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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. WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., and WATSON LABORATORIES, INC. – FLORIDA, Defendants.	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 Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"); Watson Pharma, Inc. ("Watson Pharma"); and Watson Laboratories, Inc. – Florida ("Watson Florida") (collectively, "Defendants") 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 Watson Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Nevada with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Watson Pharmaceuticals develops, manufactures, and markets numerous generic drugs for sale and use throughout the United States, including in this judicial district, alone and/or through its subsidiaries. Upon information and belief, Watson Pharmaceuticals is registered to do business in New Jersey under Business I.D. No. 0101013496, and has its "Global Headquarters" in Parsippany, NJ. Upon information and belief, Watson Pharmaceuticals is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration Nos. 5003854 (manufacturer and wholesaler); 5003318 (manufacturer); and 5003858 (wholesaler). Upon information and belief, Watson Pharmaceuticals has promulgated a Code of Conduct, through which it dictates the conduct for, among others, "all subsidiaries, divisions and affiliates." Upon information and belief, Watson Pharmaceuticals files financial statements on behalf of its

subsidiaries in its consolidated financial statements submitted to the Securities and Exchange Commission, and Watson Pharmaceuticals generally otherwise directs the policies of its subsidiaries in financial, regulatory, legal, and public relations matters.

5. Upon information and belief, Defendant Watson Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 360 Mt. Kemble Avenue, Morristown, NJ 07960. Upon information and belief, Watson Pharma also has a place of business at 100 Campus Drive, Florham Park, NJ 07932. Upon information and belief, Watson Pharma is registered to do business in New Jersey under Business I.D. No. 0100573928. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals; Watson Pharma's operations, personnel, and business overlap with Watson Pharmaceuticals' operations, personnel, and business; and Watson Pharma is subject to domination and control by Watson Pharmaceuticals. Upon information and belief, Watson Pharmaceuticals maintains Watson Pharma as its subsidiary in the United States for the purpose of acting as a sales and marketing agent of Watson Pharmaceuticals and its other subsidiaries, including Watson Florida. Upon information and belief, Watson Pharma and Watson Pharmaceuticals have a director and at least one officer in common. Upon information and belief, Watson Pharma operates, conducts, and transacts business in New Jersey and contracts to market and sell generic pharmaceutical products in New Jersey alone, or through Watson Pharmaceuticals and/or other Watson entities and agents.

6. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida is a corporation organized and existing under the laws of Florida and having its principal place of business at 4955 Orange Drive, Davie, FL 33314. Watson Florida was formerly known as Andrx Pharmaceuticals, Inc. before it was acquired by Watson Pharmaceuticals in 2006. Upon

information and belief, Andrx Pharmaceuticals, Inc. was registered to do business in New Jersey under Business I.D. No. 0100804180 until 2003. Watson Florida's ultimate parent is Watson Pharmaceuticals. Upon information and belief, Watson Florida's operations, personnel, and business are overlapping and intertwined with Watson Pharmaceuticals' operations, personnel, and business, and Watson Florida is subject to domination and control by Watson Pharmaceuticals. Upon information and belief, at least four officers of Watson Florida, including the President, Chief Financial Officer, and Chief Information Officer, are also officers of Watson Pharmaceuticals, and personnel of Watson Pharmaceuticals act on behalf of, and make decisions for, Watson Florida. Upon information and belief, Watson Pharmaceuticals has represented and bound Watson Florida in contractual matters. Upon information and belief, Watson Florida conducts business in New Jersey and sells pharmaceutical products though Watson Pharmaceuticals, Watson Pharma, and/or other Watson entities and agents.

7. Upon information and belief, Watson Florida develops and manufactures generic pharmaceutical products.

8. Upon information and belief, all three Defendants conduct themselves as part of a unified operation, and have collaborated, cooperated, directed and/or participated in the acts complained of herein, knowing that these actions would lead to and cause infringement of the patent at issue in this lawsuit.

Jurisdiction and Venue

9. 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").

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

11. This Court has personal jurisdiction over Watson Pharmaceuticals by virtue of its widespread and continuous contacts with the state of New Jersey. Among other things, upon information and belief, Watson Pharmaceutical's principal place of business and global headquarters is in New Jersey, it is registered to do business in New Jersey under Business I.D. No. 0101013496, and it is a registered manufacturer and wholesaler of drugs in New Jersey.

12. This Court has personal jurisdiction over Watson Pharma by virtue of its widespread and continuous contacts with the state of New Jersey. Upon information and belief, Watson Pharma's principal place of business is in New Jersey, Watson Pharma has other business locations in New Jersey, and Watson Pharma is registered to do business in New Jersey under Business I.D. No. 0100573928.

13. This Court has personal jurisdiction over Watson Florida because, upon information and belief, Watson Florida conducts business in New Jersey alone and/or through Watson Pharmaceuticals, Watson Pharma, and/or other Watson entities and agents. Additionally or alternatively, this Court has personal jurisdiction over Watson Florida because, upon information and belief, the subject matter of this lawsuit is connected to the state of New Jersey. For example, upon information and belief, in developing the potential generic product that is the subject of this lawsuit, Watson Florida has consulted with individuals in New Jersey, including individuals at Watson Pharmaceuticals and Watson Pharma; and Watson Florida intends for its potential product to be marketed and sold in New Jersey. Additionally or alternatively, this Court has personal jurisdiction over Watson Florida because the contacts of Watson Pharmaceuticals can be imputed to Watson Florida, given that Watson Pharmaceuticals is the

ultimate parent of Watson Florida, putting the two entities under common ownership; the operations, business, and personnel of these entities are intertwined, as demonstrated by the fact that Watson Pharmaceuticals and Watson Florida share at least four common officers; and Watson Pharmaceuticals exercises domination and control over Watson Florida's operational policies and business.

14. Watson Florida 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.*, *Mallinckrodt Inc. v. Watson Labs., Inc. – Fla.*, 2:10-cv-06424 (D.N.J.) (docket entry 10) (counterclaim filed by Watson Florida); *Warner Chilcott Co. v. Watson Labs. Inc. – Fla.*, 2:11-cv-05989 (D.N.J.) (docket entry 16) (same); *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, 3:12-cv-01358 (D.N.J.) (docket entry 47) (same).

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

Regulatory Requirements for New and Generic Drugs

16. 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).

17. 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).

18. 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).

19. 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

20. 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.

21. 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.

22. 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. 204240

23. Upon information and belief, on or before July 13, 2012, Watson Florida, itself and with the authorization, contribution, participation, assistance and/or inducement of Watson Pharmaceuticals and Watson Pharma, submitted to FDA an ANDA (ANDA No. 204240) 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.

24. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, and Watson Florida will act in concert to market and/or distribute Defendants' generic INTERMEZZO® product, if ANDA No. 204240 is approved by FDA.

25. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204240 for Defendants' 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®.

26. Upon information and belief, Watson Florida sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated July 13, 2012 (the "Notice Letter"). The Notice Letter represented that Watson Florida had submitted to FDA ANDA No. 204240 with a paragraph IV certification for the '628 Patent.

27. 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, Defendants' purpose in submitting ANDA No. 204240 is to market products described therein before expiration of the '628 Patent.

Count 1: Patent Infringement of the '628 Patent

28. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 27 above.

29. 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.

30. Upon information and belief, Watson Florida, Watson Pharma, and Watson Pharmaceuticals acted in concert to submit ANDA No. 204240 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.

31. Defendants' 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).

32. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in ANDA No. 204240 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 Defendants' behest, with their intent, knowledge, and encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '628 Patent.

33. Defendants' 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. 204240 would actively induce and contribute to infringement of the '628 Patent, and Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

34. Upon information and belief, as part of the ANDA filing, Watson Florida, with the authorization, contribution, participation, assistance, and/or inducement of Watson Pharma and Watson Pharmaceuticals, 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 Defendants' generic version of INTERMEZZO®.

35. Upon information and belief, by letter dated July 13, 2012, Watson Florida gave written notice of Defendants' certification of invalidity and/or non-infringement of the '628 Patent, alleging that the '628 Patent is invalid and that claims 9, 10, and 13 would not be infringed by Defendants' generic version of INTERMEZZO®, and informing Plaintiffs that Defendants seek approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '628 Patent.

36. Defendants have infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204240 with a paragraph IV certification and seeking FDA approval of ANDA No. 204240 to market a generic version of INTERMEZZO® prior to the expiration of the '628 Patent. Moreover, if Defendants commercially use, offer for sale, or sell

their generic version of INTERMEZZO®, or induce or contribute to such conduct, it would further infringe the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

38. Plaintiffs will be irreparably harmed if Defendants are 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 Defendants have 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. 204240 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 Defendants and their 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. 204240;

D. A judgment declaring that the making, using, selling, offering to sell, or importing of the product described in ANDA No. 204240, or inducing or contributing to such conduct,

would constitute infringement of the '628 Patent by Defendants 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: August 27, 2012

Respectfully submitted,

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NOTICE OF OTHER ACTIONS PURSUANT TO L. CIV. R. 11.2

The undersigned hereby certifies that the matter in controversy is not the subject of any other action or proceeding in any Court or of a pending arbitration proceeding, except that the same United States Patent on which this Complaint is based is the subject of another patent infringement action, *Purdue Pharmaceutical Products, Inc. et al. v. Actavis Elizabeth LLC,* 2:12-cv-05311-JLL-MAH, which was filed in this Court on August 24, 2012, and has been assigned to District Judge Jose L. Linares and Magistrate Judge Michael A. Hammer.

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Dated: August 27, 2012