UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

PAR PHARMACEUTICAL, INC (300 Tice Blvd., Woodcliff Lake, New Jersey). and EDT PHARMA HOLDINGS LTD (Monksland, Athlone, County Westmeath, Ireland). Plaintiffs, v. TWI PHARMACEUTICALS, INC. (4F, No. 41, Lane 221, Kang Chien Road, Nei Hu District, Taipei 114, Taiwan), Defendant.	C.A. No. _____ PATENT INFRINGEMENT COMPLAINT

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc. ("Par") and EDT Pharma Holdings Ltd. ("EDT") (collectively, "Plaintiffs"), for their Complaint against Defendant TWi Pharmaceuticals, Inc., allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No.7,101,576 (the "'576 patent") pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

2. Plaintiff Par is a corporation organized under the laws of Delaware, with its principal place of business in Woodcliff Lake, New Jersey.

3. Plaintiff EDT is an Irish corporation having a principal place of business in Monksland, Athlone, Co. Westmeath, Ireland.

4. Upon information and belief, Defendant is an entity organized under the laws of Taiwan, with its principal place of business in Taipei, Taiwan.

JURISDICTION

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2).

6. This Court has personal jurisdiction over Defendant by virtue of the fact that Defendant has appointed an entity within this judicial district to act as its authorized U.S. agent before the U.S. Food and Drug Administration ("FDA") for the Abbreviated New Drug Application ("ANDA") that is the subject of this action and , on information and belief, Defendant has additional contacts with this judicial district including, but not limited to, actions taken by Defendant's authorized U.S. agent in this district.

VENUE

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

PATENT-IN-SUIT

8. Plaintiff EDT is the lawful owner of the '576 patent.

9. The '576 patent, entitled "Nanoparticulate Megestrol Formulations," duly and legally issued on September 5, 2006, naming Douglas Hovey, John Pruitt, and Tuula Ryde as inventors. A copy of the '576 patent is attached as Exhibit A.

MEGACE ES®

10. Plaintiff Par is the holder of New Drug Application ("NDA") No. 21-778 for Megace ES® (megestrol acetate) oral suspension, 125 mg/mL, and is an exclusive licensee of the '576 patent.

11. On July 5, 2005, the FDA approved NDA No. 21-778 for the manufacture, marketing, and sale of Megace ES® (megestrol acetate) oral suspension for the treatment of appetite loss, severe malnutrition, or unexplained, significant weight loss in AIDS patients. Plaintiff Par has sold Megace ES® under NDA No. 21-778 since its approval.

12. The '576 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Par's product Megace ES®.

DEFENDANT'S ANDA

13. Upon information and belief, Defendant submitted ANDA No. 20-3139 to the FDA under 35 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use, and/or sale of megestrol acetate oral suspension, 125 mg/mL, ("Defendant's Generic Product") before expiration of the '576 patent.

14. Upon information and belief, ANDA No. 20-3139 refers to and relies upon Plaintiff Par's NDA for Megace ES® and purports to contain data showing bioequivalence of Defendant's Generic Product with Megace ES®.

15. Plaintiffs received from Defendant a letter dated July 21, 2011 (the "Notification Letter"), stating that ANDA No. 20-3139 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '576 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendant's Generic Product.

16. Plaintiffs commenced this action within 45 days of receiving the Notification Letter.

COUNT ONE

(Infringement of the ’576 Patent under 35 U.S.C. § 271(e)(2))

17. Plaintiffs reallege paragraphs 1-16 above as if fully set forth herein.

18. Defendant’s submission of ANDA No. 20-3139 to the FDA with a Paragraph IV certification regarding the ’576 patent, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant’s Generic Product before the expiration of the ’576 patent, constitutes infringement of the ’576 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT TWO

(Declaratory Judgment of Infringement of the ’576 Patent under 35 U.S.C. § 271(a)-(c))

19. Plaintiffs reallege paragraphs 1-16 above as if fully set forth herein.

20. Upon information and belief, Defendant intends, soon after the FDA has approved its ANDA No. 20-3139, to begin the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant’s Generic Product.

21. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, Defendant’s Generic Product before expiration of the ’576 patent.

22. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant’s Generic Product before expiration of the ’576 patent.

23. Defendant’s actions, including without limitation the filing of ANDA No. 20-3139, exhibit a refusal to change the course of its action despite Plaintiffs’ patent rights.

24. Upon information and belief, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '576 patent, and the active inducement of and/or contribution to any of those activities, will constitute infringement, inducement of infringement and/or contributory infringement of the '576 patent.

25. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '576 patent by Defendant or its agents, will constitute infringement, inducement of infringement and/or contributory infringement of the '576 patent.

INJUNCTIVE RELIEF

26. Plaintiffs will be substantially and irreparably damaged and harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

EXCEPTIONAL CASE

27. Defendant has at all relevant times been aware of the '576 patent, and has had no good faith basis for its infringement of that patent. This is an exceptional case under 35 U.S.C. §285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Enter a judgment that Defendant has infringed the ’576 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-3139 to the FDA, seeking approval to engage in commercial manufacture, use, offer to sell or sale of Defendant’s Generic Product before expiration of the ’576 patent;

B. Enter a declaration under 28 U.S.C. § 2201 that Defendant would infringe the ’576 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell or sale within the United States, or importation into the United States, of Defendant’s Generic Product before expiration of the ’576 patent;

C. Enter an order under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 20-3139, if any, shall be no earlier than the date of expiration of the ‘576 patent, including any extensions;

D. Enter an injunction under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendant’s Generic Product before the expiration of the ‘576 patent, including any extensions;

E. Grant Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Defendant’s Generic Product before the expiration of the ‘576 patent, including any extensions;

F. Declare that Defendant's activities have made this an exceptional case under 35 U.S.C. §285 and grant Plaintiffs their attorneys fees; and

G. Award Plaintiffs any further and additional relief as this Court may deem just and proper.

Respectfully submitted,

Dated: September 1, 2011

/s/ James P. Ulwick

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