IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS)
IRELAND CO., LTD., ASTELLAS)
PHARMA US, INC., and ASTELLAS)
PHARMA GLOBAL DEVELOPMENT,) C.A. No
INC.,)
)
Plaintiffs,)
) JURY TRIAL DEMANDED
v.)
)
EVITALIN LLC, d/b/a menMD,)
PHARMALABS, LLC, and)
PHARMALABS HOLDCO, INC.,)

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., Astellas Pharma US, Inc., and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

THE PARTIES

- A. <u>Astellas Pharma Inc., Astellas Ireland Co., Ltd., Astellas Pharma US, Inc., and</u> Astellas Pharma Global Development, Inc. (Collectively, "Astellas," or "Plaintiffs")
- 1. Plaintiff Astellas Pharma Inc. ("API") is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.
- 2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff API.



- 3. Astellas Pharma US, Inc. ("APUI") is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062. APUI is a subsidiary of Plaintiff API.
- 4. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062. APGD is a subsidiary of Plaintiff API.

B. Evitalin LLC, d/b/a menMD ("Evitalin" or "menMD")

- 5. On information and belief, Defendant Evitalin LLC does business, *inter alia*, under the name "menMD."
- 6. On information and belief, Defendant Evitalin, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 14440 Myerlake Circle, Clearwater, FL 33760.
- 7. On information and belief, menMD is in the business of providing sales, marketing, and consulting services to the medical community.

C. PharmaLabs, LLC and PharmaLabs HoldCo, Inc. (together, "PharmaLabs")

- 8. On information and belief, Defendant PharmaLabs, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10901 Roosevelt Blvd N, Suite 1200C, St. Petersburg, FL 33716.
- 9. On information and belief, PharmaLabs, LLC is a compounding pharmacy that is in the business of making and selling, *inter alia*, pharmaceutical products.
- 10. On information and belief, the manager of PharmaLabs, LLC is PharmaLabs HoldCo, Inc.



- 11. On information and belief, PharmaLabs HoldCo, Inc. is a corporation that is incorporated under the laws of Delaware, having a principal place of business at 10901 Roosevelt Blvd N, Suite 1200C, St. Petersburg, FL 33716.
- 12. On information and belief, PharmaLabs HoldCo, Inc. is a management company that is, *inter alia*, the manager of PharmaLabs LLC.
- 13. On information and belief, menMD and PharmaLabs share at least some common officers.

NATURE OF ACTION

- 14. This is an action for patent infringement arising under the United States patent laws, Title 35, United States Code, seeking monetary damages and other relief against menMD based on menMD's infringement of United States Patent Nos. 6,346,532 ("the '532 Patent"), 7,342,117 ("the '117 Patent"), 7,982,049 ("the '049 Patent"), 8,835,474 ("the '474 Patent"), and RE44,872 ("the '872 Patent").
- 15. This action relates to menMD's selling and offering to sell mirabegron immediate release capsules in the 20mg and 40mg dosage strengths ("Mirabegron Products").

JURISDICTION AND VENUE

- 16. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).
- 17. This Court has personal jurisdiction over menMD at least because, on information and belief, menMD is a limited liability company organized and existing under the laws of Delaware.
- 18. On information and belief, menMD conducts business throughout the United States, including in this Judicial District, and has committed acts of infringement in this Judicial District and elsewhere.



- 19. On information and belief, menMD partners with affiliates, partners, and/or agents such as pharmacies that engage in compounding medications, including those imported, sold, offered for sale, and/or used in the pharmaceutical industry throughout the United States, including in this Judicial District.
- 20. On information and belief, menMD regularly solicits business throughout the United States, including in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.
- 21. On information and belief, menMD conducts marketing and sales activities throughout the United States, including in the State of Delaware, including but not limited to distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.
- 22. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over menMD.
- 23. This Court has personal jurisdiction over PharmaLabs, LLC at least because, on information and belief, PharmaLabs, LLC is a limited liability company organized and existing under the laws of Delaware. On information and belief, PharmaLabs, LLC is registered with the Delaware Department of State, Division of Professional Regulation as a Pharmacy (license number A9-0001227) and further has a controlled substances license in Delaware under license number PH-0011109. On information and belief, PharmaLabs, LLC had a retail pharmacy drug wholesale distributor license in Florida, but that license was withdrawn.



- 24. On information and belief, PharmaLabs, LLC conducts business throughout the United States, including in this Judicial District, and has committed acts of infringement in this Judicial District and elsewhere.
- 25. On information and belief, PharmaLabs, LLC, together with its affiliates, partners, and/or agents, engage in compounding and selling medications, including those imported, sold, offered for sale, and/or used in the pharmaceutical industry throughout the United States, including in this Judicial District.
- 26. On information and belief, PharmaLabs, LLC, directly or indirectly through its subsidiaries, affiliates, partners, and agents, regularly solicits business throughout the United States, including in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.
- 27. On information and belief, PharmaLabs, LLC, directly or indirectly through its subsidiaries, affiliates, partners, and agents, conducts marketing and sales activities throughout the United States, including in the State of Delaware, including but not limited to distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.
- 28. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over PharmaLabs, LLC.
- 29. This Court has personal jurisdiction over PharmaLabs HoldCo, Inc. at least because, on information and belief, PharmaLabs HoldCo, Inc. is a corporation that is incorporated under the laws of Delaware.



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