Michael Dore
Stephen R. Buckingham
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, New Jersey 07068
Tel: (973) 597-2500

Attorneys for Plaintiffs Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Transcept Pharmaceuticals, Inc.

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. DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. _____ Document Filed Electronically

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Purdue Pharmaceutical Products L.P.; Purdue Pharma L.P.; and Transcept Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Dr. Reddy's Laboratories, Inc. ("DRL Inc.") and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "Defendants" or "Dr. Reddy's") 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 DRL Inc. is a New Jersey corporation with its principal place of business at 200 Somerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, NJ 08807.

5. Upon information and belief, Defendant DRL Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India.

6. Upon information and belief, Defendants are in the business of developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States, including in this judicial district.

7. Upon information and belief, DRL Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

8. Upon information and belief, DRL Inc., with the assistance and/or at the direction of DRL Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

Jurisdiction and Venue

9. 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").

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

11. This Court has personal jurisdiction over both Defendants because, upon information and belief, both Defendants have continuous and systematic business contacts with New Jersey.

12. This Court also has personal jurisdiction over DRL Inc. because its principal place of business is in New Jersey. DRL Inc. is registered to do business in New Jersey under Business I.D. No. 0100518911, and is registered as a wholesaler of drugs under Registration No. 5002312. Moreover, DRL Inc. 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.*, *AstraZeneca AB et al v. Dr. Reddy's Laboratories, Inc. et al*, Civ. A. No. 3:13-cv-00091-JAP-TJB (Dkt. No. 5) (counterclaim filed by Dr. Reddy's Laboratories, Inc.); *Abbott Laboratories v. Dr. Reddy's Laboratories, Inc. et al*, 3:08-cv-03390-FLW-FDR (Dkt. 5) (same); *Schering Corporation v. Dr. Reddy's Laboratories, Inc. et al*, 3:07-cv-05062-MLC-TJB (Dkt. No. 5) (same).

13. Providing further basis for personal jurisdiction over DRL Ltd., it 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.*, *Wyeth v. Dr. Reddy's Laboratories, Ltd. et al*, 3:10-cv-04551-FLW-DEA (Dkt. No. 8) (counterclaim filed by Dr. Reddy's Laboratories, Ltd.) and *Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories, Ltd. et al*, 2:08-cv-04055-SRC-MAS (Dkt. No. 9) (same).

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

Regulatory Requirements for New and Generic Drugs

15. 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).

16. 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).

17. 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).

18. 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

19. 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.

20. FDA has listed the '628, '131, and '809 Patents in the Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 022328.

21. 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.

ANDA No. 204503

22. Upon information and belief, on or before February 19, 2013, DRL Inc. and DRL Ltd. jointly submitted to FDA an ANDA (ANDA No. 204503) 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.

23. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 204503 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®.

24. Upon information and belief, Dr. Reddy's sent Plaintiffs Purdue Pharma L.P. and Transcept Pharmaceuticals, Inc. a letter dated February 19, 2013 (the "Notice Letter"). The Notice Letter represented that Dr. Reddy's had submitted to FDA ANDA No. 204503 with a paragraph IV certification for the '628, '131, and '809 Patents.

25. 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, Dr. Reddy's purpose in submitting ANDA No. 204503 is to market products described therein before expiration of the '628, '131, and '809 Patents.

Count 1: Patent Infringement of the '628 Patent

26. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 25 above.

27. 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.

28. Upon information and belief, Dr. Reddy's submitted ANDA No. 204503 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.

29. Dr. Reddy'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).

30. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Dr. Reddy's ANDA No. 204503 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 Dr. Reddy's behest, with its intent, knowledge, and encouragement, and Dr. Reddy's will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '628 Patent.

31. Dr. Reddy'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. 204503 would actively induce and contribute to infringement of the '628 Patent, and Dr. Reddy's would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

32. Upon information and belief, as part of the ANDA filing, Dr. Reddy's 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 Dr. Reddy's generic version of INTERMEZZO®.

33. Dr. Reddy's gave written notice of its certification of invalidity and/or non-infringement of the '628 Patent, alleging that claims of the '628 Patent are invalid and that certain claims would not be infringed by Dr. Reddy's generic version of INTERMEZZO®, and informing Plaintiffs that Dr. Reddy's 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.

34. Dr. Reddy's has infringed the '628 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204503 with a paragraph IV certification and seeking FDA approval of ANDA No. 204503 to market a generic version of INTERMEZZO® prior to the expiration of the '628 Patent. Moreover, if Dr. Reddy's 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).

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

36. Plaintiffs will be irreparably harmed if Dr. Reddy's 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 '131 Patent

37. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 36 above.

38. 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.

39. Upon information and belief, Dr. Reddy's submitted ANDA No. 204503 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.

40. Dr. Reddy'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).

41. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Dr. Reddy's ANDA No. 204503 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 Dr. Reddy's behest, with its intent, knowledge, and encouragement, and Dr. Reddy's will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '131 Patent.

42. Dr. Reddy'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. 204503 would actively induce and contribute to infringement of the '131 Patent, and Dr. Reddy's would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

43. Upon information and belief, as part of the ANDA filing, Dr. Reddy's 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 Dr. Reddy's generic version of INTERMEZZO®.

44. Dr. Reddy's gave written notice of its certification of invalidity and/or non-infringement of the '131 Patent, alleging that the claims of the '131 Patent are invalid, and informing Plaintiffs that Dr. Reddy's 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.

45. Dr. Reddy's has infringed the '131 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204503 with a paragraph IV certification and seeking FDA approval of ANDA No. 240503 to market a generic version of INTERMEZZO® prior to the expiration of the '131 Patent. Moreover, if Dr. Reddy's 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).

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

47. Plaintiffs will be irreparably harmed if Dr. Reddy's 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 III: Patent Infringement of the '809

48. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 47 above.

49. 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.

50. Upon information and belief, Dr. Reddy's submitted ANDA No. 204503 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.

51. Dr. Reddy'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).

52. Upon information and belief, if approved, the generic INTERMEZZO® product for which approval is sought in Dr. Reddy's ANDA No. 204503 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 Dr. Reddy's behest, with its intent,

knowledge, and encouragement, and Dr. Reddy's will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '809 Patent.

53. Dr. Reddy'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. 204503 would actively induce and contribute to infringement of the '809 Patent, and Dr. Reddy's would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

54. Upon information and belief, as part of the ANDA filing, Dr. Reddy's 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 Dr. Reddy's generic version of INTERMEZZO®.

55. Dr. Reddy's gave written notice of its certification of invalidity and/or non-infringement of the '809 Patent, alleging that claims of the '809 Patent are invalid and that certain claims would not be infringed by Dr. Reddy's generic version of INTERMEZZO®, and informing Plaintiffs that Dr. Reddy's 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.

56. Dr. Reddy's has infringed the '809 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204503 with a paragraph IV certification and seeking FDA approval of ANDA No. 204503 to market a generic version of INTERMEZZO® prior to the expiration of the '809 Patent. Moreover, if Dr. Reddy's 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).

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

58. Plaintiffs will be irreparably harmed if Dr. Reddy's 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 Dr. Reddy's has infringed the '628, '131, and '809 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204503 is not earlier than the expiration date of the '628, '131, and '809 Patents, or any later expiration of exclusivity for the '628, '131, and '809 Patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Dr. Reddy's 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, and '809 Patents, including the product described in ANDA No. 204503;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204503, or inducing or contributing to such conduct, would constitute infringement of the '628, '131, and '809 Patents by Dr. Reddy's pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

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

F. Costs and expenses in this action; and

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

Dated: April 2, 2013

Respectfully submitted,

/s/ Stephen R. Buckingham

Michael Dore
Stephen R. Buckingham
LOWENSTEIN SANDLER, PC
65 Livingston Avenue
Roseland, N.J. 07068
Tel: (973) 597-2500

Attorneys for Plaintiffs Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Transcept Pharmaceuticals, Inc.

Of Counsel:
Christopher N. Sipes
Michael N. Kennedy
Erica N. Andersen
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel: (202) 662-6000

NOTICE OF OTHER ACTIONS PURSUANT TO L. CIV. R. 11.2

The undersigned hereby certifies that the matter in controversy is not the subject of any other action or proceeding in any court or of a pending arbitration proceeding, except that the same FDA-approved pharmaceutical drug product on which this Complaint is based is the subject of a consolidated patent infringement action against multiple defendants involving the same patents that are at issue in this action, which is currently pending in this District and assigned to the same District Judge: *Purdue Pharmaceutical Products, Inc. et al. v. Actavis Elizabeth LLC*, 2:12-cv-5311-JLL-MAH.

/s/ Stephen R. Buckingham
Stephen R. Buckingham

LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, N.J. 07068
Tel: (973) 597-2500