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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL, Plaintiffs, v. PRINSTON PHARMACEUTICAL INC., Defendants.	Civil Action No. 3:18-cv-06112 (Filed Electronically)

DEFENDANT PRINSTON PHARMACEUTICAL INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Prinston Pharmaceutical Inc. ("Prinston"), by its attorneys, responds to the Complaint for patent infringement filed by Plaintiffs Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International's ("Cilag") (collectively, "Plaintiffs") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Prinston denies all allegations in Plaintiffs' Complaint, except those expressly admitted below.

THE PARTIES

1. On information and belief, Prinston admits MTPC's address. Prinston is without sufficient information or knowledge to admit or deny the remaining allegations of this paragraph and, therefore, denies them on this basis.

2. On information and belief, Prinston admits JPI's address. Prinston is without sufficient information or knowledge to admit or deny the remaining allegations of this paragraph and, therefore, denies them on this basis.

3. On information and belief, Prinston admits JNV's address. Prinston is without sufficient information or knowledge to admit or deny the remaining allegations of this paragraph and, therefore, denies them on this basis.

4. On information and belief, Prinston admits JRD's address. Prinston is without sufficient information or knowledge to admit or deny the remaining allegations of this paragraph and, therefore, denies them on this basis.

5. On information and belief, Prinston admits Cilag 's address. Prinston is without sufficient information or knowledge to admit or deny the remaining allegations of this paragraph and, therefore, denies them on this basis.

6. Prinston admits that it is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

NATURE OF THE ACTION

7. Prinston admits that Plaintiffs brought this civil action for infringement of United States Patent No. 7,943,788 (the "'788 patent") under the patent laws of the United States, 35 U.S.C. §100, *et seq.* Prinston denies the remaining allegations of this paragraph.

PERSONAL JURISDICTION AND VENUE OVER PRINSTON

8. Prinston admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Prinston denies the remaining allegations of this paragraph.

9. This paragraph states a legal conclusion to which no answer is required.

10. For purposes of this action only, Prinston does not contest that this Court has personal jurisdiction over it**.** Prinston denies any allegations of patent infringement under 35 U.S.C. § 271(e)(2). Prinston also denies any allegations that its conduct will cause any harm and injury to Plaintiffs. Prinston also admits that upon approval of Prinston's ANDA No. 210514 ("Prinston's ANDA") it will make, use, import, sell, and/or offer for sale generic 100 mg and 300 mg canagliflozin tablets ("Prinston's

ANDA Product") in the United States. The remainder of the paragraph contains a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

11. For purposes of this action only, Prinston does not contest that this Court has personal jurisdiction over it**.** Prinston admits that its counsel sent a letter dated March 27, 2018 and that the letter speaks for itself. Prinston also admits that if it succeeds in obtaining FDA approval, it would sell its Prinston ANDA Product in New Jersey and other states. Prinston denies the allegation that it will cause injury to Plaintiffs**.** The remainder of the paragraph contains a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

12. For purposes of this action only, Prinston does not contest that this Court has personal jurisdiction over it**.** The remainder of the paragraph contains a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

13. Prinston admits that it has continuously placed its products in the stream of commerce for distribution and consumption in the United States. Prinston denies the remaining allegations of this paragraph.

14. Prinston admits that it has derived revenue from the sale of generic pharmaceutical products in the United States. Prinston denies the remaining allegations of this paragraph.

15. Prinston admits that it is involved in other patent litigations in this Judicial District. The remainder of this paragraph states a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

16. Prinston admits that it has previously been sued in this Judicial District in the litigations listed in this paragraph. The remainder of this paragraph states a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

17. Prinston denies any allegations of patent infringement. Prinston does not contest that venue in this Court is proper. The remainder of this paragraph states a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

THE PATENT-IN-SUIT

18. Prinston admits that a copy of the '788 patent entitled "Glucopyranoside Compound," dated May 17, 2011, was attached to the complaint. Prinston further admits that the '788 patent identifies MTPC as assignee. Prinston denies that the '788 patent was duly and lawfully issued.

19. This paragraph concerns facts and documents solely in the possession, custody, or control of Plaintiffs, so Prinston is without sufficient information and knowledge to admit or deny those allegations and, therefore, denies them on this basis.

20. This paragraph concerns facts and documents solely in the possession, custody or control of Plaintiffs, so Prinston is without sufficient information and knowledge to admit or deny those allegations and, therefore, denies them on this basis.

21. On information and belief, Prinston admits that JPI holds approved New Drug Application ("NDA") No. 204042 for canagliflozin tablets, which are prescribed and sold under the trademark INVOKANA®.

22. Prinston admits that the '788 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to INVOKANA® . The remainder of the paragraph contains a legal conclusion to which no answer is required. To the extent necessary, Prinston denies the remaining allegations of this paragraph.

ACTS GIVING RISE TO THIS ACTION

COUNT I - [ALLEGED] INFRINGEMENT OF THE '788 PATENT BY PRINSTON'S ANDA FOR INVOKANA®

23. Prinston repeats and restates its admissions and denials to paragraphs 1-22 above as if fully set forth here.

24. Prinston admits that it filed Abbreviated New Drug Application No. 210514 with the United States Food and Drug Administration seeking approval to commercially market generic versions of JPI's 100 mg and 300 mg INVOKANA® drug product. Prinston denies the remaining allegations of this paragraph.

25. Prinston admits the allegations of this paragraph.

26. Prinston admits the allegations of this paragraph.

27. Prinston denies the allegations of this paragraph.

28. Prinston denies the allegations of this paragraph.

29. Prinston denies the allegations of this paragraph.

30. Prinston denies the allegations of this paragraph.

[PLAINTIFFS'] PRAYER FOR RELIEF

Prinston denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or to any relief whatsoever.

DEFENDANT'S AFFIRMATIVE DEFENSES

Prinston asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Prinston does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Prinston reserves the right to assert other defenses and/or to supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(No Direct Infringement)

Prinston does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '788 patent and if the products that are the subject of ANDA No. 210514 were marketed, Prinston would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '788 patent.

SECOND AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Prinston has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the '788 patent, and if the products that are the subject of ANDA No. 210514 were marketed, Prinston would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the '788 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the '788 patent 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.

FOURTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application(s) leading to the '788 patent, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the '788 patent is infringed by the product that is the subject of Prinston's ANDA No. 210514.

FIFTH AFFIRMATIVE DEFENSE
(Failure to State A Claim)

Plaintiffs failed to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

DEFENDANT'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant Prinston Pharmaceutical Inc. ("Prinston"), for its Counterclaims against Plaintiffs Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International's ("Cilag") (collectively, "Plaintiffs") state as follows:

1. Prinston repeats and incorporates by reference each of the foregoing paragraphs of Prinston's Answer and Affirmative Defenses to the Complaint.

2. This is a counterclaim for declaratory judgment of non-infringement, unenforceability, and/or invalidity of one or more claims of United States Patent Number 7,943,788 (the "'788 patent") under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2788, 12 U.S.C. § 355(j), and 21 U.S.C. § 355(J)(5)(c).

3. On information and belief, on May 17, 2011, the Patent and Trademark Office ("PTO") issued the '788 patent entitled, "Glucopyranoside Compound." The '788 patent lists, on its face, Sumihiro Nomura, Eiji Kawanishi, and Kiichiro Ueta as inventors of the patent. According to the Food and Drug Administration ("FDA") publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as "the Orange Book"), the '788 patent will expire on July 14, 2027.

4. Plaintiffs market canagliflozin under the trade name INVOKANA ®.

5. On information and belief, Plaintiffs market INVOKANA ® throughout the United States, including this judicial district.

THE PARTIES

6. Prinston is a company organized under the laws of the State of Delaware, having its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512.

7. On information and belief, MTPC is a corporation organized and existing under the laws of Japan, having an office and place of business at 3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan.

8. On information and belief, JPI is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

9. On information and belief, JNV is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, 2340 Beerse, Belgium.

10. On information and belief, JRD is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 920 Route 788, Raritan, New Jersey 08869.

11. On information and belief, Cilag is a company organized and existing under the laws of Switzerland, having its principal place of business at Gubelstrasse 34, 6300, Zug, Switzerland.

JURISDICTION

12. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 35 U.S.C. § 271(3)(5); 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2788; and/or 21 U.S.C. § 355(j), based on an actual controversy between Prinston and Plaintiffs arising under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

13. This Court has personal jurisdiction over Plaintiffs based, *inter alia*, on the filing by Plaintiffs of this lawsuit in this jurisdiction.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), and 21 U.S.C. § 355(j)(5)(c)(i)(II).

THE APPLICATIONS AT ISSUE

The NDA

15. On information and belief, JPI is the current holder of New Drug Application ("NDA") No. 204042 for canagliflozin tablets, which are prescribed and sold under the trademark INVOKANA®. INVOKANA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults.

16. On information and belief, the FDA approved NDA No. 204042 on March 29, 2013, which permitted Plaintiffs to market and sell its canagliflozin tablets in this judicial district and throughout the United Sates.

17. The Federal Food, Drug, and Cosmetic Act ("the Act") authorizes a pharmaceutical company to file an Abbreviated New Drug Application ("ANDA"), which the FDA will approve if the pharmaceutical company shows that its product has the same active ingredient as, and is bioequivalent to, a product that the FDA has

already approved. Typically, the ANDA applicant submits data showing that its product is bioequivalent to a product that has been the subject of an approved NDA.

18. The Act requires NDA holders to submit to the FDA the patent number and expiration date of any patent(s) for which the NDA holder believes "a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA—with no substantive review of the patents — lists the patent number(s) and expiration date(s) in the Orange Book.

19. If an ANDA applicant seeks approval to market its generic product before a patent listed in the Orange Book expires, the applicant must include in its ANDA a certification that its proposed product would not infringe that patent, and/or that the patent is invalid and/or unenforceable. The ANDA applicant must then send notice to the NDA holder and patent owner(s), which includes a detailed statement of the factual and legal bases of the ANDA applicant's opinion that the patent is invalid, unenforceable, and/or would not be infringed.

20. Upon information and belief, Plaintiffs, as the NDA holder for INVOKANA® (NDA No. 204042), filed requests with the FDA pursuant to 21 U.S.C. § 355(b)(1) to list the '788 patent in the Orange Book for INVOKANA®.

21. Plaintiffs' maintenance of the '788 patent in the Orange Book means that it believes these patents "claim[] the drug for which the application was submitted [i.e., INVOKANA®] and with respect to which a claim or patent infringement could

reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1).

ANDA NO. 210514

22. Prinston has filed an ANDA with the FDA seeking approval to market canagliflozin tablets, 100 mg and 300 mg ("ANDA Product"). As part of the application, Prinston certified that its ANDA Product described in ANDA No. 210514 does not infringe the '788 patent and that the '788 patents is invalid and/or unenforceable.

23. Prinston provided notice of its certification with respect to the '788 patent to Plaintiffs, by letter dated March 27, 2018. The notice provided the factual and legal bases as to why, in Prinston's opinion, the '788 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '788 patent. Prinston also enclosed an Offer of Confidential Access to Prinston's ANDA in accordance with 21 U.S.C. § 505(j)(5)(C)(i)(III).

24. On April 11, 2018, Plaintiffs sued Prinston alleging infringement of the '788 patent in the above-captioned action in the District of New Jersey.

25. Plaintiffs' conduct impairs Prinston's ability to market Prinston's ANDA Product. Prinston thus seeks a declaratory judgment that its ANDA Product does not infringe the '788 patent or that this patent is invalid or unenforceable.

THE PRESENCE OF A CASE OR ACTUAL CONTROVERSY

26. By maintaining the Orange Book listing of the '788 patent in connection with INVOKANA®, Plaintiffs continue to represent that the '788 patent could reasonably be asserted against anyone making, using, or selling a generic canagliflozin tablet without a license from Plaintiffs.

27. Prinston's Paragraph IV certifications state that the '788 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of the ANDA Product.

28. Plaintiffs' Complaint gives rise to an actual controversy with respect to the '788 patent, with respect to ANDA No. 210514.

29. Prinston has made, and will continue to make, substantial preparations in connection with its request for FDA approval of its ANDA Product.

30. To avoid legal uncertainty and to protect Prinston's substantial investment (and anticipated future investment) in Prinston's ANDA Product, Defendant seeks declaratory relief with respect to the '788 patent.

31. Prinston has not stipulated to or otherwise consented to the validity, infringement, or enforceability of the '788 patent.

32. Upon FDA approval of Prinston's ANDA, Prinston will be able to market and sell its ANDA Product in the United States.

33. A judgment declaring that the '788 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Prinston's ANDA Product will remove any independent barriers to competition that

may exist by virtue of Plaintiffs' maintenance of the listing of the '788 patent in the Orange Book in connection with NDA No. 204042.

34. The totality of circumstances support that a case or controversy exists with respect to the infringement, invalidity, and/or unenforceability of the '788 patent.

FIRST COUNT
(Declaratory Judgment of Non-Infringement of the '788 Patent)

35. Prinston repeats and incorporates by reference each of the foregoing paragraphs of Prinston's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

36. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2788. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Prinston concerning the infringement of the '788 patent.

37. Prinston's manufacture, use, offer for sale, sale, and/or importation into the United States of Prinston's ANDA Product pursuant to ANDA No. 210514 will not infringe any valid and enforceable claim of the '788 patent.

38. Prinston is entitled to a declaration that the manufacture, use, offer for sale, sale, and/or importation into the United States of Prinston's ANDA Product will not infringe any valid and enforceable claim of the '788 patent and to an award of attorneys' fees and costs under 35 U.S.C. § 285.

SECOND COUNT
(Declaratory Judgment of Invalidity of the '788 Patent)

39. Prinston repeats and incorporates by reference each of the foregoing paragraphs of Prinston's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

40. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2788. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs and Prinston concerning the invalidity of claims of the '788 patent.

41. The claims of the '788 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 et seq., including, without limitation, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation.

42. Thus, Prinston is entitled to a declaration that the claims of the '788 patent are invalid.

EXCEPTIONAL CASE

43. This case is an exceptional one, and Prinston is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYERS FOR RELIEF

WHEREFORE, Prinston Pharmaceutical Inc. prays that the Court enter judgment in its favor and against Plaintiffs as follows:

A. Declaring that the making, using, selling, offering for sale, marketing, or importation of its ANDA Product described in ANDA No. 210514 does not infringe any valid or enforceable claim of the '788 patent;

B. Declaring that the '788 patent and all of its claims are invalid;

C. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Prinston or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Prinston, or charging them either orally or in writing with infringement of any patent asserted herein against Prinston;

D. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from interfering with the FDA's approval of ANDA No. 210514;

E. Granting Prinston judgment in its favor on Plaintiffs' claims;

F. Denying Plaintiffs' claims with prejudice;

G. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Prinston its costs and reasonable attorneys' fees; and

H. Awarding any other such relief as is just and proper.

Dated: May 14, 2018

Respectfully submitted,

/s/Rebekah R. Conroy

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