

**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”), for their Complaint against Defendant Sandoz Inc. (“Sandoz”) hereby allege as follows:

**THE PARTIES**

1. 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-Shi, Osaka 541-8505 Japan.

2. 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.

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

4. 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.

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

6. Upon information and belief, Sandoz is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

7. Upon information and belief, Sandoz is registered with the Office of the Secretary of the State of Colorado as a business operating in Colorado under Business ID No. 19871287460 and is registered with the State of Colorado's Department of Regulatory Agencies as a drug manufacturer under License No. MFR.0001007 and a wholesaler under License No. WHI.0006031. Upon information and belief, Sandoz develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Sandoz manufactures, markets, distributes, and/or sells various generic pharmaceutical versions of branded products throughout the United States, including in the State of Colorado.

**NATURE OF THE ACTION**

8. This is a civil action for infringement of United States Patent No. 7,943,788 (“the ’788 patent”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

**JURISDICTION AND VENUE**

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

10. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court’s jurisdiction.

11. Venue is proper in this Court as to Sandoz pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

12. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including in the District of Colorado. This Court has personal jurisdiction over Sandoz for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction, or venue, is challenged.

13. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz: (1) is organized and existing under the laws of the State of Colorado; (2) has purposely availed itself of the privilege of doing business in this Judicial District, including, *inter alia*, registering to do business in Colorado and securing Colorado wholesale drug distributor and

manufacturer's licenses; (3) maintains extensive systematic contacts with the State of Colorado, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Colorado residents; (4) upon information and belief, derives substantial revenue from the sale of its products in Colorado; (5) has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to engage in a future course of conduct that includes acts of patent infringement in Colorado, which has led and will lead to foreseeable harm and injury to Plaintiffs in Colorado; (6) upon information and belief, following approval of Sandoz's ANDAs, Sandoz will make, use, import, sell, and/or offer for sale Sandoz ANDA Products in the United States, including in this Judicial District, prior to the expiration of the patent-in-suit; and (7) has previously consented to this Court's jurisdiction and taken advantage of the rights and protections provided by this Court.

#### **THE PATENTS-IN-SUIT**

14. On May 17, 2011, the '788 patent, titled "Glucopyranoside Compound," was duly and legally issued to MTPC as assignee. A copy of the '788 patent is attached as Exhibit 1.

15. JPI, JRD, and Cilag are exclusive licensees of the '788 patent.

16. JNV is an exclusive sublicensee of the '788 patent.

17. JPI holds approved New Drug Application ("NDA") No. 204042 for canagliflozin tablets, which are prescribed and sold under the trademark Invokana<sup>®</sup>.

18. JPI holds approved NDA No. 204353 for canagliflozin and metforminhydrochloride tablets, which are prescribed and sold under the trademark Invokamet<sup>®</sup>.

19. Pursuant to 21 U.S.C. § 355(b)(1), the '788 patent is listed in the United States Food and Drug Administration ("FDA") publication titled Approved Drug Products with

Therapeutic Equivalence Evaluations (also known as the “Orange Book”) as covering JPI’s Invokana<sup>®</sup> brand canagliflozin tablets and Invokamet<sup>®</sup> brand canagliflozin and metformin hydrochloride tablets.

**ACTS GIVING RISE TO THIS ACTION**

**COUNT I – INFRINGEMENT  
OF THE ’788 PATENT BY SANDOZ’S ANDA FOR INVOKANA<sup>®</sup>**

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

21. Upon information and belief, Sandoz submitted ANDA No. 210297 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 210297 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Colorado, of generic 100 mg and 300 mg canagliflozin tablets prior to the expiration of certain of MTPC’s Orange Book listed patents. ANDA No. 210297 specifically seeks FDA approval to market a generic version of JPI’s Invokana<sup>®</sup> brand 100 mg and 300 mg canagliflozin tablets prior to the expiration of the ’788 patent.

22. Upon information and belief, ANDA No. 210297 includes a Paragraph IV Certification that the claims of the ’788 patent are invalid.

23. Plaintiffs commenced this action within 45 days of the date of receipt of Sandoz’s Paragraph IV Certification Notice Letter.

24. Sandoz’s submission to the FDA of ANDA No. 210297, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the ’788 patent under 35 U.S.C. § 271(e)(2)(A).

25. Plaintiffs are entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells its proposed generic versions of JPI's Invokana<sup>®</sup> brand products within the United States, imports its proposed generic versions of JPI's Invokana<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Sandoz will infringe at least claims 12 and 20 of the '788 patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

27. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

**COUNT II – INFRINGEMENT  
OF THE '788 PATENT BY SANDOZ'S ANDA FOR INVOKAMET<sup>®</sup>**

28. Plaintiffs reallege paragraphs 1-27 as if fully set forth herein.

29. Upon information and belief, Sandoz submitted ANDA No. 210481 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 210481 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of Colorado, of generic 50 mg/500 mg, 50 mg/1 g, 150 mg/500 mg, and 150 mg/1 g canagliflozin and metformin hydrochloride tablets prior to the expiration of certain of MTPC's Orange Book listed patents. ANDA No. 210481 specifically seeks FDA approval to market a generic version of JPI's Invokamet<sup>®</sup> brand 50 mg/500 mg, 50 mg/1 g, 150 mg/500 mg, and 150 mg/1 g canagliflozin and metformin hydrochloride tablets prior to the expiration of the '788 patent.

30. Upon information and belief, ANDA No. 210481 includes a Paragraph IV Certification that the claims of the '788 patent are invalid.

31. Plaintiffs commenced this action within 45 days of the date of receipt of Sandoz's Paragraph IV Certification Notice Letter.

32. Sandoz's submission to the FDA of ANDA No. 210481, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '788 patent under 35 U.S.C. § 271(e)(2)(A).

33. Plaintiffs are entitled to a declaration that, if Sandoz commercially manufactures, uses, offers for sale, or sells its proposed generic versions of JPI's Invokamet<sup>®</sup> brand products within the United States, imports its proposed generic versions of JPI's Invokamet<sup>®</sup> brand products into the United States, and/or induces or contributes to such conduct, Sandoz will infringe at least claims 12 and 20 of the '788 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

35. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

#### **STATEMENT REGARDING PRIOR-FILED SUIT**

36. 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<sup>®</sup> brand canagliflozin tablets

and Invokamet<sup>®</sup> brand canagliflozin and metformin hydrochloride tablets identified in this Complaint prior to the expiration of the '788 patent. That action has been assigned Civil Action No. 3:17-cv-05319 (“the D.N.J. Action”). The D.N.J. Action is assigned to Judge Michael A. Shipp.

37. 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.

38. Judicial economy would be promoted, and Plaintiffs’ choice of forum respected, if the claims related to Plaintiffs’ action for infringement of the '788 patent is addressed by Judge Shipp in the District of New Jersey.

39. 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.

40. 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 request that:

- A. A Judgment be entered declaring that Sandoz has infringed one or more claims of the '788 patent for Invokana<sup>®</sup> by submitting ANDA No. 210297;
- B. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 210297 be a date that is not earlier than the expiration dates of the '788 patent for Invokana<sup>®</sup>, or any later expiration of exclusivity for any of those patents to which Plaintiffs are or become entitled;
- C. An Order be issued that Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, importing, or selling the proposed generic versions of JPI's Invokana<sup>®</sup> brand canagliflozin tablets identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '788 patent for Invokana<sup>®</sup>, prior to the expiration of any of those patents, including any extensions to which Plaintiffs are or become entitled;
- D. If Sandoz engages in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the proposed generic versions of JPI's Invokana<sup>®</sup> brand canagliflozin tablets identified in this Complaint prior to the expiration of the '788 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement together with interest;
- E. A Judgment be entered declaring that Sandoz has infringed one or more claims of the '788 patent for Invokamet<sup>®</sup> by submitting ANDA No. 210481;

F. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 210481 be a date that is not earlier than the expiration dates of the '788 patent for Invokamet<sup>®</sup>, or any later expiration of exclusivity for any of those patents to which Plaintiffs are or become entitled;

G. An Order be issued that Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, importing, or selling the proposed generic versions of JPI's Invokamet<sup>®</sup> brand canagliflozin and metformin hydrochloride tablets identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '788 patent for Invokamet<sup>®</sup>, prior to the expiration of any of those patents, including any extensions to which Plaintiffs are or become entitled;

H. If Sandoz engages in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the proposed generic versions of JPI's Invokamet<sup>®</sup> brand canagliflozin and metformin hydrochloride tablets identified in this Complaint prior to the expiration of the '788 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement together with interest;

I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

J. Costs and expenses in this action; and

K. Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: July 21, 2017

Respectfully submitted,

By: s/James G. Sawtelle  
James G. Sawtelle  
Christian H. Hendrickson  
SHERMAN & HOWARD L.L.C.  
633 Seventeenth Street, Suite 3000  
Denver, CO 80202  
(303) 297-2900

*Attorneys for Plaintiffs  
Mitsubishi Tanabe Pharma Corp.,  
Janssen Pharmaceuticals, Inc.,  
Janssen Pharmaceutica NV,  
Janssen Research and Development, LLC,  
and Cilag GmbH International*