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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB, Plaintiff, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. _____ COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

2. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharms") and Mylan Inc. ("Mylan Inc.), (collectively referred to as "Mylan") have been and are engaging in activities directed toward infringement of United States Patent No. 6,761,910 (the "'910 patent") by, *inter alia*, submitting an abbreviated new drug application designated ANDA

No. 20-2657 seeking FDA approval to manufacture and commercially market its proposed product called "Zolpidem Tartrate Sublingual Tablets (5 mg and 10 mg) (hereinafter referred to as "Zolpidem Tartrate Sublingual Product") containing the active ingredient zolpidem tartrate.

3. In Mylan Pharms's notice letter, dated May 19, 2010, entitled "EDLUAR-Zolpidem tartrate sublingual tablets (5 mg and 10 mg), U.S. Patent No. 6,761,910 Notice of Paragraph IV Certification" (hereinafter referred to as the "May 19, 2011 Notice Letter"), Mylan Pharms indicated that it intends to manufacture and commercially market its Zolpidem Tartrate Sublingual Product before expiration of the '910 patent.

THE PARTIES

4. Plaintiff Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business at Uppsala, Sweden. Orexo AB was a corporate name change from Diabact AB.

5. On information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. On information and belief, defendant Mylan Inc. is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action and venue is proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

8. On Information and belief, Mylan Inc. and Mylan Pharms have submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in *Pfizer Inc. et al. v. Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.*, 10-03246 (DMC); *Warner Chilcott Laboratories Ireland Ltd. et al. v. Impax Laboratories, Inc. et al.*, 08-6304 (WJM) (MF); and *Novartis Pharmaceuticals Corp. v. Mylan Pharmaceuticals Inc. and Mylan Inc.*, 08-5042 (PGS) (ES).

9. On information and belief, Mylan Inc., directly or through Mylan Pharms, is in the business of formulating, manufacturing, marketing and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. Mylan Inc.'s United States product portfolio includes approximately 180 products. On further information and belief, Mylan Inc. is conducting business within the District, and also has facilities located at One Woodbridge Center, 9th Floor, Suite 920, Woodbridge, New Jersey 07095. Mylan, Inc., either directly or through Mylan Pharms and/or through one or more of its subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey. Mylan Inc. is the majority owner of, and has controlling interests in, Mylan Pharms.

10. On information and belief, this Court has personal jurisdiction over Mylan Inc. by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sale of prescription drugs in New Jersey; (4) its registration of prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*; (5) its consent to be sued in New Jersey; (6) its systematic and continuous contacts with New Jersey; and (7) its course of conduct that is

designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey. On information and belief, the acts of Mylan Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of, Mylan Pharms, and, at least in part, benefit the latter.

11. On information and belief, Mylan Pharms, a wholly owned subsidiary of Mylan Inc., is in the business of manufacturing generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. On information and belief, the acts of Mylan Pharms complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Mylan Inc., and, at least in part, benefit the latter.

12. On information and belief, this Court has personal jurisdiction over Mylan Pharms by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey for the receipt of service of process; (3) its sale of prescription drugs in New Jersey; (4) its registration of prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*; (5) its consent to be sued in New Jersey; (6) its systematic and continuous contacts with New Jersey; and (7) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

13. On information and belief, Mylan Inc. and Mylan Pharms operate as an integrated business ultimately controlled by Mylan Inc.

CLAIM FOR RELIEF UNDER THE '910 PATENT

14. Orexo AB realleges paragraphs 1-13 above as if set forth specifically here.

15. The '910 patent (copy attached as Exhibit A), entitled "Pharmaceutical Composition for the Treatment of Acute Disorders," was issued on July 13, 2004 to Diabact AB, upon assignment from the inventors Anders Pettersson and Christer Nystrom. The '910 patent claims, *inter alia*, a pharmaceutical composition for the treatment of acute disorders and a method for treatment of said acute disorders.

16. Plaintiff Orexo AB has been and still is the owner of the '910 patent. The '910 patent will expire on September 24, 2019.

17. In Mylan's May 19, 2011 Notice Letter, Mylan notified Plaintiff that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '910 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '910 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

18. On information and belief, at the time Mylan's May 19, 2011 Notice Letter was served, Mylan was aware of the statutory provisions and regulations referred to in paragraph 17 above.

19. Mylan acknowledged and represented that its May 19, 2011 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 17, above.

20. Mylan's May 19, 2011 Notice Letter alleges that its Zolpidem Tartrate Sublingual Product does not literally infringe claims 8-10, 16, 18, 20 and 21 of the '910 Patent. Mylan alleges that it does not infringe claims 8-10 of the '910 Patent because these claims "require a surfactant as part of the composition" whereas "Mylan's ANDA products will not contain a surfactant as part of the formulation." Mylan also alleges that it does not infringe claims 16, 18, 20 and 21 of the '910 Patent because these claims "require fentanyl as the active ingredient" whereas "Mylan's ANDA product will contain zolpidem tartrate as the active ingredient" and "will not contain fentanyl."

21. Mylan's May 19, 2011 Notice Letter also alleges that its Zolpidem Tartrate Sublingual Product does not infringe under the Doctrine of Equivalents. Mylan alleges that it does not infringe claims 8-10 of the '910 Patent under the Doctrine of Equivalents because "[t]he Mylan ANDA products do not contain an excipient that is mixed with the active agent and a carrier that serves the function of a surfactant." Mylan also alleges that it does not infringe claims 16, 18, 20 and 21 of the '910 Patent under the Doctrine of Equivalents because "[t]he active ingredient in Mylan ANDA products, zolpidem, is a non-benzodiazepine hypnotic of the imidazopyridine class indicated for the treatment of insomnia," which Mylan alleges "is a completely different class, indication and structure than the fentanyl active ingredient required

by claims 16, 18, 20 and 21." do not contain an excipient that is mixed with the active agent and acarrier that serves the function of a surfactant."

22. Mylan's May 19, 2011 Notice Letter provides no other explanation or allegation why Mylan's Zolpidem Tartrate Sublingual Product does not infringe any claim of the '910 patent.

23. By failing to address any limitations relating to claims 1-7, 11-15, 17, and 19 of the '910 patent as required by statute and regulation (see paragraph 17, above), Mylan foregoes any additional defenses based on the limitations of these claims and admits that its product meets the all the limitations of these claims.

24. Mylan's May 19, 2011 Notice Letter does not certify that the '910 patent is unenforceable, nor does it provide any basis for a claim of unenforceability.

25. By failing to substantively address unenforceability of claims 1-21 of the '910 patent in its May 19, 2011 Notice Letter as required by statute and regulation (see paragraph 17, above), Mylan admits that claims 1-21 of the '910 patent are enforceable and foregoes any such claims or defenses.

26. Mylan infringed one or more of the '910 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '910 patent.

27. Upon information and belief, unless enjoined by this Court, Mylan will directly infringe at least claims 1-7, 11-15, 17, and 19 of the '910 patent (either literally or under the Doctrine of Equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling its Zolpidem Tartrate Sublingual Product in the United States in violation of 35 U.S.C. §§ 271(a), 271(e)(2), and 271(g).

28. Upon information and belief, unless enjoined by this Court, Mylan will induce the infringement of at least claims 1-7, 11-15, 17, and 19 of the '910 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Mylan's Zolpidem Tartrate Sublingual Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo AB's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

29. Upon information and belief, unless enjoined by this Court, Mylan will induce the infringement of at least claims 1-7, 11-15, 17, and 19 of the '910 patent by actively and intentionally encouraging, through its label, the infringing use of Mylan's Zolpidem Tartrate Sublingual Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo AB's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

30. Upon information and belief, unless enjoined by this Court, Mylan will contribute to the infringement of at least claims 1-7, 11-15, 17, and 19 of the '910 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Mylan's Zolpidem Tartrate Sublingual Product or equipment for the manufacture of Mylan's Zolpidem Tartrate Sublingual Product to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Mylan's Zolpidem Tartrate Sublingual Product in contravention of Orexo AB's rights under the '910 patent in violation of 35 U.S.C. § 271(c).

31. Orexo AB will be substantially and irreparably damaged and harmed if Mylan's infringement of the '910 patent is not enjoined.

32. Orexo AB does not have an adequate remedy at law for Mylan's infringement of the '910 patent.

33. This case is an exceptional one, and Orexo AB is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment be entered that Mylan infringed at least claims 1-7, 11-15, 17, and 19 of the '910 patent by submitting ANDA 20-2657;

(b) A judgment be entered declaring that the effective date of any approval of Mylan's ANDA 20-1509 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Zolpidem Tartrate Sublingual Tablets (5 mg and 10 mg)" must be later than September 24, 2019, the expiration date of the patent in suit or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(c) A declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Mylan's Zolpidem Tartrate Sublingual Product will directly infringe, induce and/or contribute to infringement of at least claims 1-7, 11-15, 17, and 19 of the '910 patent;

(d) Preliminary and permanent injunctions be granted enjoining Mylan and its officers, agents, attorneys, and employees, and those acting in privity or concert with them from making, using, selling, offering to sell, or importing Mylan's Zolpidem Tartrate Sublingual Product until after the expiration of the '910 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(e) A permanent injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Mylan, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the '910 patent, or from actively inducing or contributing to the infringement of at least claims 1-7, 11-15, 17, and 19 of the '910 patent, until after the expiration of the '910 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted for and to the extent Mylan has committed any acts with respect to the methods or compositions claimed in the '910 patent, other than those expressly exempted by 35 U.S.C. §271(e)(1);

(g) An award of damages be granted if Mylan engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Mylan's Zolpidem Tartrate Sublingual Product prior to the expiration of the '910 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(h) A judgment be entered declaring that the '910 patent remains valid, remains enforceable and has been infringed by Mylan;

(i) A judgment be entered that Mylan's defenses and claims for relief are limited to those presented in Mylan's May 19, 2011 Notice Letter;

(j) A judgment be entered that Mylan admits to the enforceability of the '910 patent by failing to address the issue of enforceability in its May 19, 2011 Notice Letter;

(k) A judgment be entered that Mylan's conduct is exceptional;

(l) An award of attorneys' fees be granted pursuant to 35 U.S.C. § 285;

(m) An award of costs and expenses be granted in this action; and

(n) Such other relief as this Court may deem proper.

Respectfully Submitted,

Dated: June 30, 2011

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the patent at issue in the matter in controversy is the subject of the following action pending before the Honorable Freda L. Wolfson:

OREXO AB v. EDICT PHARMACEUTICALS PVT. LTD., 3:10-cv-05548-FLW-LHG (District of New Jersey).

Dated: June 30, 2011

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