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Merck Sharp & Dohme LLC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME LLC,

Plaintiff,

v.

GLAND PHARMA LIMITED,

Defendant.

Civil Action No. _____

Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme LLC (“Merck” or “Plaintiff”), by and through its undersigned attorneys, hereby files this Complaint for Patent Infringement against Defendant Gland Pharma Limited (“Gland” or “Defendant”) and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 9,023,790 (the “’790 Patent”) and 9,358,297 (the “’297 Patent”) arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and, in particular, under 35 U.S.C. § 271(e). Gland notified Merck pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the “Notice Letter”) that Gland is the owner of Abbreviated New Drug Application (“ANDA”) No. 217553, (the “Gland ANDA”), which Gland filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”) for approval to engage in the commercial manufacture, use or sale of a generic version of Merck’s NOXAFIL® (posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL), which is sold in the United States. The Gland posaconazole intravenous solution product described in the Gland ANDA is referred to herein as the “Generic Posaconazole IV Solution Product.”

THE PARTIES

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 E Lincoln Ave Rahway, NJ, 07065-4607. Merck is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health. Merck Sharp & Dohme LLC is the surviving entity after a merger with Merck Sharp & Dohme Corp., which was the previous owner of Merck’s NOXAFIL® product and the patents and NDA covering the

same.

3. On information and belief, Defendant Gland is a corporation organized and existing under the laws of India, with a place of business at Survey No. 143-148, 150 & 151 Near Gandimaisamma 'X' Roads D.P. Pally, Dundigal Gandimaisamma Mandal Medchal-Malkjiri District, Hyderabad, Telangana, 500043 India. On information and belief Gland is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

5. This Court has personal jurisdiction over Gland by virtue of its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drug products within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products within this judicial district, and through its pursuit of regulatory approval for its Generic Posaconazole IV Solution Product to market and sell its Generic Posaconazole IV Solution Product, if approved, in this judicial district and to residents of this judicial district, and having sent or caused to have sent the Notice Letter to Merck in New Jersey, prompting the filing of this lawsuit.

6. According to Gland, it has filed 139 ANDAs in the United States and has had 100 approved. *See* Gland Pharma Limited 2021-2022 Annual Report, pg. 35 available at [https://glandpharma.com/images/Annual_Report_2021-22_\(Double_Page\).pdf](https://glandpharma.com/images/Annual_Report_2021-22_(Double_Page).pdf). Gland's website

further states that Gland has “a global footprint across 60 countries, including the United States.”

See Home, available at <https://glandpharma.com/> (last visited September 8, 2022):



WHO ARE WE?

Established in Hyderabad, India in 1978, Gland Pharma has grown over the years from a contract manufacturer of small volume liquid parenteral products, to become one of the largest and fastest growing generic injectables manufacturing companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India and other markets. We operate primarily under a **business to business (B2B) model** and have an excellent track record in the pharmaceutical research and development, manufacturing and marketing of complex injectables. This presence across the value chain has helped us witness exponential growth. We have a professional management team and one of our Promoters, Shanghai Fosun Pharma, is a global pharmaceutical major.

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7. Although this Court has personal jurisdiction over Gland for at least the reasons set forth above, in the absence of such personal jurisdiction in any single state, a foreign entity such as Gland is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293–94 (Fed. Cir. 2012).

8. Upon information and belief, Gland has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in at least the following actions: *Fresenius Kabi Deutschland GmbH et al v. Gland Pharma Limited*, No. 3:20-cv-12347 (D.N.J.) (Sept. 4, 2020); *Merck Sharp & Dohme B.V. et al v. Gland Pharma Limited*, No. 2:20-cv-02750 (D.N.J.) (Mar. 12, 2020); *Chiesi USA Inc. et al v. Gland Pharma Limited*, No. 2:19-cv-18565 (D.N.J.) (Sept. 30, 2019); *Medicure Int’l, Inc. v. Gland Pharma Limited*, No. 2:18-cv-16246 (D.N.J.) (Nov. 16, 2018).

9. Venue is proper as to Gland in this judicial district under 28 U.S.C. § 1391(c)(3) because Gland is a foreign entity who may be sued in any judicial district. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

NOXAFIL®

10. Merck is the holder of New Drug Application (“NDA”) N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the registered trademark NOXAFIL® (“NOXAFIL® for Injection”). NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

11. NOXAFIL® for Injection is an embodiment of one or more claims of the ’790 Patent and the ’297 Patent (collectively, the “Patents-in-Suit”). The Patents-in-Suit are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for NOXAFIL®.

PATENTS-IN-SUIT

12. The ’790 Patent, entitled “Posaconazole Intravenous Solution Formulations Stabilized by Substituted β -Cyclodextrin,” was duly and legally issued by the USPTO on May 5, 2015. The Orange Book lists the expiration date of the ’790 Patent as July 4, 2031. Merck is the owner of all title, right and interest in and to the ’790 Patent by assignment. A copy of the ’790 Patent is attached as **Exhibit A**.

13. The ’297 Patent, entitled “Posaconazole Intravenous Solution Formulations Stabilized by Substituted β -Cyclodextrin” was duly and legally issued by the USPTO on June 7, 2016. The Orange Book lists the expiration date of the ’297 Patent as June 24, 2031. Merck is the owner of all title, right and interest in and to the ’297 Patent by assignment. A copy of the ’297 Patent is attached as **Exhibit B**.

GLAND’S ANDA

14. Gland filed or caused to be filed the Gland ANDA with the FDA, seeking FDA approval to market and sell within the United States the Generic Posaconazole IV Solution Product before the expiration of the Patents-in-Suit.

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