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

OREXO AB and OREXO US, INC.,)

Plaintiffs,)

v.)

C.A. No.: _____

SUN PHARMACEUTICAL)
INDUSTRIES LIMITED, SUN)
PHARMA GLOBAL FZE, and SUN)
PHARMACEUTICAL INDUSTRIES,)
INC.)

Defendants.)

**COMPLAINT FOR PATENT
INFRINGEMENT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Orexo AB and Orexo US, Inc. (“Orexo US,” collectively with Orexo AB, “Orexo” or “Plaintiffs”), for their Complaint against defendants Sun Pharmaceuticals Industries Limited (“Sun Ltd.”), Sun Pharma Global FZE (“Sun FZE”),¹ and Sun Pharmaceutical Industries, Inc. (“Sun Inc.”) (collectively, “Sun”) hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Sun’s filing of an Abbreviated New Drug Application (“ANDA”) No. 214737 (“Sun’s ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of Orexo’s Zubsolv® (buprenorphine/naloxone sublingual tablets) at doses of 1.4/0.36 mg, 2.9/0.71 mg, 5.7/1.4 mg, 8.6/2.1 mg, and 11.4/2.9 mg (“Sun’s ANDA Products”) prior to the expiration of United States Patent Nos. 10,874,661 (“the ’661 patent”) and 10,946,010 (“the ’010 patent”), both owned by Orexo AB (collectively, the “Patents-in-Suit”).

THE PARTIES

2. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Virdings allé 32 A, 754 50 Uppsala, Sweden.

3. Plaintiff Orexo US is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 150 Headquarters Plaza, East Tower, Morristown, New Jersey 07960. Orexo US is a wholly owned subsidiary of Orexo AB.

¹ NTD: Sun Pharma Global Inc., which was included in the first complaint, is intentionally omitted. Sun’s corporate disclosure statement filed in response to the first complaint states that “Sun Global is no longer an existing corporation,” which is confirmed by Sun’s annual reports.

4. On information and belief, Sun Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400 063, Maharashtra, India.

5. On information and belief, Sun FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office # 43, Block Y, SAIF-Zone, P.O. Box #122304, Sharjah, United Arab Emirates. On information and belief, Sun FZE is a wholly-owned subsidiary of Sun Ltd.

6. On information and belief, Sun Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540. On information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd.

JURISDICTION AND VENUE

7. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

Sun Ltd.

8. This Court has personal jurisdiction over Sun Ltd. because it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Orexo US in the State of New Jersey.

9. On information and belief, Sun Ltd. intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Sun Ltd. knows

and intends that, upon FDA approval of Sun's ANDA, Sun's ANDA Products will be distributed and sold, by Sun Ltd., in New Jersey and will thereby displace sales of Zubsolv[®], causing injury to Orexo in this District.

10. This Court has personal jurisdiction over Sun Ltd. also because Sun Ltd. 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, Sun Ltd. is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Sun Ltd., either directly or indirectly, manufactures, distributes, markets and/or sells throughout the United States, including in this District.

11. Sun Ltd.'s website states that its "U.S. headquarters are in Princeton, New Jersey," that it has "distribution and customer service teams at multiple locations across the country," and that "Sun Pharma is present in the U.S. through its legal entities [and] . . . continue to expand our product portfolio in the U.S. market." Sun Pharmaceutical Industries Limited, <http://www.sunpharma.com/usa> (last visited June 1, 2021).

12. Sun Ltd. has done business in New Jersey, including through its wholly-owned subsidiary, agent, and/or alter ego, Sun Inc., a company registered as a manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003437 and registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID Nos. 0100954087 and/or 0100970132. Sun Ltd. maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including

through, directly or indirectly, Sun Inc. On information and belief, Sun Inc. acts at the direction, and for the benefit, of Sun Ltd., and is controlled and/or dominated by Sun Ltd.

13. This Court has personal jurisdiction over Sun Ltd. also because it has taken advantage of the jurisdiction of this Court by filing claims and counterclaims in this Court. On information and belief, Sun Ltd. has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases. For example, Sun Ltd. has previously been sued in this Judicial District and has availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and has not challenged personal jurisdiction. *See, e.g., Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, Civil Action No. 18-11630 (SDW)(LDW); *Jazz Pharms., Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 15-8229 (ES)(JAD); *Boehringer Ingelheim Pharms. Inc., et al. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 15-5982 (PGS)(TJB); *Jazz Pharms., Inc. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 15-3217 (ES)(JAD); *Otsuka Pharm. Co. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 14-6397 (JBS)(KMW); *Otsuka Pharm. Co. v. Sun Pharm. Indus., Inc., et al.*, Civil Action No. 14- 4307 (JBS)(KMW); *Cephalon, Inc. v. Sun Pharm. Indus., Inc., et al.*, Civil Action No. 11-5474 (FLW)(DEA); *Depomed, Inc., et al. v. Sun Pharm. Indus., Inc., et al.*, Civil Action No. 11-3553 (JAP)(TJB); *Orexo AB et al. v. Sun Pharm. Indus. Ltd., et al.*, Civil Action No. 20-12588 (BRM)(DEA).

14. Sun Ltd. has further availed itself of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g., Sun Pharm. Indus. Ltd., et al. v. Altana Pharma AG, et al.*, Civil Action No. 05-2391 (KSH)(PS); *Sun Pharm. Indus. Ltd., et al. v. Novartis Pharms. Corp., et al.*, Civil Action No. 19-21733.



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