IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: _____

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International ("Cilag") (collectively, "Plaintiffs"), by their attorneys, for their complaint against Sandoz, Inc. ("Sandoz") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 7,943,582 (the "'582 patent") and 8,513,202 (the "'202 patent") (collectively, the "Patents-in-suit") under the patent laws of the United States, 35 U.S.C. §100, *et seq.* This action arises from Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 210297 ("the Sandoz '297

ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of JPI's 100 mg and 300 mg INVOKANA® drug product ("the Sandoz '297 ANDA Product") and Sandoz's filing of ANDA No. 210481 ("the Sandoz '481 ANDA") with the FDA seeking approval to commercially market generic versions of JPI's 50 mg/500 mg; 50 mg/1 g; 150 mg/500 mg; and 150 mg/1 g INVOKAMET® drug product ("the Sandoz '481 ANDA Product") prior to the expiration of the Patents-in-suit.

THE PARTIES

2. 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.

3. 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.

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

5. 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 202, Raritan, New Jersey 08869.

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

7. On information and belief, defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, and having its principal place of business at 100 College Road West, Princeton, NJ 08540.

THE PATENTS-IN-SUIT

8. On May 17, 2011, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '582 patent, entitled "Crystalline form of 1-(β-D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate" to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the '582 patent is attached as Exhibit 1.

9. JPI, JRD, and Cilag are exclusive licensees of the '582 patent.

10. JNV is an exclusive sublicensee of the '582 patent.

11. On August 20, 2013, the USPTO duly and lawfully issued the '202 patent, entitled "Crystalline form of 1-(β-D-glucopyransoyl)-4-methyl-3-[5-(4-fluorophenyl)-2-thienylmethyl]benzene hemihydrate" to MTPC as assignee of inventors Sumihiro Nomura and Eiji Kawanishi. A copy of the '202 patent is attached as Exhibit 2.

12. JPI, JRD, and Cilag are exclusive licensees of the '202 patent.

13. JNV is an exclusive sublicensee of the '202 patent.

THE INVOKANA® AND INVOKAMET® DRUG PRODUCTS

14. JPI holds approved 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 with type 2 diabetes mellitus.

15. JPI holds approved NDA No. 204353 for canagliflozin and metformin hydrochloride tablets, which are prescribed and sold under the trademark INVOKAMET®. INVOKAMET® is indicated as an adjunct to diet and exercise to improve glycemic control in adults

with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients who are already being treated with both canagliflozin and metformin.

16. The claims of the Patents-in-suit cover, *inter alia*, certain polymorphic forms of canagliflozin.

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '582 and '202 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to both INVOKANA® and INVOKAMET®.

JURISDICTION AND VENUE

18. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

19. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz is a corporation organized and existing under the laws of the State of Colorado.

20. Venue is proper for Sandoz under 28 U.S.C. § 1400(b) because, *inter alia*, Sandoz is a corporation organized and existing under the laws of the State of Colorado.

SANDOZ'S INFRINGING ANDA NO. 210297 SUBMISSION

21. On or about June 8, 2017, JPI received from Sandoz's counsel a letter, dated June 7, 2017 ("the Sandoz '297 Letter"), stating that Sandoz had submitted the Sandoz '297 ANDA to the FDA seeking approval to market the Sandoz '297 ANDA Product before the

expiration of the Patents-in-suit. MTPC received the Sandoz '297 Letter on or about June 12, 2017.

22. The Sandoz '297 ANDA Product is intended to be a generic version of INVOKANA®.

23. The Sandoz '297 Letter does not allege or argue that the Sandoz '297 ANDA Product does not infringe the Patents-in-suit.

24. The Sandoz '297 Letter alleges that the Patents-in-suit are invalid.

25. This action is being commenced before the expiration of 45 days from the date MTPC and JPI received the Sandoz '297 Letter.

SANDOZ'S INFRINGING ANDA NO. 210481 SUBMISSION

26. On or about June 7, 2017, JPI received from Sandoz's counsel a letter, dated June 6, 2017 ("the Sandoz '481 Letter"), stating that Sandoz had submitted the Sandoz '481 ANDA to the FDA seeking approval to market the Sandoz '481 ANDA Product before the expiration of the Patents-in-suit. MTPC received the Sandoz '481 Letter on or about June 9, 2017.

27. The Sandoz '481 ANDA Product is intended to be a generic version of INVOKAMET®.

28. The Sandoz '481 Letter does not allege or argue that the Sandoz '481 ANDA Product does not infringe the Patents-in-suit.

29. The Sandoz '481 Letter alleges that the Patents-in-suit are invalid.

30. This action is being commenced before the expiration of 45 days from the date MTPC and JPI received the Sandoz '481 Letter.

COUNT I
Infringement of U.S. Patent No. 7,943,582 by Sandoz

31. Plaintiffs repeat and reallege paragraphs 1-30 above as if fully set forth herein.

32. By filing its ANDA No. 210297 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Sandoz '297 ANDA Product before the expiration of the '582 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

33. By filing its ANDA No. 210481 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Sandoz '481 ANDA Product before the expiration of the '582 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

34. Sandoz does not argue or allege in its Paragraph IV Notice Letter for ANDA No. 210297 that its proposed Sandoz '297 ANDA Product does not infringe the '582 patent.

35. Sandoz does not argue or allege in its Paragraph IV Notice Letter for ANDA No. 210481 that its proposed Sandoz '481 ANDA Product does not infringe the '582 patent.

36. On information and belief, discovery/testing will show that if Sandoz commercially makes, uses, offers to sell, or sells the Sandoz '297 ANDA Product within the United States, or imports the Sandoz '297 ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '582 patent, it would further infringe at least claims 1, 6, and 7 of the '582 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

37. On information and belief, discovery/testing will show that if Sandoz commercially makes, uses, offers to sell, or sells the Sandoz '481 ANDA Product within the United States, or imports the Sandoz '481 ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '582 patent, it would further infringe at least claims 1, 6, and 7 of the '582 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

38. Sandoz has had knowledge of the '582 patent since at least the date it submitted the Sandoz '297 ANDA and the Sandoz '481 ANDA.

39. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing the '582 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II
Infringement of U.S. Patent No. 8,513,202 by Sandoz

40. Plaintiffs repeat and reallege paragraphs 1-39 above as if fully set forth herein.

41. By filing its ANDA No. 210297 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Sandoz '297 ANDA Product before the expiration of the '202 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

42. By filing its ANDA No. 210481 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Sandoz '481 ANDA Product before the expiration of the '202 patent, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

43. Sandoz does not argue or allege in its Paragraph IV Notice Letter for ANDA No. 210297 that its proposed Sandoz '297 ANDA Product does not infringe the '202 patent.

44. Sandoz does not argue or allege in its Paragraph IV Notice Letter for ANDA No. 210481 that its proposed Sandoz '481 ANDA Product does not infringe the '202 patent.

45. On information and belief, discovery/testing will show that if Sandoz commercially makes, uses, offers to sell, or sells the Sandoz '297 ANDA Product within the United States, or imports the Sandoz '297 ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '202 patent, it would further infringe at least claims 1 and 3-5 of the '202 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

46. On information and belief, discovery/testing will show that if Sandoz commercially makes, uses, offers to sell, or sells the Sandoz '481 ANDA Product within the United States, or imports the Sandoz '481 ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '202 patent, it would further infringe at least claims 1 and 3-5 of the '202 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Sandoz has had knowledge of the '202 patent since at least the date it submitted the Sandoz '297 ANDA and the Sandoz '481 ANDA.

48. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing the '202 patent. Plaintiffs do not have an adequate remedy at law.

STATEMENT REGARDING PRIOR-FILED SUIT

49. Plaintiffs previously filed, on July 20, 2017, an action in the District of New Jersey seeking to enjoin Sandoz from commercially manufacturing, using, offering for sale, importing, or selling the proposed generic versions of JPI's Invokana® brand canagliflozin tablets and Invokamet® brand canagliflozin and metformin hydrochloride tablets identified in this Complaint prior to the expiration of the '582 and '202 patents. That action has been assigned Civil Action No. 17-cv-5302 ("the D.N.J. Action"). The D.N.J. Action is assigned to Judge Freda L. Wolfson.

50. In the D.N.J. Action, Plaintiffs alleged that the District Court for the District of New Jersey is the appropriate venue with regard to Plaintiffs' claim of patent infringement against Sandoz.

51. Judicial economy would be promoted, and Plaintiffs' choice of forum respected, if the claims related to Plaintiffs' action for infringement of the '582 and '202 patents are addressed by Judge Wolfson in the District of New Jersey.

52. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiffs filed the D.N.J. action within 45 days from receipt of Sandoz's ANDA Notice Letter. Plaintiffs filed this action as a further protective measure with regard to this statutory right.

53. Plaintiffs expect that personal jurisdiction and venue will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and will be voluntarily dismissed without prejudice in favor of continued prosecution of the D.N.J. Action, transferred to the District of New Jersey for

consolidation with the D.N.J. Action, or subject to such other non-substantive disposition that would ensure maintenance of Plaintiffs' rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Sandoz has infringed one or more claims of the '582 patent by filing ANDA No. 210297;

B. A Judgment that Sandoz has infringed one or more claims of the '582 patent by filing ANDA No. 210481;

C. A Judgment that Sandoz has infringed, and that Sandoz's making, using, selling, offering to sell, or importing the Sandoz '297 ANDA Product would constitute infringement of one or more claims of the '582 patent, and/or induce or contribute to infringement of one or more claims of the '582 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

D. A Judgment that Sandoz has infringed, and that Sandoz's making, using, selling, offering to sell, or importing the Sandoz '481 ANDA Product would constitute infringement of one or more claims of the '582 patent, and/or induce or contribute to infringement of one or more claims of the '582 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

E. A permanent injunction restraining and enjoining Sandoz, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz '297 ANDA Product until after the expiration

of the ’582 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. A permanent injunction restraining and enjoining Sandoz, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz ’481 ANDA Product until after the expiration of the ’582 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

G. An Order that the effective date of any approval of ANDA No. 210297 relating to the Sandoz ’297 ANDA Product be a date that is not earlier than the expiration date of the ’582 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of ANDA No. 210481 relating to the Sandoz ’481 ANDA Product be a date that is not earlier than the expiration date of the ’582 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. A Judgment that Sandoz has infringed one or more claims of the ’202 patent by filing ANDA No. 210297;

J. A Judgment that Sandoz has infringed one or more claims of the ’202 patent by filing ANDA No. 210481;

K. A Judgment that Sandoz has infringed, and that Sandoz’s making, using, selling, offering to sell, or importing the Sandoz ’297 ANDA Product would constitute

infringement of one or more claims of the ’202 patent, and/or induce or contribute to infringement of one or more claims of the ’202 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

L. A Judgment that Sandoz has infringed, and that Sandoz’s making, using, selling, offering to sell, or importing the Sandoz ’481 ANDA Product would constitute infringement of one or more claims of the ’202 patent, and/or induce or contribute to infringement of one or more claims of the ’202 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

M. A permanent injunction restraining and enjoining Sandoz, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz ’297 ANDA Product until after the expiration of the ’202 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

N. A permanent injunction restraining and enjoining Sandoz, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Sandoz ’481 ANDA Product until after the expiration of the ’202 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

O. An Order that the effective date of any approval of ANDA No. 210297 relating to the Sandoz ’297 ANDA Product be a date that is not earlier than the expiration date of

the ’202 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

P. An Order that the effective date of any approval of ANDA No. 210481 relating to the Sandoz ’481 ANDA Product be a date that is not earlier than the expiration date of the ’202 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled; and

Q. Such other and further relief as the Court may deem just and proper.

Dated: July 21, 2017

By: s/James G. Sawtelle

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