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*Attorneys for Plaintiff  
Orexo AB*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

_____ )	
OREXO AB, )	
)	
Plaintiff, )	Civil Action No. _____
)	
v. )	
)	
ACTAVIS LABORATORIES FL, INC., )	
ANDRX CORPORATION, ACTAVIS, INC., )	
and ACTAVIS PHARMA, INC. )	
)	
Defendants. )	
_____ )	

**COMPLAINT**

1. Plaintiff Orexo AB (“Plaintiff or “Orexo”), for its Complaint against Actavis Laboratories FL, Inc. (“Actavis FL”), Andrx Corporation (“Andrx”), Actavis, Inc., and Actavis Pharma, Inc. (“Actavis Pharma”) (collectively, “Actavis” or “Defendants”), alleges as follows:

### **NATURE OF THE ACTION**

2. 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.

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 6,759,059 (“the ’059 patent”), United States Patent No. 6,761,910 (“the ’910 patent”), and United States Patent No. 7,910,132 (“the ’132 patent”), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 207338 seeking FDA approval to manufacture and commercially market their proposed products called “Fentanyl Sublingual tablets, CII” (hereinafter referred to as “Actavis’s ANDA Products”) containing the active ingredient Fentanyl Citrate.

4. In a letter dated December 23, 2014, titled “Notification of Certifications for U.S. Patent Nos. 6,759,059; 6,761,910 and 7,910,132 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act” (hereinafter referred to as the “December 23 Notice Letter”), Actavis FL notified Orexo that it had filed ANDA No. 207338 and that it intends to manufacture and commercially market Actavis’s ANDA Products (a generic version of Abstral<sup>®</sup>) before expiration of the ’059, ’910, and ’132 patents.

### **THE PARTIES**

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

6. On information and belief, defendant Actavis FL is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis FL is a wholly-owned subsidiary of Andrx.

7. On information and belief, Actavis FL is in the business of manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

8. On information and belief, defendant Andrx is a corporation organized under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Andrx is a wholly-owned subsidiary of Actavis, Inc.

9. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. On information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

10. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

11. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis, Inc. holds a current and valid “Wholesale Drug & Medical Device” registration in New Jersey (Registration No. 5003854).

12. On information and belief, Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

## JURISDICTION AND VENUE

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

14. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic.

15. On information and belief, Defendants share common officers and directors and are agents of each other, or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in the State of New Jersey.

16. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in *AstraZeneca AB, et al. v. Andrx Corporation, et al.*, No. 3:14-08030-JAP-TJB (D.N.J.); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07870-JAP-TJB (D.N.J.); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07263-MLC-TJB (D.N.J.); *Vivus Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:14-cv-03786-FSH-MAH (D.N.J.); *Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al.*, No. 13-

04740-RMB-JS (D.N.J.); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, No. 3:13-01669-JAP-TJB (D.N.J.).

17. On information and belief, Actavis FL, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

18. On information and belief, this Court has personal jurisdiction over Actavis FL by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

19. On information and belief, this Court has personal jurisdiction over Actavis Pharma by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

20. On information and belief, this Court has personal jurisdiction over Andrx by virtue of, *inter alia*: (1) its course of conduct that is designed to cause the sale of its products in New Jersey; and (2) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

21. On information and belief, this Court has personal jurisdiction over Actavis, Inc. by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; (3) its wholesale drug and medical device license in New Jersey; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

**FIRST CLAIM FOR RELIEF: '059 PATENT**

22. Orexo realleges paragraphs 1-21 above as if set forth specifically here.

23. The '059 patent, (copy attached as Exhibit A), titled "Fentanyl Composition For The Treatment Of Acute Pain," was issued on July 6, 2004 to Diabact AB, upon assignment from the inventors Anders Pettersson, Christer Nyström, Hans Lennernäs, Bo Lennernäs and Thomas Hedner. Diabact AB changed its name to Orexo. The '059 patent claims, *inter alia*, a pharmaceutical composition for the treatment of acute pain by sublingual administration, and methods of treatment of a patient with such a composition.

24. Plaintiff Orexo has been and still is the owner of the '059 patent. The '059 patent will expire on September 24, 2019.

25. Defendant Actavis infringed one or more of the '059 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 '059 patent.

26. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '059 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '059 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). 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.”

27. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 26 above.

28. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 26, above.

29. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the ‘059 patent claims.

30. The December 23 Notice Letter alleges that Actavis’s ANDA Products do not infringe claims 1-20 of the ‘059 patent. Actavis refused Orexo’s requests for information and samples that would permit investigation of Actavis’s allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis’s ANDA Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

31. Unless enjoined by this Court, Actavis will directly infringe the ‘059 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis’s ANDA Products in the United States in violation of 35 U.S.C. § 271(a).

32. Unless enjoined by this Court, Actavis will induce the infringement of the ‘059 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 Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '059 patent and in violation of 35 U.S.C. § 271(b).

33. Unless enjoined by this Court, Actavis will induce the infringement of the '059 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '059 patent and in violation of 35 U.S.C. § 271(b).

34. Unless enjoined by this Court, Actavis will contribute to the infringement of the '059 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products 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 Actavis's ANDA Products in contravention of Orexo's rights under the '059 patent in violation of 35 U.S.C. § 271(c).

35. Orexo will be substantially and irreparably damaged and harmed if Actavis's infringement of the '059 patent is not enjoined.

36. Orexo does not have an adequate remedy at law for Actavis's infringement of the '059 patent.

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



**SECOND CLAIM FOR RELIEF: '910 PATENT**

38. Orexo realleges paragraphs 1-37 above as if set forth specifically here.

39. The '910 patent, (copy attached as Exhibit B), titled "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 Nyström. Diabact AB changed its name to Orexo. The '910 patent claims, *inter alia*, a pharmaceutical composition for the treatment of acute disorders by sublingual administration, and methods of treatment of a patient with such a composition.

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

41. Defendant Actavis 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.

42. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) 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 . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). 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.”

43. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 42 above.

44. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 42, above.

45. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the ‘910 patent claims.

46. The December 23 Notice Letter alleges that Actavis’s ANDA Products do not infringe claims 1-21 of the ‘910 patent. Actavis refused Orexo’s requests for information and samples that would permit investigation of Actavis’s allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis’s ANDA Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

47. Unless enjoined by this Court, Actavis will directly infringe 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 Actavis’s ANDA Products in the United States in violation of 35 U.S.C. § 271(a).

48. Unless enjoined by this Court, Actavis will induce the infringement 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 Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

49. Unless enjoined by this Court, Actavis will induce the infringement of the '910 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

50. Unless enjoined by this Court, Actavis will contribute to the infringement of the '910 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products 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 Actavis's ANDA Products in contravention of Orexo's rights under the '910 patent in violation of 35 U.S.C. § 271(c).

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

52. Orexo does not have an adequate remedy at law for Actavis's infringement of the '910 patent.

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

**THIRD CLAIM FOR RELIEF: '132 PATENT**

54. Orexo realleges paragraphs 1-53 above as if set forth specifically here.

55. The '132 patent, (copy attached as Exhibit C), titled "Pharmaceutical Composition For The Treatment Of Acute Disorders," was issued on March 22, 2011 to Orexo upon assignment from the inventors, Anders Pettersson, Christer Nyström, Hans Lennernäs, Bo Lennernäs, and Thomas Hedner. The '132 patent claims, *inter alia*, methods of treatment of breakthrough pain by sublingual administration of a pharmaceutical composition.

56. Plaintiff Orexo has been and still is the owner of the '132 patent. The '132 patent will expire on September 24, 2019.

57. Defendant Actavis infringed one or more of the '132 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 '132 patent.

58. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '132 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '132 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). 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.”

59. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 58 above.

60. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 58, above.

61. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the ‘132 patent claims.

62. The December 23 Notice Letter alleges that Actavis’s ANDA Products do not infringe claims 1-11 of the ‘132 patent. Actavis refused Orexo’s requests for information and samples that would permit investigation of Actavis’s allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis’s ANDA Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

63. Unless enjoined by this Court, Actavis will directly infringe the ‘132 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis’s ANDA Products in the United States in violation of 35 U.S.C. § 271(a).

64. Unless enjoined by this Court, Actavis will induce the infringement of the '132 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 Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '132 patent and in violation of 35 U.S.C. § 271(b).

65. Unless enjoined by this Court, Actavis will induce the infringement of the '132 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '132 patent and in violation of 35 U.S.C. § 271(b).

66. Unless enjoined by this Court, Actavis will contribute to the infringement of the '132 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products 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 Actavis's ANDA Products in contravention of Orexo's rights under the '132 patent in violation of 35 U.S.C. § 271(c).

67. Orexo will be substantially and irreparably damaged and harmed if Actavis's infringement of the '132 patent is not enjoined.

68. Orexo does not have an adequate remedy at law for Actavis's infringement of the '132 patent.

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

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Orexo respectfully requests the following relief:

(a) A judgment be entered that Actavis has infringed the '059 patent, the '910 patent, and the '132 patent by submitting ANDA 207338 to the FDA;

(b) A judgment be entered declaring that the effective date of any approval of Actavis's ANDA 207338 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug products "Fentanyl Sublingual tablets, CII" must be later than September 24, 2019, the expiration date of the patents 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 Actavis's ANDA Products will directly infringe, induce and/or contribute to infringement of the '059 patent, the '910 patent, and the '132 patent;

(d) Preliminary and permanent injunctions be granted enjoining Actavis 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 Actavis's ANDA Products until after the expiration of the '059 patent, the '910 patent, the '132 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 Actavis, its officers, agents, attorneys, and employees, and those acting in privity or concert with them from practicing any composition or method claimed in the '059 patent, the '910 patent, or the '132 patent, or from actively inducing or contributing to the

infringement of the '059 patent, the '910 patent, and the '132 patent, until after the expiration of, respectively, the '059 patent, the '910 patent, and the '132 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(f) An award of damages be granted if Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis's ANDA Products prior to the expiration of the '059 patent, the '910 patent, or the '132 patent, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(g) A judgment be entered declaring that the '059 patent, the '910 patent, and the '132 patent remain valid, remain enforceable and have been infringed by Actavis;

(h) A judgment be entered that Actavis's defenses and claims for relief with respect to the '059 patent, the '910 patent and the '132 patent are limited to those presented in the December 23 Notice Letter;

(i) A judgment be entered that Actavis's conduct is exceptional;

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

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

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



Dated: February 4, 2015

s/John E. Flaherty  
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*Attorneys for Plaintiff Orexo AB*

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject of the following action:

*Orexo AB v. Mylan Pharmaceuticals, Inc., et al.*, No. 3:11-cv-03788-FLW-LHG, filed in the U.S. District Court for the District of New Jersey on June 30, 2011 (the “Mylan case”).

The present New Jersey action is related to the Mylan case (which is also pending in this Court) in that it involves the validity and/or infringement of United States Patent No. 6,761,910 (“the ’910 patent”). The ’910 patent is being asserted by Plaintiff Orexo AB in the Mylan case.

Dated: February 4, 2015

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