter and reserve the right to respond in detail to all such arguments and contentions after obtaining discovery and access to Ipca's ANDA and related materials.

29. Provided here as a representative claim for exemplary purposes, claim 1 of the '323 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m^2 and <60 ml/min/1.73 m^2, wherein empagliflozin is administered orally in a total daily amount of 10 mg or 25 mg, wherein the glycemic control in said patient is improved, and discontinuing empagliflozin if the eGFR of the patient falls below 30 ml/min/1.73 m^2."

30. Further, provided here as a representative claim for exemplary purposes, claim 1 of the '166 patent recites: "1. A method for improving glycemic control in a patient with type 2 diabetes mellitus comprising: a) assessing the renal function of the patient; and b) administering empagliflozin to the patient if the eGFR of the patient is ≥45 ml/min/1.73 m^2 and <60 ml/min/1.73 m^2, wherein empagliflozin is administered orally in a total daily amount of 10 mg or 25 mg, and wherein the glycemic control in said patient is improved."

COUNT I — INFRINGEMENT OF THE '323 PATENT

31. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–30.

32. Plaintiffs received a notice letter from Ipca on or about August 18, 2025 stating that Ipca had included certifications in the Ipca ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '323 patent are either invalid or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of the Ipca ANDA Products. Ipca intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ipca ANDA Products prior to the expiration of the '323 patent.

33. In the Ipca Letter received on or about August 18, 2025, Ipca did not dispute infringement of the '323 patent.

34. Ipca has infringed at least one claim of the '323 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Ipca ANDA, by which Ipca seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ipca ANDA Products prior to the expiration of the '323 patent.

35. Ipca has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Ipca ANDA Products in the event that the FDA approves the Ipca ANDA. Accordingly, an actual and immediate controversy exists regarding Ipca's infringement of the '323 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. On information and belief, Ipca's use, offer to sell, or sale of the Ipca ANDA Products in the United States during the term of the '323 patent would further infringe at least one claim of the '323 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

37. On information and belief, the Ipca 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 '323 patent either literally or under the doctrine of equivalents.

38. On information and belief, the use of the Ipca ANDA Products constitutes a material part of at least one of the claims of the '323 patent; Ipca knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

39. On information and belief, the offering to sell or sale of the Ipca ANDA Products would contributorily infringe at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

40. On information and belief, Ipca had knowledge of the '323 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

41. On information and belief, the offering to sell or sale of the Ipca ANDA Products by Ipca would actively induce infringement of at least one of the claims of the '323 patent, either literally or under the doctrine of equivalents.

42. Plaintiffs will be substantially and irreparably harmed if Ipca is not enjoined from infringing the '323 patent.

43. 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 '166 PATENT

44. Plaintiffs reallege and incorporate by reference the allegations contained in paragraphs 1–43.

45. Plaintiffs received a notice letter from Ipca on or about August 18, 2025 stating that Ipca had included certifications in the Ipca ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, inter alia, certain claims of the '166 patent are either invalid or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of the Ipca ANDA Products. Ipca intends to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Ipca ANDA Products prior to the expiration of the '166 patent.

46. Ipca has infringed at least one claim of the '166 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Ipca ANDA, by which Ipca seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ipca ANDA Products prior to the expiration of the '166 patent.

47. In the Ipca Letter received on or about August 18, 2025, Ipca did not dispute infringement of the '166 patent.

48. Ipca has infringed at least one claim of the '166 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Ipca ANDA, by which Ipca seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Ipca ANDA Products prior to the expiration of the '166 patent.

49. Ipca has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Ipca ANDA Products in the event that the FDA approves the Ipca ANDA. Accordingly, an actual and immediate controversy exists regarding Ipca's infringement of the '166 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

50. On information and belief, Ipca's use, offer to sell, or sale of the Ipca ANDA Products in the United States during the term of the '166 patent would further infringe at least one claim of the '166 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

51. On information and belief, the Ipca 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 '166 patent either literally or under the doctrine of equivalents.

52. On information and belief, the use of the Ipca ANDA Products constitutes a material part of at least one of the claims of the '166 patent; Ipca knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '166 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

53. On information and belief, the offering to sell or sale of the Ipca ANDA Products would contributorily infringe at least one of the claims of the '166 patent, either literally or under the doctrine of equivalents.

54. On information and belief, Ipca had knowledge of the '166 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '166 patent, either literally or under the doctrine of equivalents.

55. On information and belief, the offering to sell or sale of the Ipca ANDA Products by Ipca would actively induce infringement of at least one of the claims of the '166 patent, either literally or under the doctrine of equivalents.

56. Plaintiffs will be substantially and irreparably harmed if Ipca is not enjoined from infringing the '166 patent.

57. 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 Ipca and for the following relief:

a. A judgment that Ipca has infringed at least one claim of the '323 and '166 patents;

b. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 enjoining Ipca, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from: (i) manufacturing, using, offering to sell, or selling the Ipca ANDA Product within the United States, or importing the Ipca ANDA Product into the United States prior to the expiration of the '323 and '166 patents, and

(ii) seeking, obtaining or maintaining approval of the Ipca ANDA until the expiration of the '323 and '166 patents or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ipca ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '323 and/or '166 patents, including any extensions;

d. If Ipca manufactures, uses, offers to sell, or sells the Ipca ANDA Product within the United States, or imports the Ipca ANDA Product into the United States, prior to the expiration of the '323 and '166 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

e. A judgment that this is an exceptional case and that Plaintiffs be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

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/ Megan E. Dellinger

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