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. 1:20-cv-01585-CFC
v.	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., and OHM LABORATORIES, INC.,	)	
Defendants.	)	

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS FOR DECLARATORY JUDGMNET OF DEFENDANTS SUN PHARMACEUTICAL INDUSTRIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., AND OHM LABORATORIES, INC.

Defendants Sun Pharmaceutical Industries Limited ("Sun Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), and Ohm Laboratories, Inc. ("Ohm Labs") (collectively, "Sun") by and through the undersigned attorneys, answer the Complaint of Plaintiffs Boehringer Ingelheim Inc., Boehringer Ingelheim International GMBH, and Boehringer Ingelheim Corporation (collectively, "Boehringer") 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 generic versions of Plaintiffs' TRIJARDY XR® (empagliflozin/linagliptin/metformin extended-release) tablets prior to the expiration of United States Patent No. 7,579,449 ("the '449 Patent").

ANSWER: Sun admits that Plaintiffs' Complaint against Sun is for infringement of U.S. Patent Nos. 7,579,449 ("the '449 Patent") arising under the Food and Drug Laws and Patent

Laws of the United States, Titles 21 and 35 of the United States Code, respectively, but denies that Plaintiffs are entitled to any such relief. Sun further admits that it submitted an Abbreviated New Drug Application ("ANDA") seeking U.S. Food and Drug Administration ("FDA") approval to market a generic empagliflozin/linagliptin/metformin extended-release tablets product, which Plaintiffs market as Trijardy® XR, prior to the expiration of the patent-in-suit. Sun denies any remaining allegations in paragraph 1.

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, Sun admits that Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a company organized and existing under the laws of the state of Delaware. Sun lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 2, and therefore, denies those allegations.

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, Sun admits that Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany. Sun lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 3, and therefore, denies those allegations.

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, Sun admits that Plaintiff Boehringer Ingelheim Corporation ("BIC") is a company organized and existing under the laws of Nevada. Sun lacks

knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 4, and therefore, denies those allegations.

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

ANSWER: Paragraph 5 does not contain any allegations and, therefore, no response is required.

6. On information and belief, Defendant Sun Pharmaceutical Industries Limited ("Sun Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot No. 201 B/l, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India, 400063.

ANSWER: Admitted.

7. On information and belief, Sun Ltd. controls and directs a wholly owned subsidiary in the United States named Sun Pharmaceutical Industries, Inc. ("Sun Inc"). Sun Inc. is a Michigan corporation having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. is a wholly owned subsidiary of Sun Ltd., but denies that Sun Inc. is a Michigan corporation with a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

8. On information and belief, Sun Ltd. controls and directs a wholly owned subsidiary in the United States named Ohm Laboratories, Inc. ("Ohm Labs"). Ohm Labs is a Delaware corporation, having a principal place of business at 14 Terminal Rd, New Brunswick, NJ 08901.

ANSWER: Admitted.

9. Sun Ltd., Sun Inc., and Ohm Labs are collectively referred to as "Sun."

ANSWER: Paragraph 9 does not contain any allegations and, therefore, no response is required.

10. On information and belief, Sun 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 Sun Inc. and Ohm Labs from which Sun Ltd. derives a substantial portion of its revenue.

ANSWER: Sun admits that Sun Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, and that it distributes, sells, and markets generic drugs throughout the United States, including within the state of Delaware, through its agents and subsidiaries, including Sun Inc. and Ohm Labs. Sun denies any remaining allegations of paragraph 10.

11. On information and belief, Sun Ltd. acted in concert with Sun Inc. and Ohm Labs to prepare and submit ANDA No. 214843 (the "Sun ANDA") for Sun's 5 mg/2.5 mg/1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/2.5 mg/1000 mg, and 25 mg/5 mg/1000 mg empagliflozin- linagliptin-metformin hydrochloride extended-release tablets (the "Sun ANDA Product").

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Sun Ltd. admits that it consulted with Sun Inc. and Ohm Labs to prepare ANDA No. 214843 ("Sun's ANDA") and submitted Sun's ANDA for Sun's empagliflozin/linagliptin/metformin extended-release tablets product ("Sun's ANDA Product"). Sun denies any remaining allegations in paragraph 11.

12. On information and belief, following FDA approval of the Sun ANDA, Ohm Labs will manufacture and supply the approved generic products to Sun Inc., which will then market and sell the products throughout the United States, all at the direction, under the control, and for the direct benefit of Sun Ltd.

ANSWER: Sun admits that it filed Sun's ANDA to market Sun's ANDA Product. Sun denies any remaining allegations in paragraph 12.

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).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that this action cites the patent laws of the United States generally. Sun does not contest that this Court has jurisdiction over the subject

matter of this action against Sun for the purposes of the asserted patents in this action only. Sun denies any remaining allegations in paragraph 13.

14. Venue is proper in this Court because, among other things, each Defendant 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 and/or is a foreign corporation or the agent of a foreign corporation not residing in any United States judicial district, which may be sued in any judicial district. 28 U.S.C. § 1391(c); 28 U.S.C. § 1400(b). Moreover, Sun has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun does not contest that venue for Plaintiffs' infringement action is proper in this Court for the purposes of this action only. Ohm Labs further admits that it is incorporated in Delaware. Sun also admits that it has litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware. Sun denies any remaining allegations in paragraph 14.

PERSONAL JURISDICTION OVER SUN LTD.

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

ANSWER: Sun repeats and incorporates by reference its answers to paragraphs 1–14 as if fully set forth herein.

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

ANSWER: Sun admits that Sun Ltd. is in the business of developing and manufacturing generic pharmaceutical products for sale and use throughout the United States. Sun denies any remaining allegations in this paragraph.

17. This Court has personal jurisdiction over Sun Ltd. because, *inter alia*, Sun, 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 the infringing Sun ANDA Product to residents of this State upon approval of ANDA No. 214843, 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 Ohm Labs, which is incorporated in Delaware and through Sun Inc., which is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation; (4) wholly owns Ohm Labs, which is a Delaware corporation; and (5) wholly owns Sun Inc., which is registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun Ltd. does not contest personal jurisdiction for Plaintiffs' infringement action in this Court for the purposes of this action only. Sun denies any remaining allegations in Paragraph 17.

18. On information and belief, Sun Ltd. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its AND As, and it has filed counterclaims in such cases. *See, e.g., Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1765-CFC (D. Del.); *Pfizer Inc. et al. v. Sun Pharmaceutical Industries Ltd. Et al.*, C.A. No. 17-1597-LPS (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1153-CFC (D. Del).

ANSWER: Admitted.

19. Alternatively, to the extent the above facts do not establish personal jurisdiction over Sun Ltd., this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Sun Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing AND As 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 Sun Ltd. satisfies due process.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun Ltd. does not contest personal jurisdiction for Plaintiffs' infringement actions in this Court for the purposes of this action only. Sun denies any remaining allegations in paragraph 19.

PERSONAL JURISDICTION OVER OHM LABS

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

ANSWER: Sun repeats and incorporates by reference its answers to paragraphs 1–19 as if fully set forth herein.

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

ANSWER: Admitted.

22. This court has personal jurisdiction over Ohm Labs because, *inter alia*, Ohm Labs, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to make Sun's ANDA Product available in this State; and (3) enjoys substantial income from sales of its generic products in this State.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Ohm Labs does not contest personal jurisdiction for Plaintiffs' infringement action in this Court for the purposes of this action only. Ohm Labs further admits that it is incorporated in Delaware. Sun denies any remaining allegations in paragraph 22.

23. On information and belief, Ohm Labs has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its AND As. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1765-CFC (D. Del.); *Shire LLC et al. v. Ranbaxy Laboratories Ltd. et al.*, C.A. No. 14-827-RGA (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1153-CFC (D. Del.).

ANSWER: Admitted.

PERSONAL JURISDICTION OVER SUN INC.

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

ANSWER: Sun repeats and incorporates by reference its answers to paragraphs 1–23 as if fully set forth herein.

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

ANSWER: Admitted.

26. This Court has personal jurisdiction over Sun Inc. because, *inter alia*, Sun Inc., on information and belief: (1) is registered to do business in this State (File Number 4020865); (2) is

registered as a pharmacy wholesaler and controlled substances distributor/manufacturer with the Delaware Division of Professional Regulation; (3) intends to market, sell, or distribute Sun's ANDA Product to residents of this State; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sale of its generic pharmaceutical products in this State.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun Inc. does not contest personal jurisdiction for Plaintiffs' infringement action in this Court for the purposes of this action only. Sun further admits that it is registered to do business in Delaware. Sun denies any remaining allegations in paragraph 26.

27. On information and belief, Sun Inc. has not contested jurisdiction in Delaware in one or more prior cases arising out of the filing of its AND As. *See, e.g., Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.,* C.A. No. 18-1765-CFC (D. Del.); *Novartis Pharmaceuticals Corporation v. Sun Pharmaceutical Industries, Ltd. et al.,* C.A. No. 18-1040-LPS (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.,* C.A. No. 20-1153-CFC (D. Del).

ANSWER: Admitted.

BACKGROUND

U.S. PATENT NO. 7,579,449

28. On August 25, 2009, the USPTO duly and legally issued United States Patent No. 7,579,449 ("the '449 Patent") entitled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process For Their Manufacture" to inventors Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Barsoumian, and Leo Thomas. A true and correct copy of the '449 Patent is attached as Exhibit 1. The '449 Patent is assigned to BII. BIC and BIPI are licensees of the '449 Patent.

ANSWER: Sun admits that the USPTO issued the '449 patent titled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process For Their Manufacture" on August 25, 2009, but specifically denies the patent was duly and legally issued. Sun admits that the '449 patent lists Matthias Eckhardt, Peter Eickelmann, Frank Himmelsbach, Edward Leon Barsoumian, and Leo Thomas as inventors on the face of the patent. Sun admits that a purported copy of the '449 patent was attached to Plaintiffs' Complaint

as Exhibit 1. Sun also admits that the face of the '449 patent lists BII as an assignee. Sun denies any remaining allegations of paragraph 28.

TRIJARDY XR®

29. BIPI is the holder of New Drug Application ("NDA") No. 212614 for empagliflozin-linagliptin-metformin hydrochloride extended-release tablets, for oral use, in 5 mg/2.5 mg/1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/2.5 mg/1000 mg, and 25 mg/5 mg/1000 mg dosages, which is sold under the trade name TRIJARDY XR®.

ANSWER: Sun admits that the FDA's website indicates that BIPI is the holder of NDA No. 212614 for empagliflozin/linagliptin/metformin hydrochloride extended-release tablets, for oral use, in 5 mg/2.5 mg/1000 mg, 10 mg/5 mg/1000 mg, 12.5 mg/1.5 mg/1000 mg, and 25 mg/5 mg/1000 mg dosages, which is sold as Trijardy® XR.

30. TRIJARDY XR® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book").

ANSWER: Sun admits that Trijardy® XR is listed in the FDA's Orange Book.

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '449 Patent is listed in the Orange Book with respect to TRIJARDY XR®.

ANSWER: Sun admits that as of the date of this Answer the '449 patent is listed in the FDA's Orange Book in connection with NDA No. 212614. Sun denies any remaining allegations in paragraph 31.

32. The '449 Patent covers the pharmaceutical composition and use of TRIJARDY XR®.

ANSWER: This paragraph contains conclusions of law for which no response is required. Sun admits that, as of the date of this Answer, the '449 patent is listed in the FDA's Orange Book in connection with NDA No. 212614. Sun denies any remaining allegations of Paragraph 32.

ACTS GIVING RISE TO THIS ACTION

COUNT I — INFRINGEMENT OF THE '449 PATENT

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

ANSWER: Sun repeats and incorporates by reference its answers to paragraphs 1–32 as if fully set forth herein.

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

ANSWER: Admitted.

35. Sun has represented that the Sun ANDA refers to and relies upon the TRIJARDY XR® NDA and contains data that, according to Sun, demonstrate the bioavailability or bioequivalence of the Sun ANDA Product to TRIJARDY XR®.

ANSWER: Admitted.

36. Plaintiffs received a letter from Sun on or about October 14, 2020 stating that Sun had included certifications in the Sun ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '449 Patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Sun ANDA Product (the "Sun Paragraph IV Certification"). Sun intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Sun ANDA Product prior to the expiration of the '449 Patent.

ANSWER: Sun admits that it sent letters to Plaintiffs on or about October 12, 2020 that provided written notice of Sun's ANDA and Paragraph IV Certifications and included a statement of the factual and legal bases for stating that the '449 patent is invalid, unenforceable, and/or will not be infringed by Sun's ANDA Product. Sun lacks knowledge of information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

37. Sun has infringed at least one claim of the '449 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted, the Sun AND A, by which Sun seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sun AND A Product prior to the expiration of the '449 Patent.

ANSWER: Denied.

38. Sun has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sun ANDA Product in the event that the FDA approves the Sun ANDA. Accordingly, an actual and immediate controversy exists regarding Sun's infringement of the '449 Patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that it filed the Sun ANDA seeking FDA approval for the commercial marketing and sale of its ANDA Product in the United States. Sun denies the remaining allegations of this paragraph and specifically denies that Sun's ANDA infringes any valid patents.

39. Sun's use, offer to sell, or sale of the Sun ANDA Product in the United States during the term of the '449 Patent would further infringe at least one claim of the '449 Patent under 35 U.S.C. §§271 (a), (b), and/or (c).

ANSWER: Denied.

40. On information and belief, the Sun ANDA Product, 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 '449 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

41. On information and belief, the use of the Sun ANDA Product constitutes a material part of at least one of the claims of the '449 Patent; Sun knows that its ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents; and its ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

ANSWER: Denied.

42. On information and belief, the offering to sell or sale of the Sun ANDA Product would contributorily infringe at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

43. On information and belief, Sun had knowledge of the '449 Patent and, by its promotional activities and package inserts for its ANDA Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

ANSWER: Sun admits that it was aware of the existence of the '449 patent when it submitted its ANDA, but Sun denies that Sun's ANDA infringes any valid patents. Sun denies any remaining allegations in paragraph 43.

44. On information and belief, the offering to sell or sale of the Sun ANDA Product by Sun would actively induce infringement of at least one of the claims of the '449 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

45. On information and belief, Sun does not deny that the Sun ANDA Product will infringe the claims of the '449 Patent and in the Sun Paragraph IV Certification, Sun did not deny that the Sun ANDA Product subject to ANDA No. 214843 will infringe the claims of the '449 Patent.

ANSWER: Denied.

46. Plaintiffs will be substantially and irreparably harmed if Sun is not enjoined from infringing the '449 Patent.

ANSWER: Denied.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Sun denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or to any relief whatsoever, including those specifically requested as against Sun.

SUN'S AFFIRMATIVE DEFENSES

Further Answering the Complaint, Sun asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses denominated below. Sun reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Sun asserts the

following defenses without prejudice to the denials in this answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

The ’449 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(No Direct Infringement)

Sun does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’449 patent. If the product that is the subject of ANDA No. 214843 were marketed, Sun would not infringe any valid and enforceable claim of the ’449 patent.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Sun has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the of the ’449 patent. If the product that is the subject of ANDA Nos. 214843 were marketed, Sun would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’449 patent.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Sun.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Sun for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Sun has not willfully infringed any claim of the ’449 patent.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Defendant Sun respectfully requests that Plaintiffs take nothing by way of their Complaint, that judgment be entered in favor of Sun, that Sun be awarded its attorneys' fees and costs, and all other just and proper relief.

SUN LTD., SUN PHARMACEUTICALS, INC., AND OHM LABS' COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For their counterclaim against Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI"); Boehringer Ingelheim International GmbH ("BII"); and Boehringer Ingelheim Corporation ("BIC"),[1] Defendants Sun Pharmaceutical Industries Limited ("Sun Ltd."), Sun Pharmaceutical Industries, Inc. ("Sun Inc."), and Ohm Laboratories, Inc. ("Ohm Labs") (collectively, "Counterclaim Plaintiffs" or "Sun") state as follows:

THE PARTIES

1. On information and belief, 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.

2. On information and belief, 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.

[1] BIPI, BII, and BIC hereinafter are collectively referred to as "Counterclaim Defendants" or "Boehringer."

3. On information and belief, 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.

4. Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, Plot No 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India, 400063.

5. Sun Inc. is a Michigan corporation having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

6. Ohm Labs is a Delaware corporation having a principal place of business at 14 Terminal Rd., New Brunswick, NJ 08901.

JURISDICTION AND VENUE

7. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Counterclaim Defendants on the basis of, *inter alia*, their contacts with Delaware relating to the subject matter of this action, including having filed suit.

9. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

10. Upon information and belief, BIPI holds approved New Drug Application ("NDA") No. 214843 for TRIJARDY XR®, which contains the active ingredients empagliflozin, linagliptin, and metformin extended-release.

11. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a

claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

12. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. U.S. Patent No. 7,579,449 ("'449 patent") titled "Glucopyranosyl-Substituted Phenyl Derivatives, Medicaments Containing Such Compounds, Their Use and Process for Their Manufacture" was issued August 25, 2009.

14. Upon information and belief, BII is the assignee of the '449 patent.

15. Upon information and belief, Counterclaim Defendants caused the '449 patent to be listed in the Orange Book as patents that claim a method of using such a drug for which BIPI submitted NDA No. 212614.

16. Sun submitted Abbreviated New Drug Application ("ANDA") Nos. 214843 to obtain FDA approval to engage in the commercial manufacture, use, and sale of Empagliflozin, Linagliptin and Metformin Hydrochloride Extended Release Tablets ("Sun's ANDA Product") prior to the expiration of the '449 patent.

17. Sun's ANDA No. 214843 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '449 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sun's ANDA Products.

18. By letter dated October 12, 2020 (the "Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Sun notified Counterclaim Defendants that ANDA No. 214843 includes Paragraph IV Certifications with respect to the '449 patent. Sun's Notice Letters,

which are incorporated herein by reference, contained a detailed statement of the factual and legal bases for Sun's Paragraph IV certification that the claims of the '449 patent are invalid, unenforceable, and/or will not be infringed by Sun's ANDA Products.

19. On November 23, 2020, Counterclaim Defendants filed this instant lawsuit alleging infringement of the '449 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '449 Patent)

20. Sun re-alleges and incorporates by reference the allegations in paragraphs 1–19 of its Counterclaims.

21. BII alleges ownership of the '449 patent, and Counterclaim Defendants have brought claims against Sun alleging infringement of the '449 patent.

22. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of Sun's ANDA No. 214843 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Sun's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '449 patent.

23. Sun has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '449 patent and is not liable for such infringement. Sun is entitled to a declaration that the manufacture, use, or sale of its ANDA Product would not infringe any valid or enforceable claim of the '449 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '449 Patent)

24. Sun re-alleges and incorporates by reference the allegations in paragraphs 1–23 of its Counterclaims.

25. BII alleges ownership of the '449 patent, and Counterclaim Defendants have brought claims against Sun alleging infringement of the '449 patent.

26. One or more claims of the ’449 patent are invalid under one or more provisions of 35 §§ U.S.C. 101, 102, 103, and/or 112.

27. One or more claims of the ’449 patent are invalid under 35 U.S.C. § 103 in view of, at least, the prior art references identified in Sun’s October 12, 2020 Notice Letter that Counterclaim Defendants received.

28. The ’449 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

29. The alleged invention of the ’449 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’449 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’449 patent and would have had a reasonable expectation of success in doing so.

30. The subject matter claimed in the ’449 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

31. There is an actual, substantial, continuing and justiciable controversy between the parties regarding whether the filing of Sun’s ANDA No. 214843 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Sun’s ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’449 patent.

32. Sun is entitled to a declaration that all claims of the '449 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Sun requests judgment in its favor and against Counterclaim Defendants as follows:

a. Declaring that all claims of the '449 patent are invalid;

b. Declaring that the filing of Sun's ANDA No. 214843 has not infringed and does not infringe any valid and enforceable claim of the '449 patent.

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Sun's ANDA Products does not, and would not, if marketed, infringe any valid and enforceable claim of the '449 patent.

d. Declaring this an exceptional case in favor of Sun and awarding its attorneys' fees pursuant to 35 U.S.C. § 285.

e. Awarding costs and expenses; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: December 23, 2020

Respectfully submitted,

/s/ John C. Phillips, Jr.

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