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

**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.

MACLEODS PHARMACEUTICALS, LTD. and  
MACLEODS PHARMA USA, INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT  
INFRINGEMENT**

(Filed Electronically)

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 Defendants Macleods Pharmaceuticals, Ltd. (“Macleods India”) and Macleods Pharma USA, Inc. (“Macleods USA”) (collectively, “Macleods”), 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 Macleods India’s filing of Abbreviated New Drug Application (“ANDA”) No. 215255 (“the Macleods ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of JPI’s 50 mg/500 mg, 50 mg/1000 mg, 150 mg/500 mg, and 150 mg/1000 mg INVOKAMET<sup>®</sup> XR drug product (“the Macleods ANDA Products”) 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 Macleods India is a corporation organized and existing under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 40059, India.

8. On information and belief, defendant Macleods USA is a corporation organized under the laws of the State of Delaware, having its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

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

9. On May 17, 2011, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’582 patent, entitled, “Crystalline form of 1-( $\beta$ -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.

10. JPI, JRD, and Cilag are exclusive licensees of the ’582 patent.

11. JNV is an exclusive sublicensee of the ’582 patent.

12. On August 20, 2013, the USPTO duly and lawfully issued the ’202 patent entitled, “Crystalline form of 1-( $\beta$ -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.

13. JPI, JRD, and Cilag are exclusive licensees of the ’202 patent.

14. JNV is an exclusive sublicensee of the ’202 patent.

### THE INVOKAMET<sup>®</sup> XR DRUG PRODUCT

15. JPI holds approved New Drug Application (“NDA”) No. 205879 for extended-release canagliflozin and metformin tablets, which are prescribed and sold under the trademark INVOKAMET<sup>®</sup> XR. INVOKAMET<sup>®</sup> XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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 Patents-in-suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to INVOKAMET<sup>®</sup> XR.

### 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 Macleods USA because, *inter alia*, on information and belief, Macleods USA has its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. On information and belief, Macleods USA also is registered as a wholesaler in the State of New Jersey (No. 5004370). *See* New Jersey Wholesale Drug & Medical Device Registration Verification, <https://healthapps.state.nj.us/fooddrug/fdList.aspx> (last visited January 13, 2021). Further, on information and belief, Macleods USA is registered as a business in the State of New Jersey (No. 0101021236). *See* New Jersey Business Registration Certificate, [https://www1.state.nj.us/TYTR\\_BRC/servlet/common/BRCLLogin](https://www1.state.nj.us/TYTR_BRC/servlet/common/BRCLLogin) (last visited January 13, 2021).

20. This Court has personal jurisdiction over Macleods USA because, *inter alia*, Macleods USA intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of the Macleods ANDA, Macleods USA will work in concert with Macleods India to make, use, offer for sale, sell, and/or import the Macleods ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-suit.

21. This Court also has personal jurisdiction over Macleods USA because, *inter alia*, this action arises from actions of Macleods USA directed toward New Jersey, and because Macleods USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Macleods USA maintains its principal place of business in New Jersey and regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Macleods USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Macleods USA is registered as a wholesaler in the State of New Jersey (No. 5004370). See Wholesale Drug & Medical Device Registration Verification, <https://healthapps.state.nj.us/fooddrug/fdList.aspx> (last visited January 13, 2021).

22. On information and belief, Macleods USA has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

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