IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM CORPORATION, Plaintiffs, v. ALKEM LABORATORIES LTD., Defendant	C.A. No. 19-01493-CFC

ALKEM LABORATORIES LIMITED'S ANSWER TO COMPLAINT, ADDITIONAL DEFENSES, AND COUNTERCLAIMS

Defendant, Alkem Laboratories Ltd. ("Alkem" or "Defendant"), hereby answers the Complaint of Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI"), Boehringer Ingelheim International GmbH ("BII"), and Boehringer Ingelheim Corporation ("BIC" and, collectively with BIPI and BII, "Plaintiffs"), 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 and/or GLYXAMBI® (empagliflozin/linagliptin) tablets prior to the expiration of United States Patent No. 10,258,637.

ANSWER

Alkem admits that Plaintiffs' Complaint asserts claims for patent infringement purporting to arise under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. Alkem further admits that Plaintiffs' claims

relate to Alkem's submission of Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of JARDIANCE® (empagliflozin) tablets and GLYXAMBI® (empagliflozin/linagliptin) tablets prior to the expiration of United States Patent No. 10,258,637. Alkem denies the remaining allegations in Paragraph 1 of the Complaint.

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.

ANSWER

On information and belief, Alkem admits the allegations in Paragraph 2 of the Complaint.

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.

ANSWER

On information and belief, Alkem admits the allegations in Paragraph 3 of the Complaint.

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.

ANSWER

On information and belief, Alkem admits the allegations in Paragraph 4 of the Complaint.

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

ANSWER

Paragraph 5 of the Complaint sets forth a statement to which no response is required.

6. On information and belief, Defendant Alkem Laboratories Ltd. ("Alkem Labs") is a corporation organized and existing under the laws of India, having a principal place of business at Senapati Bapat Road, Lower Parel, Mumbai, India 400013.

ANSWER

Alkem admits the allegations in Paragraph 6 of the Complaint.

7. On information and belief, Alkem Labs controls and directs a wholly owned subsidiary in the United States named Ascend Laboratories, LLC ("Ascend Labs"). Ascend Labs is a New Jersey limited liability company having a principal place of business at 339 Jefferson Road, Parsippany, New Jersey 07054.

ANSWER

The allegations in Paragraph 7 of the Complaint appear to be directed to a party, Ascend Laboratories, LLC ("Ascend Labs"), which has been dismissed from the case. On August 26, 2019, the parties filed a Joint Stipulation and [Proposed] Order Dismissing Complaint as to Defendant Ascend Laboratories, LLC and Amendment of Caption (D.I. 7), which was so ordered by Judge Connolly on August 28, 2019 (D.I. 8). Accordingly, no response is required for the allegations in Paragraph 7 of the Complaint. To the extent a response is required, Alkem admits that Ascend Labs is a wholly owned subsidiary of Alkem and has a principal place of business at 339 Jefferson Road, Parsippany, New Jersey 07054. Alkem denies the remaining allegations in Paragraph 7 of the Complaint.

8. On information and belief, Ascend Labs is acting as the U.S. agent of Alkem Labs with respect to ANDA Nos. 212382 and 212366.

ANSWER

Alkem admits that Ascend Labs is listed as the U.S. agent of Alkem with respect to ANDA Nos. 212382 and 212366. Alkem denies the remaining allegations in Paragraph 8 of the Complaint.

9. Alkem Laboratories Ltd. and Ascend Labs are collectively referred to as "Alkem."

ANSWER

Paragraph 9 of the Complaint sets forth a statement to which no response is required.

10. On information and belief, Alkem Labs 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 Ascend Labs, from which Alkem Labs derives a substantial portion of its revenue.

ANSWER

Alkem admits that it is in the business of, *inter alia*, developing, manufacturing, marketing, and selling generic pharmaceutical products. Alkem does not contest personal jurisdiction only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 10 of the Complaint.

11. On information and belief, Alkem Labs acted in concert with Ascend Labs to prepare and submit ANDA No. 212382 (the "Alkem empagliflozin ANDA") for Alkem Labs' 10 mg and 25 mg empagliflozin tablets and ANDA No. 212366 (the "Alkem empagliflozin/linagliptin ANDA") for Alkem Labs' 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (the "Alkem ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Alkem Labs. Following FDA approval of the Alkem empagliflozin ANDA and the Alkem empagliflozin/linagliptin ANDA, Alkem Labs will manufacture and supply the approved generic product to Ascend Labs, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Alkem Labs.

ANSWER

Alkem admits that it prepared and submitted ANDA No. 212382 for its 10 mg and 25 mg empagliflozin tablets and ANDA No. 212366 for its 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets (collectively, "Alkem ANDA Products") and plans to market and sell the Alkem ANDA Products in the United States upon FDA approval. Alkem further admits that Ascend Labs is listed as the U.S. agent of Alkem with respect to ANDA Nos.

212382 and 212366. Alkem denies that it has made any final decision as to the location of any sales of Alkem ANDA Products within the United States or the intermediary or agent for any potential sales. Alkem denies the remaining allegations in Paragraph 11 of the Complaint.

JURISDICTION AND VENUE

12. 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).

ANSWER

Paragraph 12 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alkem admits that Plaintiffs purport to bring this action under the patent laws of the United States, and does not dispute that this Court has subject matter jurisdiction over this action. Alkem denies the remaining allegations in Paragraph 12 of the Complaint.

13. Venue is proper in this Court because, among other things, the defendants are either a foreign corporation not residing in any United States judicial district, or the agent of a foreign corporation. 28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Alkem has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

ANSWER

Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Alkem does not contest venue only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 13 of the Complaint.

14. Ascend has been sued in this district previously, and has not contested personal jurisdiction or venue. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Alkem Labs. Ltd.*, C.A. No. 18-1738-CFC (D. Del.); *Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

ANSWER

The allegations in Paragraph 14 of the Complaint appear to be directed to Ascend Labs which has been dismissed from the case. (D.I. 7, 8). Accordingly, no response is required for Paragraph 14 of the Complaint.

PERSONAL JURISDICTION OVER ALKEM LABS

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

ANSWER

Alkem incorporates by reference and repeats its responses to paragraphs 1-14 above as if fully contained herein.

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

ANSWER

Alkem does not contest personal jurisdiction only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 16 of the Complaint.

17. This Court has personal jurisdiction over Alkem Labs because, *inter alia*, Alkem Labs, 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 Alkem Labs infringing ANDA Products to residents of this State upon approval of ANDA No. 212382 or ANDA No. 212366, 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.

ANSWER

Paragraph 17 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alkem does not contest personal jurisdiction only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 17 of the Complaint.

18. On information and belief, Alkem Labs 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. Alkem Labs. Ltd.*, C.A. No. 18-1738-CFC (D. Del.); *Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

ANSWER

Paragraph 18 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alkem does not contest personal jurisdiction only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 18 of the Complaint.

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

ANSWER

Paragraph 19 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alkem does not contest personal jurisdiction only for the purposes of this case. Alkem denies the remaining allegations in Paragraph 19 of the Complaint.

PERSONAL JURISDICTION OVER ASCEND LABS

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

ANSWER

Alkem incorporates by reference and repeats its responses to paragraphs 1-19 above as if fully contained herein.

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

ANSWER

The allegations in Paragraph 21 of the Complaint appear to be directed to Ascend Labs which has been dismissed from the case. (D.I. 7, 8). Accordingly, no response is required for Paragraph 21 of the Complaint.

22. This Court has personal jurisdiction over Ascend Labs because, *inter alia*, Ascend Labs, on information and belief: (1) intends to market, sell, or distribute Alkem Labs' ANDA Products to residents of this State; (2) is controlled by Defendant Alkem Labs and is acting as the agent of Alkem Labs with respect to Alkem's ANDAs; (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.

ANSWER

The allegations in Paragraph 22 of the Complaint appear to be directed to Ascend Labs which has been dismissed from the case. (D.I. 7, 8). Accordingly, no response is required for Paragraph 22 of the Complaint.

23. On information and belief, Ascend has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Alkem Labs. Ltd.*, C.A. No. 18-1738-CFC (D. Del.); *Takeda Pharms. USA, Inc. v. Alkem Labs., Ltd.*, C.A. No. 18-189-RGA (D. Del.).

ANSWER

The allegations in Paragraph 23 of the Complaint appear to be directed to Ascend Labs which has been dismissed from the case. (D.I. 7, 8). Accordingly, no response is required for Paragraph 23 of the Complaint.

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

24. 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.

ANSWER

Alkem admits that United States Patent No. 10,258,637 ("the '637 patent") is entitled "Pharmaceutical Composition, Method for Treating and Uses Thereof" and states on its face that it was issued on April 16, 2019 to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. Alkem further admits that a purported copy of the '637 patent is attached as Exhibit 1 to the Complaint. On information and belief, Alkem admits that BII is listed as the assignee on the face of the '637 patent. Alkem is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 24 of the Complaint, and therefore denies them.

JARDIANCE®

25. 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®.

ANSWER

Alkem admits that BIPI has been identified to the public as 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®.

26. 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.

ANSWER

Alkem admits that the listing for JARDIANCE® in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") has an entry for New Chemical Entity exclusivity with an expiration date of August 1, 2019.

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

ANSWER

Alkem admits that the '637 patent is listed in the Orange Book in connection with JARDIANCE®. Alkem denies the remaining allegations in Paragraph 27 of the Complaint.

28. The '637 patent covers the use of the JARDIANCE® product.

ANSWER

Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint, and therefore denies them.

GLYXAMBI®

29. 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®.

ANSWER

Alkem admits that BIPI has been identified to the public as the holder of 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®.

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

ANSWER

Alkem admits that the listing for GLYXAMBI® in the Orange Book has an entry for New Chemical Entity exclusivity with an expiration date of August 1, 2019.

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

ANSWER

Alkem admits that the '637 patent is listed in the Orange Book in connection with GLYXAMBI®. Alkem denies the remaining allegations in Paragraph 31 of the Complaint.

32. The '637 patent covers the use of the GLYXAMBI® product.

ANSWER

Alkem is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 32 of the Complaint, and therefore denies them.

ACTS GIVING RISE TO THIS ACTION
CLAIM FOR RELIEF — INFRINGEMENT OF THE '637 PATENT

33. Plaintiffs reallege paragraphs 1-32 as if fully set forth herein.

ANSWER

Alkem incorporates by reference and repeats its responses to paragraphs 1-32 above as if fully contained herein.

34. On information and belief, Alkem submitted the Alkem empagliflozin ANDA and the Alkem empagliflozin/linagliptin ANDA (collectively, the "Alkem ANDAs") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Alkem ANDA Products.

ANSWER

Alkem admits the allegations in Paragraph 34 of the Complaint.

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

ANSWER

Alkem admits the allegations in Paragraph 35 of the Complaint.

36. Plaintiffs received letters from Alkem on or about June 7, 2019 stating that Alkem had included certifications in the Alkem ANDAs, 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 Alkem ANDA Products (the "Alkem Paragraph IV Certifications"). Alkem intends to engage in the commercial manufacture, use, offer for sale, and/or sale of their ANDA Product prior to the expiration of the '637 patent.

ANSWER

Alkem admits the allegations in Paragraph 36 of the Complaint.

37. Alkem 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 Alkem ANDAs, by which Alkem seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Alkem ANDA Products prior to the expiration of the '637 patent.

ANSWER

Alkem denies the allegations in Paragraph 37 of the Complaint.

38. Alkem has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alkem ANDA Products in the event that the FDA approves the Alkem ANDAs. Accordingly, an actual and immediate controversy exists regarding Alkem infringement of the '637 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

ANSWER

The allegations in Paragraph 38 contain conclusions of law as to which no response is required. To the extent any response is required, Alkem admits that it intends to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Alkem ANDA Products in the event that the FDA approves the Alkem ANDAs.

39. Alkem's use, offer to sell, or sale of the Alkem ANDA Products in 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).

ANSWER

Alkem denies the allegations in Paragraph 39 of the Complaint.

40. On information and belief, Alkem's ANDA Products, when offered for sale, sold, and/or 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.

ANSWER

Alkem denies the allegations in Paragraph 40 of the Complaint.

41. On information and belief, the use of Alkem's ANDA Products constitutes a material part of at least one of the claims of the '637 patent; Alkem 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.

ANSWER

Alkem denies the allegations in Paragraph 41 of the Complaint.

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

ANSWER

Alkem denies the allegations in Paragraph 42 of the Complaint.

43. On information and belief, Alkem had knowledge of the '637 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 '637 patent, either literally or under the doctrine of equivalents.

ANSWER

Alkem states that it was not aware of the '637 patent when it submitted its ANDA Nos. 212382 and 212366 because the '637 patent issued after Alkem's ANDAs were filed. Alkem admits that it became aware of the '637 patent after it issued. Alkem denies the remaining allegations in Paragraph 43 of the Complaint.

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

ANSWER

Alkem denies the allegations in Paragraph 44 of the Complaint.

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

ANSWER

Alkem denies the allegations in Paragraph 45 of the Complaint.

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

ANSWER

Alkem denies the allegations in Paragraph 46 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Alkem denies that Plaintiffs are entitled to the judgment or other relief prayed for in paragraphs a-g under the heading "Prayer for Relief" in the Complaint. Alkem respectfully requests that the Court dismiss the complaint with prejudice, enter judgment in favor of Alkem, award Alkem its reasonable attorneys' fees and costs incurred in defending this suit, and award Alkem such other relief as the Court deems just and proper.

ADDITIONAL DEFENSES

Further answering the complaint, and as additional defenses thereto, Alkem asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Alkem does not assume the burden of proof with respect to those matters that, under law, Plaintiffs bear the burden of proof.

First Additional Defense

The manufacture, use, or sale of the Alkem ANDA Products has not infringed, induced infringement or contributed to infringement, and, if marketed, will not infringe, induce the infringement of, or contribute to the infringement of any valid and/or enforceable claim of the '637 patent, either literally or under the doctrine of equivalents.

Second Additional Defense

The claims of the '637 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. § 101 et seq., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, double patenting, or under other judicially-created bases for invalidation or unenforceability.

Third Additional Defense

The complaint fails to state a claim upon which relief can be granted.

Fourth Additional Defense

Plaintiffs are not entitled to injunctive relief because they have not and cannot prove the required elements to obtain such relief, including that: (1) they have suffered irreparable injury; (2) there is no adequate remedy at law; (3) a remedy in equity is warranted; and (4) the public interest warrants an injunction.

Fifth Additional Defense

Any additional legal or equitable defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability, as well as any defenses raised by another defendant in another action concerning the '637 patent.

COUNTERCLAIMS

Counterclaim-Plaintiff Alkem Laboratories Ltd. ("Alkem"), for its counterclaims against Counterclaim-Defendants Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI"), Boehringer Ingelheim International GmbH ("BII") and Boehringer Ingelheim Corporation ("BIC") (collectively, "Boehringer" or "Counterclaim-Defendants"), alleges as follows:

THE PARTIES

1. Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, India.

2. Upon information and belief, and based on Paragraph 2 of the Complaint, 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. Upon information and belief, and based on Paragraph 3 of the Complaint, 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. Upon information and belief, and based on Paragraph 4 of the Complaint, BIC is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT 06877.

JURISDICTION AND VENUE

5. This is an action for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202, together with such further and other relief that may be necessary or proper. The basis for declaratory judgment is an actual controversy between Alkem and Counterclaim-Defendants arising under the United States patent laws, Title 35 of the

United States Code. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§1331 and 1338 and 21 U.S.C. §355(j)(5)(C).

6. This Court has personal jurisdiction over Counterclaim-Defendants at least because they voluntarily filed, in this Court, the Complaint to which these Counterclaims are directed.

7. Venue is proper in this District pursuant to 28 U.S.C. §§1391 and 1400.

BACKGROUND

8. Alkem filed with the United States Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") No. 212382 seeking approval to engage in the commercial manufacture, use or sale of its 10 mg and 25 mg empagliflozin tablets ("Alkem's empagliflozin Product"), referencing Boehringer's approved NDA No. 204629.

9. Alkem also filed with the FDA its ANDA No. 212366 seeking approval to engage in the commercial manufacture, use or sale of its 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets ("Alkem's empagliflozin/linagliptin Product" and collectively with Alkem's empagliflozin Product, "Alkem's ANDA Products"), referencing Boehringer's approved NDA No. 206073.

10. Upon information and belief, BIPI is the current holder of NDA No. 204629 for empagliflozin, for oral use, in 10 mg and 25 mg dosages, which is sold under the trade name JARDIANCE®.

11. Upon information and belief, BIPI is the current holder of 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®.

12. United States Patent No. 10,258,637 ("the '637 patent") is entitled "Pharmaceutical Composition, Method for Treating and Uses Thereof" and states on its face that it was issued on April 16, 2019 to inventors Uli Christian Broedl, Sreeraj Macha, Maximilian von Eynatten, and Hans-Juergen Woerle. Counterclaim-Defendant BII is listed as the assignee on the face of the '637 patent.

13. The '637 patent is listed in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluation," also known as the "Orange Book," in connection with both JARDIANCE® and GLYXAMBI®.

14. On or about June 5, 2019, for each of its ANDAs, Alkem submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) ("Paragraph IV certification") stating that the '637 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the Alkem's ANDA Products.

15. On or about June 5, 2019, Alkem also sent notice letters concerning its Paragraph IV certifications for ANDA Nos. 212382 and 212366 (the "Notice Letters") by FedEx to the Counterclaim-Defendants.

16. The Notice Letters included detailed statements of the factual and legal bases for Alkem's view that the '637 patent is invalid, unenforceable, and/or would not be infringed by the Alkem's ANDA Products. The Notice letters also contained Offers of Confidential Access ("OCA") offering to provide certain Authorized Evaluators with certain portions of Alkem's ANDAs for the purpose of evaluating whether suit should be brought.

17. Counterclaim-Defendants have actual knowledge of the contents of the Notice Letters.

18. Counterclaim-Defendants filed the Complaint in this Court against Alkem alleging that the filing of Alkem's ANDA Nos. 212382 and 212366 infringed the '637 patent and that any commercial manufacture, use, or sale of the products which are the subject of these ANDAs would infringe the '637 patent.

19. An actual and justiciable controversy exists regarding the '637 patent by virtue of the filing of the Complaint by Counterclaim-Defendants. Thus, an actual controversy exists between Alkem and Counterclaim-Defendants as to whether any valid claim of the '637 patent is or will be infringed by the commercial manufacture, use or sale of Alkem's ANDA Products. Alkem requires an immediate declaration of its rights vis-à-vis Counterclaim-Defendants with respect to the products which are the subject of Alkem's ANDA Nos. 212382 and 212366 and the '637 patent.

FIRST COUNTERCLAIM

(Declaration of Invalidity of the '637 Patent)

20. Alkem incorporates by reference the allegations set forth in each preceding paragraph of the Counterclaims as if fully set forth herein.

21. All claims of the '637 patent are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, double patenting, and/or other judicially-created bases for invalidation, at least for the reasons Alkem presented in the Notice Letters, which are incorporated hereby by reference.

22. For example, all of the claims of the '637 patent are invalid for obviousness.

23. As an example, claim 1 of the '637 patent is directed to a method for improving glycemic control in patients with type-2 diabetes mellitus ("T2DM") comprising administering empagliflozin to a patient if the eGFR of the patient is within the recited range of ≥45

ml/min/1.73 m^2 and <60 ml/min/1.73 m^2 and discontinuing empagliflozin if the eGFR falls below 45 ml/min/1.73 m^2.

24. Empagliflozin, 1-chloro-4-(β-D-glucopyranos-1-yl)-2-4-((R)-tetrahydrofuran-3-yloxy)-benzyl-benzene, was disclosed in the prior art as an SGLT2 inhibitor, for example, in US 2006/0251728. As of at least January 2012, the name "empagliflozin" and the code number "BI 10773" were disclosed to be the same compound. Grempler, et al., "Empagliflozin, a novel selective sodium glucose cotransporter-2 (SGLT-2) inhibitor: characterization and comparison with other SGLT-2 inhibitors," *Diabetes, Obesity and Metabolism* **2012**, *14*, 83-90 ("Grempler") at p. 84.

25. Prior art disclosed that "BI 10773," *i.e.*, empagliflozin, had been tested for efficacy and safety in 495 T2DM patients inadequately controlled on metformin. Seman et al., "ENCORE: efficacy and safety of BI 10773, a new sodium glucose co-transporter-2 (SGLT-2) inhibitor, in type 2 diabetes patients inadequately controlled on metformin (abstract), *Diabetologia* **2011**, *54 (Suppl. 1)*, S67-S68, ("Seman").

26. Grempler disclosed that empagliflozin was being investigated in Phase III clinical trials as a selective SGLT2 inhibitor for the treatment of T2DM. Grempler at pp. 83, 88.

27. As of at least October 23, 2011, Clinical Trials.gov was reporting an October 19, 2011 update of a Phase III Trial on the use of empagliflozin in T2DM patients with insufficient glycemic control. Study NCT01210001, v15, October 19, 2011. *See* Wayback Machine https://web.archive.org/web/20111023032502/https://clinicaltrials.gov/ct2/show/NCT01210001. This report disclosed treatment of patients with T2DM and insufficient glycemic control by administering a total daily amount of 10 mg or 25 mg empagliflozin where patients with eGFR < 30 ml/min were excluded from the study.

28. Further, before the effective filing date of the '637 patent, a person of ordinary skill in the art knew that canagliflozin, an SGLT2 inhibitor in the same class as empagliflozin, had only been approved for patients with eGFR of at least 45. Thus, based on the need for glycemic control in T2DM patients with eGFR less than 60, and the known method of action for SGLT2 inhibitors, which requires kidney function to be effective, it was obvious for the person of ordinary skill to be focused on the group of T2DM patients with eGFR of at least 45 and less than 60.

29. On March 29, 2013, the FDA approved canagliflozin for sale under the tradename Invokana®. The '637 patent states that the Label for Invokana® was published by the FDA on March 29, 2013, making the Label prior art to the '637 patent under the AIA. The Invokana® Label stated that (i) canagliflozin should not be initiated in patients with an eGFR less than 45 mL/min/1.73 m^2, and (ii) canagliflozin should be discontinued if eGFR is persistently less than 45 mL/min/1.73 m^2.

30. It was well known that there were challenges to achieving glycemic control in T2DM Patients with chronic renal disease ("CKD"). *E.g.* Chow, et al., "Challenges in achieving optimal glycemic control in type 2 diabetes patients with declining renal function: The Southeast Asia perspective," *Journal of Diabetes Investigation* **2012**, *3*, 481-489) ("Chow"). Chow discloses that although there were a number of oral anti-diabetics for patients with CKD, the use of oral drugs to treat diabetes in patients with CKD stages 3-5 "poses a particular challenge." *Id.* p. 485. It was further known that stage 3 CKD corresponded to a GFR of at least 30 to less than 60 mL/min/1.73 m^2. Levey et al., "Definition and classification of chronic kidney disease: A position statement from Kidney Disease: Improving Global Outcomes (KDIGO)," *Kidney International* **2005**, *67*, 2089-2100, p. 2094, Table 4.

31. Accordingly, a person of ordinary skill was highly motivated to develop oral drugs to achieve glycemic control in T2DM patients with GFR less than 60 mL/min/1.73 m^2.

32. It was known that because the mechanism of action for an SGLT2 inhibitor depends on inhibiting the reabsorption of glucose filtered by the kidney, the effectiveness of SGLT2 inhibitors in lowering blood sugar decreases with decreasing GFR. Ferrannini, et al., "SGLT2 inhibition in diabetes mellitus: rationale and clinical prospects," *Nature Reviews Endocrinology* **2012**, *8*, 495-502 ("Ferrannini") at p. 5. Thus, the person of ordinary skill understood that although there was a need for oral antidiabetics drugs to treat patients with GFR lower than 60, it was important to determine a lower limit of GFR when using an SGLT2 inhibitor for glycemic control in patients with T2DM

33. Accordingly, based on the disclosure of the prior art (*e.g.*, Seman, Grempler, Ferrannini and Study NCT01210001), it was obvious to orally administer a total daily amount of 10 mg or 25 mg of empagliflozin as an SGLT2 inhibitor for glycemic control in patients with type 2 diabetes with a reasonable expectation of success. Based on at least NCT01210001, a Phase III trial which excluded patients with eGFR below 30, it was reasonable to expect that empagliflozin would show at least some efficacy for patients with eGFR greater than 30. Based on the recognized need for glycemic control in T2DM patients with GFR less than 60 (*e.g.*, Chow) and the fact that a drug in the same class, canagliflozin, was only approved to be initiated in patients with eGFR of at least 45 (Invokana® Label), it was obvious to select T2DM patients with eGFR assessed to be at least 45 and less than 60 as a specific target population, with a reasonable expectation of success. Based on the Invokana® Label, it was obvious to discontinue treatment with empagliflozin if eGFR falls below 45. Accordingly, the method of claim 1 of the '637 patent is prima facie obvious.

34. Further, the efficacy of empagliflozin for patients with eGFR in the range of at least 45 to less than 60 was not unexpected. To the contrary, the decrease in empagliflozin's efficacy at eGFR of at least 45 to below 60 compared to its efficacy at eGFR of at least 60 to below 90 (*see* Jardiance Summary Basis of Approval, Summary, Table 2, p. 8 of 15) was expected based on what was known about the method of action for SGLT2 inhibitors. Accordingly, the effectiveness of empagliflozin at eGFR of at least 45 to below 60 does nothing to rebut the overwhelming evidence of obviousness

35. Alkem reserves the right to provide additional bases for invalidity of the '637 patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

36. Alkem is entitled to a declaratory judgment that the claims of the '637 patent are invalid.

SECOND COUNTERCLAIM

(Declaration of Non-Infringement of the '637 Patent)

37. Alkem incorporates by reference the allegations set forth in each preceding paragraph of the Counterclaims as if fully set forth herein.

38. The commercial manufacture, use, offer for sale, sale or importation of Alkem's empagliflozin Product has not infringed, does not infringe, and will not directly or indirectly infringe any claims of the '637 patent, either literally or under the doctrine of equivalents, for at least the reasons Alkem presented in the Notice Letters, which are incorporated herein by reference.

39. The commercial manufacture, use, offer for sale, sale or importation of Alkem's empagliflozin/linagliptin Product has not infringed, does not infringe, and will not directly or

indirectly infringe any valid and enforceable claims of the '637 patent, either literally or under the doctrine of equivalents, for at least the reasons Alkem presented in the Notice Letters, which are incorporated herein by reference.

40. For example, Alkem's ANDA Products will not directly infringe any claim of the '637 patent because each of these claims is directed to a method and Alkem will be marketing a product. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 & n.7 (Fed. Cir. 2003) (finding no evidence of direct infringement under § 271(a), which is "hardly surprising" because "pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians.").

41. Alkem will not induce infringement of the '637 patent because the proposed labels of Alkem's ANDA Products do not encourage, recommend, or promote determining if the patient's eGFR is within the range recited in the claims.

42. Alkem reserves the right to provide additional bases for non-infringement of the '637 patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

43. Counterclaim-Defendants bear the burden of proving infringement and will not be able to meet that burden.

44. Alkem is entitled to a declaratory judgment that Alkem's ANDA Products do not infringe, directly or indirectly, any claims of the '637 patent.

PRAYER FOR RELIEF

WHEREFORE, Alkem respectfully requests the Court enter a Judgment and Order in its favor and against Counterclaim-Defendants to include:

A. A declaration that the claims of the '637 patent are invalid;

B. A declaration that Alkem's submission of ANDA No. 212382 seeking FDA approval to market its 10 mg and 25 mg empagliflozin tablets, and ANDA No. 212366 seeking FDA approval to market its 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets, before the expiration of the '637 patent, has not infringed, and will not infringe, any valid and enforceable claim of the '637 patent;

C. A declaration that Alkem's commercial manufacture, use, offer for sale, sale, or importation of the 10 mg and 25 mg empagliflozin tablets that are the subject of ANDA No. 212382, and the 10 mg/5 mg and 25 mg/5 mg empagliflozin/linagliptin tablets that are the subject of ANDA No. 212366, will not infringe, induce infringement, or contribute to any infringement of any valid and enforceable claim of the '637 patent;

D. A declaration that Counterclaim-Defendants are entitled to no damages, interest, costs, or other relief from or against Alkem;

E. A declaration that this is an exceptional case under 35 U.S.C. § 285 and awarding Alkem its attorneys' fees, costs, and expenses;

F. A declaration that Counterclaim-Defendants are not entitled to injunctive relief;

G. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendants, from taking any action to prevent FDA approval of ANDA Nos. 212382 and 212366 and the Alkem ANDA Products described therein;

H. A declaration preliminarily and permanently enjoining Counterclaim-Defendants, their officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendants, from asserting or otherwise seeking to enforce the

'637 patent against Alkem or anyone in privity with Alkem in connection with the Alkem ANDA Products;

I. Awarding Alkem the costs of this action;

J. Dismissing Counterclaim-Defendants' Complaint with prejudice and denying each and every request for relief contained therein; and

K. Awarding to Alkem such other and further relief as the Court may deem just and proper.

Dated: September 4, 2019

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