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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB, Plaintiff,	:	Civil Action No. _____
v.	:	COMPLAINT FOR PATENT INFRINGEMENT
EDICT PHARMACEUTICALS PVT. LTD., Defendant.	:	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, Edict Pharmaceuticals Pvt. Ltd. ("Edict") has been and is 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. 20-1509 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 sublingual tablets.

3. In Edict's notice letter, dated September 13, 2010, entitled "Certification of Non-Infringement and/or Invalidity of United States Patent No. 6,761,910" (hereinafter referred to as the "September 13, 2010 Letter"), Edict 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 Edict Pharmaceuticals Pvt. Ltd. is a company organized and existing under the laws of India having a principal place of business at New No. 1/58, Pudupakkam Main Road, Kelambakkam – 603103, Tamil Nadu, India.

6. On information and belief, defendant Edict Pharmaceuticals Pvt. Ltd. maintains a U.S. office, located at #9 – Revere Road, Monmouth Junction, New Jersey 08852.

7. On information and belief, Edict Pharmaceuticals Pvt. Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

8. On information and belief, Edict seeks approval to market its Zolpidem Tartrate Sublingual Product throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

9. 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.

10. This Court has personal jurisdiction over Edict by virtue of its establishing an office for conducting business in the State of New Jersey, conducting business and engaging in activities related to the subject matter of this action in the State of New Jersey, and maintaining continuous and systematic contacts with the State of New Jersey.

CLAIM FOR RELIEF UNDER THE '910 PATENT

11. Orexo AB realleges paragraphs 1-10 above as if set forth specifically here.

12. 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.

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

14. In Edict's September 13, 2010 Letter, Edict 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."

15. On information and belief, at the time Edict's September 13, 2010 Letter was served, Edict was aware of the statutory provisions and regulations referred to in paragraph 14 above.

16. Edict acknowledged and represented that its September 13, 2010 Letter meets the statutory and regulatory requirements referred to in paragraph 14, above.

17. Edict's September 13, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 14 above), identifies a single basis for its allegation that the Edict Zolpidem Tartrate Sublingual Product does not literally infringe the independent claims of the '910 patent and two bases for its allegation of that the Edict Zolpidem Tartrate Sublingual Product does not infringe under the Doctrine of Equivalents.

18. Edict's September 13, 2010 Letter alleges that its Zolpidem Tartrate Sublingual Product does not literally infringe independent claims 1 and 19 of the '910 patent because both claims "require[] that the compound is 'essentially water free'" whereas "[t]he Edict zolpidem tartrate sublingual tablet product comprises water."

19. Edict's September 13, 2010 Letter also alleges that its Zolpidem Tartrate Sublingual Product does not infringe under the Doctrine of Equivalents because, based on the Doctrine of Prosecution History Estoppel, Plaintiff will be unable to argue that claims cover compositions that comprise water, since "Patentees relied on the 'essentially water free' limitation to overcome an obviousness rejection," while the Edict Zolpidem Tartrate Sublingual Product comprises water.

20. Edict's September 13, 2010 Letter also alleges that its Zolpidem Tartrate Sublingual Product does not infringe under the Doctrine of Equivalents because, based on the Doctrine of Prosecution History Estoppel, Plaintiff will be unable to argue that claims cover compositions that comprise an insoluble ingredient, whereas the Edict Zolpidem Tartrate Sublingual Product comprises crospovidone, which is insoluble.

21. Edict's September 13, 2010 Letter provides no other explanation or allegation why Edict's Zolpidem Tartrate Sublingual Product does not infringe any claim of the '910 patent.

22. To further investigate Edict's allegations of non-infringement of the '910 patent, in a letter dated September 24, 2010, Orexo AB requested access to certain documents and information and asked that Edict confirm that its September 13, 2010 Letter discloses all of Edict's bases for non-infringement.

23. Edict did not dispute the completeness of its September 13, 2010 Letter, produced a limited number of the requested confidential documents, and by letter dated October 8, 2010 represented that "Edict believes it has supplied [Orexo AB with] sufficient information from its ANDA for evaluation [of Edict's non-infringement allegations]."

24. Upon information and belief, Edict's Zolpidem Tartrate Sublingual Product is "essentially free of water" as set forth in claim 1 and 19 of the '910 patent and therefore literally infringes these claims.

25. By failing to address any additional limitations relating to the '910 patent claims 1 and 19 as required by statute and regulation (see paragraph 14, above), Edict foregoes any additional defenses based on the remaining limitations and admits that its product meets the other limitations of these claims.

26. By failing to address infringement as required by statute and regulation (see paragraph 14, above), Edict foregoes any additional defenses based on the limitations of the '910 patent claims 2-18 and 20-21, beyond the allegations of non-infringement of independent claims 1 and 19 disclosed in Edict's September 13, 2010 Letter and admits that its product meets all the limitations of at least claims 2-15 and 17.

27. Edict's September 13, 2010 Letter does not certify that the '910 patent is invalid or unenforceable, nor does it provide any basis for a claim of invalidity or unenforceability. The only reference to any such allegation is the general and unsupported statement that "there may be other bases for the invalidity and/or unenforceability of the '910 patent."

28. By failing to substantively address invalidity or unenforceability of claims 1-21 of the '910 patent in its September 13, 2010 Letter as required by statute and regulation (see paragraph 14, above), Edict admits that claims 1-21 of the '910 patent are not invalid and are enforceable and foregoes any such claims or defenses.

29. Edict 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.

30. Upon information and belief, unless enjoined by this Court, Edict will directly infringe at least claims 1-15, 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).

31. Upon information and belief, unless enjoined by this Court, Edict will induce the infringement of at least claims 1-15, 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 Edict'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).

32. Upon information and belief, unless enjoined by this Court, Edict will induce the infringement of at least claims 1-15, 17, and 19 of the '910 patent by actively and intentionally encouraging, through its label, the infringing use of Edict'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).

33. Upon information and belief, unless enjoined by this Court, Edict will contribute to the infringement of at least claims 1-15, 17, and 19 of the '910 patent by knowingly

and intentionally selling materials and/or apparatuses, including chemical precursors of Edict's Zolpidem Tartrate Sublingual Product or equipment for the manufacture of Edict'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 Edict'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).

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

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

36. 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 Edict infringed at least claims 1-15, 17, and 19 of the '910 patent by submitting ANDA 20-1509;

(b) A judgment be entered declaring that the effective date of any approval of Edict'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 Edict's Zolpidem Tartrate Sublingual Product will directly

infringe, induce and/or contribute to infringement of at least claims 1-15, 17, and 19 of the '910 patent;

(d) Preliminary and permanent injunctions be granted enjoining Edict 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 Edict'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 Edict, 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 1-15, 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 Edict 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 Edict engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Edict'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 defendant Edict;

(i) A judgment be entered that Edict's defenses and claims for relief are limited to those presented in Edict's September 13, 2010 Letter;

(j) A judgment be entered that Edict admits to the validity of claims 1-21 of the '910 patent by failing to address the validity of those claims in its September 13, 2010 Letter;

(k) A judgment be entered that Edict admits to the enforceability of the '910 patent by failing to address the issue of enforceability in its September 13, 2010 Letter;

(l) A judgment be entered that Edict's conduct is exceptional;

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

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

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

Respectfully Submitted,

Dated: October 26, 2010

By: */s/ John E. Flaherty*

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, arbitration, or administrative proceeding.

Dated: October 26, 2010

By: */s/ John E. Flaherty*

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