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

PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., and TRANSCEPT PHARMACEUTICALS, INC., Plaintiffs, v. NOVEL LABORATORIES, INC., Defendant.	Civil Action No. _____ Document Filed Electronically

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Transcept Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Novel Laboratories, Inc. ("Novel") allege as follows:

The Parties

1. Plaintiff Purdue Pharmaceutical Products L.P. is a limited partnership organized and existing under the laws of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

2. Plaintiff Purdue Pharma L.P. is a limited partnership organized and existing under the laws of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

3. Plaintiff Transcept Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1003 W. Cutting Blvd., Suite #110, Pt. Richmond, CA 94804.

4. Upon information and belief, Defendant Novel Laboratories, Inc. is a Delaware corporation with its principal place of business at 400 Campus Drive, Somerset, NJ 08873.

5. Upon information and belief, Novel is in the business of developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States, including in this judicial district.

Jurisdiction and Venue

6. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the U.S. Code, for infringement of U.S. Patent No. 7,682,628 (the "'628 Patent").

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant by virtue of its widespread and continuous contacts with the state of New Jersey. Among other things, Novel's principal

place of business is in New Jersey. Upon information and belief, Novel's Somerset, New Jersey facility consists of a cGMP manufacturing plant, packaging area, laboratories, warehousing areas, and corporate offices. Novel is registered to do business in New Jersey under Business I.D. No. 0100971912, and is registered as a manufacturer and wholesaler of drugs under Registration No. 5003657.

9. Novel has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing counterclaims in this Court. *See, e.g.*, *Salix Pharms., Inc. et al. v. Novel Labs., Inc.*, Civ. A. No. 3:08-cv-02311-FLW-TJB (D.N.J.) (Dkt. No. 9) (counterclaim filed by Novel); *Salix Pharms., Inc. v. Novel Labs., Inc. et al.*, Civ. A. No. 3:08-cv-4638-FLW-JJH (D.N.J.) (Dkt. No. 21) (same); *Braintree Labs., Inc. v. Novel Labs., Inc.*, Civ. A. No. 3:11-cv-01341-GEB-TJB (D.N.J.) (Dkt. No. 11) (same).

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for New and Generic Drugs

11. A person wishing to market a new drug that has not previously been approved by the U.S. Food and Drug Administration ("FDA") (a "pioneering" drug) must file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b).

12. A person wishing to market a generic copy of a drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of that drug. In the ANDA, the applicant must

demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

13. Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions. 21 U.S.C. § 355(j).

14. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

The Approved Drug Product

15. Purdue Pharmaceutical Products L.P. is the current holder of NDA No. 022328, for sublingual tablets containing 1.75 mg and 3.5 mg of zolpidem tartrate, which was first approved by FDA on November 23, 2011. Purdue Pharma L.P. markets the approved drug product under the tradename INTERMEZZO®. INTERMEZZO® is approved for treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep. A copy of the prescribing information for INTERMEZZO® approved in NDA No. 022328 is attached as Exhibit A.

16. FDA has listed U.S. Patent No. 7,682,628 in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 022328.

17. Transcept Pharmaceuticals, Inc. is the owner of the '628 Patent. Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P. are exclusive licensees under the '628 Patent, the former to sell or offer to sell, and the latter to manufacture, zolpidem tartrate sublingual tablets.

ANDA No. 204299

18. Upon information and belief, on or before July 30, 2012, Novel submitted to FDA an ANDA (ANDA No. 204299) with paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for 1.75 mg and 3.5 mg zolpidem tartrate sublingual tablets purportedly bioequivalent to INTERMEZZO®. The purpose of the ANDA is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic INTERMEZZO® product.

19. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204299 for the generic INTERMEZZO® product is the treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep, *i.e.*, the same indication as that set forth in the approved labeling for INTERMEZZO®.

20. Upon information and belief, Novel sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter with a U.S. Postal Service envelope dated July 26, 2012 (the "Notice Letter"). The Notice Letter represented that Novel had submitted to FDA ANDA No. 204299 with a paragraph IV certification for the '628 Patent.

21. Upon information and belief, the purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of INTERMEZZO® before the expiration of the patents listed in the Orange Book for NDA No. 022328. Hence, Novel's purpose in

submitting ANDA No. 204299 is to market products described therein before expiration of the '628 Patent.

Count 1: Patent Infringement of the '628 Patent

22. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 21 above.

23. United States Patent No. 7,682,628, entitled "COMPOSITIONS FOR DELIVERING HYPNOTIC AGENTS ACROSS THE ORAL MUCOSA AND METHODS OF USE THEREOF," was duly and legally issued by the United States Patent and Trademark Office on March 23, 2010. Plaintiff Transcept Pharmaceuticals, Inc. is the owner of the '628 Patent. Plaintiffs Purdue Pharmaceutical Products L.P. and Purdue Pharma L.P. are exclusive licensees of the '628 Patent. A true and complete copy of the '628 Patent is attached hereto as Exhibit B.

24. Upon information and belief, Novel submitted ANDA No. 204299 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of INTERMEZZO® before the expiration of the '628 Patent.

25. Novel's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Novel's ANDA No. 204299 will be administered to human patients for the treatment of insomnia when middle-of-the-night awakening is followed by difficulty returning to sleep, which administration would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '628 Patent. Upon information and belief, this infringement will occur at Novel's behest, with its intent, knowledge,

and encouragement, and Novel will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '628 Patent.

27. Novel's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic INTERMEZZO® product for which approval is sought in ANDA No. 204299 would actively induce and contribute to infringement of the '628 Patent, and Novel would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

28. Upon information and belief, as part of the ANDA filing, Novel purportedly provided written certification to FDA that the claims of the '628 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Novel's generic version of INTERMEZZO®.

29. Upon information and belief, Novel gave written notice of its certification of invalidity and/or non-infringement of the '628 Patent, alleging that claims of the '628 Patent are invalid and that claims 10, 11, and 13 would not be infringed by Novel's generic version of INTERMEZZO®, and informing Plaintiffs that Novel seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '628 Patent.

30. Novel has infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204299 with a paragraph IV certification and seeking FDA approval of ANDA No. 204299 to market a generic version of INTERMEZZO® prior to the expiration of the '628 Patent. Moreover, if Novel commercially uses, offers for sale, or sells its generic version of INTERMEZZO®, or induces or contributes to such conduct, it would further infringe the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

31. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

32. Plaintiffs will be irreparably harmed if Novel is not enjoined from infringing or actively inducing or contributing to infringement of the '628 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendant has infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204299 is not earlier than the expiration date of the '628 Patent, or any later expiration of exclusivity for the '628 Patent to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendant and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the '628 Patent, including the product described in ANDA No. 204299;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204299, or inducing or contributing to such conduct, would constitute infringement of the '628 Patent by Defendant pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

Dated: September 10, 2012

Respectfully submitted,

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