IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., and TRANSCEPT PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	Civil Action No.: 13-cv-5999
v.	)	
TWi PHARMACEUTICALS, INC.,	)	
Defendant.	)	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 TWi Pharmaceuticals, Inc. ("TWi") 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 TWi is a corporation organized under the laws of Taiwan with its principal place of business at 4F, No. 41, Lane 221, Kang Chien Rd., Nei Hu Dist., Taipei 114, Taiwan.

5. Upon information and belief, TWi 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.

6. Upon information and belief, TWi, either directly or through one or more of its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

Jurisdiction and Venue

7. 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. 8,242,131 (the "'131 Patent") and U.S. Patent No. 8,252,809 (the "'809 Patent").

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

9. TWi is subject to personal jurisdiction in this judicial district by virtue of consenting to such jurisdiction in a letter dated July 8, 2013 to Purdue Pharma L.P., in which TWi named Don Mizerk of the Chicago office of Husch Blackwell LLP as its agent for acceptance of service of process. Purdue Pharma L.P. received said letter on July 9, 2013.

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 the '131 and '809 Patents 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 '131 and '809 Patents. Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P. are exclusive licensees under the '131 and '809 Patents, the former to sell or offer to sell, and the latter to manufacture, zolpidem tartrate sublingual tablets.

ANDA No. 205061

18. Upon information and belief, on or before July 8, 2013, TWi submitted to FDA an ANDA (ANDA No. 205061) 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. 205061 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, TWi sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated July 8, 2013 (the "Notice Letter"). The Notice Letter represented that TWi had submitted to FDA ANDA No. 205061 with a paragraph IV certification for, among others, the '131 and '809 Patents. Purdue Pharma L.P. received the Notice Letter on July 9, 2013.

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, TWi's purpose in submitting ANDA No. 205061 is to market products described therein before expiration of the '131 and '809 Patents.

Count I: Patent Infringement of the '131 Patent

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

23. United States Patent No. 8,242,131, entitled "METHODS OF TREATING MIDDLE-OF-THE-NIGHT INSOMNIA," was duly and legally issued by the United States Patent and Trademark Office on August 14, 2012. Plaintiff Transcept Pharmaceuticals, Inc. is the owner of the '131 Patent. Plaintiffs Purdue Pharmaceutical Products L.P. and Purdue Pharma L.P. are exclusive licensees of the '131 Patent. A true and complete copy of the '131 Patent is attached hereto as Exhibit B.

24. Upon information and belief, TWi submitted ANDA No. 205061 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 '131 Patent.

25. TWi's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '131 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 TWi's ANDA No. 205061 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 '131 Patent. Upon information and belief, this infringement will occur at TWi's behest, with its intent, knowledge, and encouragement, and TWi will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

27. TWi'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. 205061 would actively induce and contribute to infringement of the '131 Patent, and TWi 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, TWi purportedly provided written certification to FDA that the claims of the '131 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of TWi generic version of INTERMEZZO®.

29. TWi gave written notice to Plaintiffs of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that the claims of the '131 Patent are invalid, and informing Plaintiffs that TWi seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '131 Patent.

30. TWi has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205061 with a paragraph IV certification and seeking FDA approval of

ANDA No. 205061 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if TWi commercially uses, offers for sale, or sells its generic version of INTERMEZZO®, or induces or contributes to such conduct, it would further infringe the '131 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 TWi is not enjoined from infringing or actively inducing or contributing to infringement of the '131 Patent. Plaintiffs do not have an adequate remedy at law.

Count II: Patent Infringement of the '809

33. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 32 above.

34. United States Patent No. 8,252,809, entitled "COMPOSITIONS FOR TREATING INSOMNIA," was duly and legally issued by the United States Patent and Trademark Office on August 28, 2012. Plaintiff Transcept Pharmaceuticals, Inc. is the owner of the '809 Patent. Plaintiffs Purdue Pharmaceutical Products L.P. and Purdue Pharma L.P. are exclusive licensees of the '809 Patent. A true and complete copy of the '809 Patent is attached hereto as Exhibit C.

35. Upon information and belief, TWi submitted ANDA No. 205061 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 '809 Patent.

36. TWi's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '809 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

37. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in TWi ANDA No. 205061 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 '809 Patent. Upon information and belief, this infringement will occur at TWi's behest, with its intent, knowledge, and encouragement, and TWi will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

38. TWi'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. 205061 would actively induce and contribute to infringement of the '809 Patent, and TWi would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

39. Upon information and belief, as part of the ANDA filing, TWi purportedly provided written certification to FDA that the claims of the '809 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of TWi's generic version of INTERMEZZO®.

40. TWi gave written notice to Plaintiffs of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that claims of the '809 Patent are invalid and that certain claims would not be infringed by TWi's generic version of INTERMEZZO®, and informing Plaintiffs that TWi seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '809 Patent.

41. TWi has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205061 with a paragraph IV certification and seeking FDA approval of ANDA No. 205061 to market a generic version of INTERMEZZO® prior to the expiration of the

’809 Patent. Moreover, if TWi commercially uses, offers for sale, or sells its generic version of INTERMEZZO®, or induces or contributes to such conduct, it would further infringe the ’809 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

43. Plaintiffs will be irreparably harmed if TWi is not enjoined from infringing or actively inducing or contributing to infringement of the ’809 Patent. Plaintiffs do not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that TWi has infringed the ’131 and ’809 Patents 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. 205061 is not earlier than the expiration date of the ’131 and ’809 Patents, or any later expiration of exclusivity for the ’131 and ’809 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining TWi 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 ’131 or ’809 Patents, including the product described in ANDA No. 205061;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 205061, or inducing or contributing to such conduct, would

constitute infringement of the ’131 and ’809 Patents by TWi 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 22, 2013

Respectfully submitted,

/s/John L. Abramic

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