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

PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., and TRANSCEPT PHARMACEUTICALS, INC., Plaintiffs, v. ACTAVIS ELIZABETH LLC, NOVEL LABORATORIES, INC., PAR PHARMACEUTICAL, INC., and PAR FORMULATIONS PRIVATE LTD., Defendants.	**Consolidated Civil Action No. 2:12-CV-05311(JLL)(MAH)** **CONSOLIDATED AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Pursuant to leave granted in the Court's Pretrial Scheduling Order (Dkt. No. 30), Plaintiffs Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Transcept Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their attorneys, for their consolidated amended complaint against Defendants Actavis Elizabeth LLC, Novel Laboratories, Inc., Par Pharmaceutical, Inc., and Par Formulations Private Ltd., (collectively, "Defendants") 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 Actavis Elizabeth, LLC ("Actavis") is a Delaware limited liability company with its principal place of business at 200 Elmora Ave., Elizabeth, NJ 07202.

5. Upon information and belief, Actavis is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district.

6. Upon information and belief, Defendant Novel Laboratories, Inc. ("Novel") is a Delaware corporation with its principal place of business at 400 Campus Drive, Somerset, NJ 08873.

7. Upon information and belief, Novel is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district.

8. Upon information and belief, Defendant Par Formulations Private Ltd. ("Par Formulations") is an Indian corporation with its principal place of business located at New No 1/58, Main Road, Pudupakkam, 603103 India. Upon information and belief, Par Formulations has a place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

9. Upon information and belief, Par Formulations is in the business of developing, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district.

10. Upon information and belief, Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 Ram Ridge Rd., Spring Valley, NY 10977.

11. Upon information and belief, Par Pharmaceutical is in the business of developing, manufacturing, and distributing generic pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Par Pharmaceutical has a least one place of business in New Jersey, and is registered to do business in New Jersey under Business I.D. No. 0100071541. Upon information and belief, Par Pharmaceutical is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration Nos. 5001143 (manufacturer) and 5004032 (manufacturer and wholesaler). Upon information and belief, the CEO and Chairman of the Board of Par Pharmaceutical is located in Woodcliff Lake, New Jersey. Upon information and belief, Par Pharmaceutical shares a CEO and Board Chairman with parent company Par Pharmaceutical Companies, Inc., which has its principal place of business in Woodcliff Lake, New Jersey.

Jurisdiction and Venue

12. 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. 7,682,628 (the "'628 Patent"); U.S. Patent No. 8,242,131 (the "'131 Patent"); and U.S. Patent No. 8, 252,809 (the "'809 Patent").

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

14. This Court has personal jurisdiction over Defendant Actavis by virtue of its widespread and continuous contacts with the state of New Jersey. Among other things, Actavis's principal place of business is in New Jersey, and it is registered to do business in New Jersey under Business I.D. No. 0600272818.

15. Actavis has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing counterclaims in this Court. *See, e.g.*, *Depomed, Inc. v. Actavis Elizabeth LLC*, 3:12-cv-01358 (D.N.J.) (Dkt. No. 40) (counterclaim filed by Actavis Elizabeth LLC); *Abbott Labs. v. Actavis Elizabeth LLC*, 2:10-cv-02352 (D.N.J.) (Dkt. No. 18) (same); *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 2:07-cv-03770 (D.N.J.) (Dkt. No. 10) (same). Actavis also submitted itself to the personal jurisdiction of the court of New Jersey because it has asserted counterclaims against Plaintiffs in this action. (Dkt. No. 8).

16. This Court has personal jurisdiction over Defendant Novel by virtue of its widespread and continuous contacts with the state of New Jersey. Among other things, Novel's principal place of business is in New Jersey. Upon information and belief, Novel's Somerset, New Jersey facility consists of a cGMP manufacturing plant, packaging area, laboratories, warehousing areas, and corporate offices. Novel is registered to do business in New Jersey under Business I.D. No. 0100971912, and is registered as a manufacturer and wholesaler of drugs under Registration No. 5003657.

17. Novel has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing

counterclaims in this Court. *See, e.g., Salix Pharms., Inc. et al. v. Novel Labs., Inc.*, Civ. A. No. 3:08-cv-02311-FLW-TJB (D.N.J.) (Dkt. No. 9) (counterclaim filed by Novel); *Salix Pharms., Inc. v. Novel Labs., Inc. et al.*, Civ. A. No. 3:08-cv-4638-FLW-JJH (D.N.J.) (Dkt. No. 21) (same); *Braintree Labs., Inc. v. Novel Labs., Inc.*, Civ. A. No. 3:11-cv-01341-GEB-TJB (D.N.J.) (Dkt. No. 11) (same). Novel has also submitted itself to the personal jurisdiction of the court of New Jersey because it has asserted counterclaims against Plaintiffs in this action. (Civ. A. No. 2:12-cv-05650-JLL-MAH (D.N.J.) Dkt. No. 15).

18. This Court has personal jurisdiction over Defendant Par Formulations because, upon information and belief, Par Formulations conducts business in New Jersey alone and/or through related entities Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. (Par Formulations' ultimate parent); and/or other Par entities and agents. Upon information and belief, Par Formulations has a place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677. Upon information and belief, Par Formulations sent a letter dated September 10, 2012 to Plaintiffs Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals L.P., with letterhead from the Woodcliff Lake, NJ address. Upon information and belief, Par Pharmaceutical Companies, Inc. is a corporation with its principal place of business in Woodcliff Lake, NJ, and is registered to do business in New Jersey under Business I.D. No. 0100946477. Upon information and belief, Par Pharmaceutical, Inc. is registered to do business in New Jersey under Business I.D. No. 0100071541; it is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration Nos. 5001143 (manufacturer) and 5004032 (manufacturer and wholesaler).

19. Additionally or alternatively, this Court has personal jurisdiction over Par Formulations because, upon information and belief, the subject matter of this lawsuit is

connected to the state of New Jersey. For example, upon information and belief, in developing the potential generic product that is the subject of this lawsuit, Par Formulations consulted with individuals in New Jersey, including individuals at Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.; and Par Formulations intends for its potential product to be marketed and sold in New Jersey. Additionally or alternatively, this Court has jurisdiction over Par Formulations because, upon information and belief, the contacts of Par Pharmaceutical Companies, Inc. can be imputed to Par Formulations, given that Par Pharmaceutical Companies, Inc. is the ultimate parent of Par Formulations, putting the two entities under common ownership, and Par Pharmaceutical Companies, Inc. exercises dominion and control over Par Formulations' operational policies and business.

20. Par Formulations has submitted itself to the personal jurisdiction of the court of New Jersey because it has asserted counterclaims against Plaintiffs in this action. (Civ. A. No. 2:12-cv-06741-JLL-MAH (D.N.J.) Dkt. No. 10).

21. This Court has personal jurisdiction over Defendant Par Pharmaceutical by virtue of its widespread and continuous contacts with the state of New Jersey. Among other things, upon information and belief, Par Pharmaceutical has at least one business location in New Jersey and is registered to do business in New Jersey under Business I.D. No. 0100071541. Upon information and belief, Par Pharmaceutical is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration Nos. 5001143 (manufacturer) and 5004032 (manufacturer and wholesaler). Upon information and belief, the CEO and Chairman of the Board of Par Pharmaceutical is located in Woodcliff Lake, New Jersey.

22. Par Pharmaceutical has previously submitted to, and purposefully availed itself of, the jurisdiction of the U.S. District Court for the District of New Jersey, including by filing

counterclaims in this Court. *See, e.g.*, *Medeva Pharma Suisse A.G. et al. v. Par Pharm., Inc. et al.*, 3:10-cv-04008 (D.N.J.) (Dkt. No. 11) (counterclaim filed by Par); *Abbott Labs. et al. v. Par Pharm. Inc.*, 2:04- cv-00325 (D.N.J.) (Dkt. No. 4) (same); *Hoechst Marion v. Par Pharm. Inc.*, 2:95-cv-03673 (D.N.J.) (Dkt. No. 16) (same). Par Pharmaceutical has submitted itself to the personal jurisdiction of the court of New Jersey because it has asserted counterclaims against Plaintiffs in this action. (Civ. A. No. 2:12-cv-06738-JLL-MAH (D.N.J.) Dkt. No. 10).

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

Regulatory Requirements for New and Generic Drugs

24. 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).

25. 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).

26. 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).

27. 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

28. 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.

29. FDA has listed U.S. Patent Nos. 7,682,628; 8,242,131; and 8,252,809 in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 022328.

30. Transcept Pharmaceuticals, Inc. is the owner of the '628, '131, and '809 Patents. Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P. are exclusive licensees under the '628, '131, and '809 Patents, the former to sell or offer to sell, and the latter to manufacture, zolpidem tartrate sublingual tablets.

Defendant Actavis' ANDA No. 204-322

31. Upon information and belief, on or before July 12, 2012, Actavis submitted to FDA an ANDA (ANDA No. 204-322) with, among other things, a paragraph IV certification to the '628 Patent 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.

32. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204-322 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®.

33. Upon information and belief, Actavis sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated July 12, 2012 (the "Notice Letter"). The Notice Letter represented that Actavis had submitted to FDA ANDA No. 204-322 with a paragraph IV certification for the '628 Patent.

34. Upon information and belief, on or before January 24, 2013, Actavis amended its ANDA No. 204-322 to include paragraph IV certifications with respect to the '131 and '809 Patents.

35. Upon information and belief, Actavis sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated January 24, 2013 (the "Notice of Amended Certification Letter"). The Notice of Amended Certification Letter represented that Actavis had submitted to FDA ANDA No. 204-322, and that ANDA No. 204-322, as amended, includes paragraph IV certifications with respect to the '131 and '809 Patents.

36. 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, Actavis's purpose in submitting ANDA No. 204-322 is to market products described therein before expiration of the '628, '131, and '809 Patents.

Defendant Novel's ANDA No. 204299

37. Upon information and belief, on or before July 30, 2012, Novel submitted to FDA an ANDA (ANDA No. 204299) with, among other things, a paragraph IV certification to the '628 Patent 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.

38. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204299 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®.

39. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204299 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®.

40. Upon information and belief, Novel sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter with a U.S. Postal Service envelope dated July 26, 2012 (the "Notice Letter"). The Notice Letter represented that Novel had submitted to FDA ANDA No. 204299 with a paragraph IV certification for the '628 Patent.

41. Upon information and belief, on or before December 10, 2012, Novel amended its ANDA No. 204299 to include paragraph IV certifications with respect to the '131 and '809 Patents.

42. Upon information and belief, Novel sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated December 10, 2012 (the "Notice of Amended Certification Letter"). The Notice of Amended Certification Letter represented that Novel had submitted to FDA ANDA No. 204299, and that ANDA No. 204299, as amended, includes paragraph IV certifications with respect to the '131 and '809 Patents.

43. 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, Novel's purpose in submitting ANDA No. 204299 is to market products described therein before expiration of the '628, '131, and '809 Patents.

Defendant Par Formulations' ANDA No. 204301

44. Upon information and belief, on or before September 10, 2012, Par Formulations submitted to FDA an ANDA (ANDA No. 204301) 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.

45. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204301 for Par Formulations' 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®.

46. Upon information and belief, Par Formulations sent Plaintiffs Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. a letter dated September 10, 2012 (the "Notice Letter"). The Notice Letter represented that Par Formulations had submitted to FDA ANDA No. 204301 with paragraph IV certifications for the '131 and '809 Patents.

47. 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, Par Formulations' purpose in submitting ANDA No. 204301 is to market the product described therein before expiration of the '131 and '809 Patents.

Defendant Par Pharmaceutical's ANDA No. 204229

48. Upon information and belief, on or before September 10, 2012, Par Pharmaceutical submitted to FDA an ANDA (ANDA No. 204229) 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.

49. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204229 for Par Pharmaceutical's 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®.

50. Upon information and belief, Par Pharmaceutical sent Plaintiffs Purdue Pharmaceutical Products L.P. and Transcept Pharmaceuticals, Inc. a letter dated September 10, 2012 (the "Notice Letter"). The Notice Letter represented that Par Pharmaceutical had submitted to FDA ANDA No. 204229 with paragraph IV certifications for the '131 and '809 Patents.

51. 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, Par Pharmaceutical's purpose in submitting ANDA No. 204229 is to market the product described therein before expiration of the '131 and '809 Patents.

Count I: Patent Infringement of the '628 Patent by Actavis

52. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 51 above.

53. United States Patent No. 7,682,628, entitled "COMPOSITIONS FOR DELIVERING HYPNOTIC AGENTS ACROSS THE ORAL MUCOSA AND METHODS OF USE THEREOF," was duly and legally issued by the United States Patent and Trademark Office on March 23, 2010. Plaintiff Transcept Pharmaceuticals, Inc. is the owner of the '628 Patent.

Plaintiffs Purdue Pharmaceutical Products L.P. and Purdue Pharma L.P. are exclusive licensees of the '628 Patent. A true and complete copy of the '628 Patent is attached hereto as Exhibit B.

54. Upon information and belief, Defendant Actavis submitted ANDA No. 204-322 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 '628 Patent.

55. Actavis's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

56. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Actavis's ANDA No. 204-322 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 '628 Patent. Upon information and belief, this infringement will occur at Actavis's behest, with its intent, knowledge, and encouragement, and Actavis will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '628 Patent.

57. Actavis'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. 204-322 would actively induce and contribute to infringement of the '628 Patent, and Actavis would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

58. Upon information and belief, as part of the ANDA filing, Actavis purportedly provided written certification to FDA that the claims of the '628 Patent are invalid and/or will

not be infringed by the manufacture, use, or sale of Actavis's generic version of INTERMEZZO®.

59. Upon information and belief, by letter dated July 12, 2012, Actavis gave written notice of its certification of invalidity and/or non-infringement of the '628 Patent, alleging that all claims of the '628 Patent are invalid and that no claim would be infringed by Actavis's generic version of INTERMEZZO®, and informing Plaintiffs that Actavis seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '628 Patent.

60. Actavis has infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204-322 with a paragraph IV certification and seeking FDA approval of ANDA No. 204-322 to market a generic version of INTERMEZZO® prior to the expiration of the '628 Patent. Moreover, if Actavis commercially uses, offers for sale, or sells its generic version of INTERMEZZO®, or induces or contributes to such conduct, it would further infringe the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

62. Plaintiffs will be irreparably harmed if Actavis is not enjoined from infringing or actively inducing or contributing to infringement of the '628 Patent. Plaintiffs do not have an adequate remedy at law.

Count II: Patent Infringement of the '628 Patent by Novel

63. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 62 above.

64. United States Patent No. 7,682,628, entitled "COMPOSITIONS FOR DELIVERING HYPNOTIC AGENTS ACROSS THE ORAL MUCOSA AND METHODS OF USE THEREOF," was duly and legally issued by the United States Patent and Trademark Office on March 23, 2010. Plaintiff Transcept Pharmaceuticals, Inc. is the owner of the '628 Patent. Plaintiffs Purdue Pharmaceutical Products L.P. and Purdue Pharma L.P. are exclusive licensees of the '628 Patent. A true and complete copy of the '628 Patent is attached hereto as Exhibit B.

65. Upon information and belief, Defendant Novel submitted ANDA No. 204299 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 '628 Patent.

66. Novel's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

67. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Novel's ANDA No. 204299 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 '628 Patent. Upon information and belief, this infringement will occur at Novel's behest, with its intent, knowledge, and encouragement, and Novel will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '628 Patent.

68. Novel'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. 204299 would actively induce and contribute to infringement of the '628 Patent, and Novel would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

69. Upon information and belief, as part of the ANDA filing, Novel purportedly provided written certification to FDA that the claims of the '628 Patent are invalid and/or will not be infringed by the manufacture, use, or sale of Novel's generic version of INTERMEZZO®.

70. Upon information and belief, Novel gave written notice of its certification of invalidity and/or non-infringement of the '628 Patent, alleging that all claims of the '628 Patent are invalid and that claims 10, 11, and 13 would not be infringed by Novel's generic version of INTERMEZZO®, and informing Plaintiffs that Novel seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to INTERMEZZO® prior to the expiration of the '628 Patent.

71. Novel has infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204299 with a paragraph IV certification and seeking FDA approval of ANDA No. 204299 to market a generic version of INTERMEZZO® prior to the expiration of the '628 Patent. Moreover, if Novel commercially uses, offers for sale, or sells its generic version of INTERMEZZO®, or induces or contributes to such conduct, it would further infringe the '628 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

73. Plaintiffs will be irreparably harmed if Novel is not enjoined from infringing or actively inducing or contributing to infringement of the '628 Patent. Plaintiffs do not have an adequate remedy at law.

Count III: Patent Infringement of the '131 Patent by Actavis

74. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 73 above.

75. 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 C.

76. Upon information and belief, Actavis submitted ANDA No. 204-322 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.

77. Actavis'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).

78. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Actavis's ANDA No. 204-322 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 Actavis's behest, with its intent, knowledge, and encouragement, and Actavis will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

79. Actavis'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. 204-322 would actively induce and contribute to infringement of the '131 Patent, and Actavis would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

80. Upon information and belief, as part of an amendment to ANDA No. 204-322, Actavis 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 Actavis's generic version of INTERMEZZO®.

81. Upon information and belief, by letter dated January 24, 2013, Actavis gave written notice of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that all claims of the '131 Patent are invalid and that some of the claims of the '131 Patent would not be infringed by Actavis's generic version of INTERMEZZO®, and informing Plaintiffs that Actavis 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.

82. Actavis has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204-322 with a paragraph IV certification and seeking FDA approval of ANDA No. 204-322 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if Actavis 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).

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

84. Plaintiffs will be irreparably harmed if Actavis 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 IV: Patent Infringement of the '131 Patent by Novel

85. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 84 above.

86. 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 C.

87. Upon information and belief, Novel submitted ANDA No. 204299 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.

88. Novel'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).

89. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Novel's ANDA No. 204299 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 Novel's behest, with its intent, knowledge, and encouragement, and Novel will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

90. Novel'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. 204299 would actively induce and contribute to infringement of the '131 Patent, and Novel would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

91. Upon information and belief, as part of an amendment to ANDA No. 204299, Novel 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 Novel generic version of INTERMEZZO®.

92. Upon information and belief, Novel gave written notice of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that all claims of the '131 Patent are invalid and that claims 7 and 17 of the '131 Patent would not be infringed by Novel's generic version of INTERMEZZO®, and informing Plaintiffs that Novel 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.

93. Novel has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204299 with a paragraph IV certification and seeking FDA approval of ANDA No. 204299 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if Novel 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).

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

95. Plaintiffs will be irreparably harmed if Novel 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 V: Patent Infringement of the '131 Patent by Par Formulations

96. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 95 above.

97. 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 C.

98. Upon information and belief, Par Formulations submitted ANDA No. 204301 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.

99. Par Formulations' 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).

100. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Par Formulations' ANDA No. 204301 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 Par Formulations' behest, with its intent,

knowledge, and encouragement, and Par Formulations will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

101. Par Formulations' 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. 204301 would actively induce and contribute to infringement of the '131 Patent, and Par Formulations would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

102. Upon information and belief, as part of ANDA No. 204301, Par Formulations 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 Par Formulations' generic version of INTERMEZZO®.

103. Upon information and belief, by letter dated September 10, 2012, Par Formulations gave written notice of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that all claims of the '131 Patent are invalid, and informing Plaintiffs that Par Formulations 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.

104. Par Formulations has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204301 with a paragraph IV certification and seeking FDA approval of ANDA No. 204301 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if Par Formulations 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).

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

106. Plaintiffs will be irreparably harmed if Par Formulations 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 VI: Patent Infringement of the '131 Patent by Par Pharmaceutical

107. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 106 above.

108. 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 C.

109. Upon information and belief, Par Pharmaceutical submitted ANDA No. 204229 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.

110. Par Pharmaceutical'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).

111. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Par Pharmaceutical's ANDA No. 204229 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 Par Pharmaceutical's behest, with its intent, knowledge, and encouragement, and Par Pharmaceutical will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

112. Par Pharmaceutical'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. 204229 would actively induce and contribute to infringement of the '131 Patent, and Par Pharmaceutical would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

113. Upon information and belief, as part of ANDA No. 204229, Par Pharmaceutical 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 Par Pharmaceutical's generic version of INTERMEZZO®.

114. Upon information and belief, by letter dated September 10, 2012, Par Pharmaceutical gave written notice of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that all claims of the '131 Patent are invalid and informing Plaintiffs that Par Pharmaceutical 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.

115. Par Pharmaceutical has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204229 with a paragraph IV certification and seeking FDA approval of ANDA No. 204229 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if Par Pharmaceutical 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).

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

117. Plaintiffs will be irreparably harmed if Par Pharmaceutical 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 VII: Patent Infringement of the '809 Patent by Actavis

118. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 117 above.

119. 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 D.

120. Upon information and belief, Actavis submitted ANDA No. 204-322 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.

121. Actavis'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).

122. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Actavis's ANDA No. 204-322 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 Actavis's behest, with its intent, knowledge, and encouragement, and Actavis will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

123. Actavis'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. 204-322 would actively induce and contribute to infringement of the '809 Patent, and Actavis would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

124. Upon information and belief, as part of an amendment to ANDA No. 204-322, Actavis 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 Actavis's generic version of INTERMEZZO®.

125. Upon information and belief, by letter dated January 24, 2013, Actavis gave written notice of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that all claims of the '809 Patent are invalid and that some of the claims would not be infringed by Actavis's generic version of INTERMEZZO®, and informing Plaintiffs that Actavis 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.

126. Actavis has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204-322 with a paragraph IV certification and seeking FDA approval of

ANDA No. 204-322 to market a generic version of INTERMEZZO® prior to the expiration of the '809 Patent. Moreover, if Actavis 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).

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

128. Plaintiffs will be irreparably harmed if Actavis 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.

Count VIII: Patent Infringement of the '809 Patent by Novel

129. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 128 above.

130. 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 D.

131. Upon information and belief, Novel submitted ANDA No. 204299 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.

132. Novel'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).

133. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Novel's ANDA No. 204299 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 Novel's behest, with its intent, knowledge, and encouragement, and Novel will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

134. Novel'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. 204299 would actively induce and contribute to infringement of the '809 Patent, and Novel would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

135. Upon information and belief, as part of an amendment to ANDA No. 204299, Novel 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 Novel generic version of INTERMEZZO®.

136. Upon information and belief, Novel gave written notice of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that all claims of the '809 Patent are invalid and informing Plaintiffs that Novel 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.

137. Novel has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204299 with a paragraph IV certification and seeking FDA approval of

ANDA No. 204299 to market a generic version of INTERMEZZO® prior to the expiration of the '809 Patent. Moreover, if Novel 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).

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

139. Plaintiffs will be irreparably harmed if Novel 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.

Count IX: Patent Infringement of the '809 Patent by Par Formulations

140. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 139 above.

141. 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 D.

142. Upon information and belief, Par Formulations submitted ANDA No. 204301 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.

143. Par Formulations' 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).

144. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Par Formulations' ANDA No. 204301 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 Par Formulations' behest, with its intent, knowledge, and encouragement, and Par Formulations will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

145. Par Formulations' 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. 204301 would actively induce and contribute to infringement of the '809 Patent, and Par Formulations would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

146. Upon information and belief, as part of ANDA No. 204301, Par Formulations 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 Par Formulations' generic version of INTERMEZZO®.

147. Upon information and belief, by letter dated January September 10, 2012 Par Formulations gave written notice of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that all claims of the '809 Patent are invalid and informing Plaintiffs that Par Formulations 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.

148. Par Formulations has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204301 with a paragraph IV certification and seeking FDA approval of ANDA No. 204301 to market a generic version of INTERMEZZO® prior to the expiration of the '809 Patent. Moreover, if Par Formulations 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).

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

150. Plaintiffs will be irreparably harmed if Par Formulations 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.

Count X: Patent Infringement of the '809 Patent by Par Pharmaceutical

151. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 150 above.

152. 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 D.

153. Upon information and belief, Par Pharmaceutical submitted ANDA No. 204229 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.

154. Par Pharmaceutical'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).

155. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Par Pharmaceutical's ANDA No. 204229 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 Par Pharmaceutical's behest, with its intent, knowledge, and encouragement, and Par Pharmaceutical will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

156. Par Pharmaceutical'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. 204229 would actively induce and contribute to infringement of the '809 Patent, and Par Pharmaceutical would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

157. Upon information and belief, as part of ANDA No. 204229, Par Pharmaceutical 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 Par Pharmaceutical's generic version of INTERMEZZO®.

158. Upon information and belief, by letter dated January September 10, 2012 Par Pharmaceutical gave written notice of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that all claims of the '809 Patent are invalid and informing Plaintiffs

that Par Pharmaceutical 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.

159. Par Pharmaceutical has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204229 with a paragraph IV certification and seeking FDA approval of ANDA No. 204229 to market a generic version of INTERMEZZO® prior to the expiration of the '809 Patent. Moreover, if Par Pharmaceutical 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).

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

161. Plaintiffs will be irreparably harmed if Par Pharmaceutical 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 Actavis has infringed the '628, '131, and '809 Patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Novel has infringed the '628, '131, and '809 Patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that Par Formulations has infringed the '131 and '809 Patents under 35 U.S.C. § 271(e)(2)(A);

D. A judgment that Par Pharmaceutical has infringed the '131 and '809 Patents under 35 U.S.C. § 271(e)(2)(A);

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Actavis' ANDA No. 204-322 is not earlier than the expiration date of the '628, '131, and '809 Patents; or any later expiration of exclusivity for the '628, '131, or '809 Patent to which Plaintiffs are or become entitled;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Novel's ANDA No. 204299 is not earlier than the expiration date of the '628, '131, and '809 Patents; or any later expiration of exclusivity for the '628, '131, or '809 Patent to which Plaintiffs are or become entitled;

G. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Par Formulation's ANDA No. 204301 is not earlier than the expiration date of the'131 and '809 Patents; or any later expiration of exclusivity for the '131 or '809 Patent to which Plaintiffs are or become entitled;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Par Pharmaceutical's ANDA No. 204229 is not earlier than the expiration date of the'131 and '809 Patents; or any later expiration of exclusivity for the'131 or '809 Patent to which Plaintiffs are or become entitled;

I. A permanent injunction restraining and enjoining Defendant Actavis 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 '628, '131, or '809 Patent, including the product described in ANDA No. 204-322;

J. A permanent injunction restraining and enjoining Defendant Novel 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 ’628, ’131, or ’809 Patent, including the product described in ANDA No. 204299;

K. A permanent injunction restraining and enjoining Defendant Par Formulations 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 Patent, including the product described in ANDA No. 204301;

L. A permanent injunction restraining and enjoining Defendant Par Pharmaceutical 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 Patent, including the product described in ANDA No. 204229;

M. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204-322, or inducing or contributing to such conduct, would constitute infringement of the ’628, ’131, and ’809 Patents by Actavis pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

N. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204299, or inducing or contributing to such conduct, would constitute infringement of the ’628, ’131, and ’809 Patents by Novel pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

O. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204301, or inducing or contributing to such conduct, would

constitute infringement of the ’131 and ’809 Patents by Par Formulations pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

P. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204229, or inducing or contributing to such conduct, would constitute infringement of the’131 and ’809 Patents by Par Pharmaceutical pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

Q. A finding that this is an exceptional case, and an award of attorneys’ fees in this action pursuant to 35 U.S.C. § 285;

R. Costs and expenses in this action; and

S. Such further and other relief as this Court determines to be just and proper.

Dated: February 22, 2013

Respectfully submitted,

/s/ Michael Dore
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