IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PHARMACEUTICALS USA, 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 Teva Pharmaceuticals USA, Inc. ("Teva") 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 Teva's filing of Abbreviated New Drug Application ("ANDA") No. 210451 ("the Teva 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 Teva 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, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

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 A.

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 B.

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 Teva because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

20. Venue is proper for Teva under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

TEVA'S INFRINGING ANDA SUBMISSION

21. On or about June 8, 2017, JPI received from Teva's counsel a letter, dated June 7, 2017 ("the Teva June 7 Letter"), stating that Teva had submitted the Teva ANDA to the FDA seeking approval to market the Teva ANDA Product before the expiration of the Patents-in-suit. MTPC received the Teva June 7 Letter on or about June 9, 2017.

22. The Teva ANDA Product is intended to be a generic version of INVOKANA®.

23. The Teva June 7 Letter alleges that the Teva ANDA Product does not infringe the Patents-in-suit. Notwithstanding these allegations, on information and belief, discovery/testing will show that the Teva ANDA Product infringes the Patents-in-suit.

24. This action is being commenced before the expiration of 45 days from the date MTPC and JPI received the Teva June 7 Letter.

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

25. Plaintiffs repeat and reallege paragraphs 1-24 above as if fully set forth herein.

26. By filing its ANDA No. 210451 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 Teva ANDA Product before the expiration of the '582 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

27. On information and belief, discovery/testing will show that if Teva commercially makes, uses, offers to sell, or sells the Teva ANDA Product within the United States, or imports the Teva 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).

28. Teva has had knowledge of the '582 patent since at least the date it submitted the Teva ANDA.

29. Plaintiffs will be irreparably harmed if Teva 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 Teva

30. Plaintiffs repeat and reallege paragraphs 1-29 above as if fully set forth herein.

31. By filing its ANDA No. 210451 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 Teva ANDA Product before the expiration of the '202 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

32. On information and belief, discovery/testing will show that if Teva commercially makes, uses, offers to sell, or sells the Teva ANDA Product within the United States, or imports the Teva 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).

33. Teva has had knowledge of the '202 patent since at least the date it submitted the Teva ANDA.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed one or more claims of the '582 patent by filing ANDA No. 210451;

B. A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing the Teva 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);

C. A permanent injunction restraining and enjoining Teva, 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 Teva ANDA Product until after the expiration of the '582 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of ANDA No. 210451 relating to the Teva 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;

E. A Judgment that Teva has infringed one or more claims of the '202 patent by filing ANDA No. 210451;

F. A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing the Teva 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);

G. A permanent injunction restraining and enjoining Teva, 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 Teva ANDA Product until after the expiration of the '202 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of ANDA No. 210451 relating to the Teva 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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
rsmith@mnat.com
mdellinger@mnat.com

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

OF COUNSEL:

Raymond N. Nimrod
Matthew A. Traupman
Catherine T. Mattes
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue
New York, NY 10010
(212) 849-7000

July 21, 2017