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Attorney for Plaintiffs Alcon Pharmaceuticals Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd.

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

ALCON PHARMACEUTICALS LTD., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., 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 Alcon Pharmaceuticals Ltd. ("Alcon Pharmaceuticals"), Alcon Laboratories, Inc. ("Alcon Laboratories"), and Alcon Research, Ltd. ("Alcon Research") (collectively, "Plaintiffs" or "Alcon"), 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 Alcon Pharmaceuticals is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Louis d'Affry 6, 1701 Fribourg, Switzerland.

2. Plaintiff Alcon Laboratories is a corporation organized and existing under the laws of Delaware with its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

3. Plaintiff Alcon Research is a corporation organized and existing under the laws of Delaware with its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon information and belief, Defendant DRL Inc. is a New Jersey corporation with its principal place of business at 107 College Road East, Princeton, NJ 08540.

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, Andhra Pradesh 500034, India.

6. Upon information and belief, Defendant DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

7. Upon information and belief, DRL Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, including DRL Inc., 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. 6,284,804 ("the '804 Patent") and U.S. Patent No. 6,359,016 ("the '016 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. Upon information and belief, 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 suit in this Court. *See, e.g., Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al.*, 08 Civ. 2496 (D.N.J. 2008).

13. Upon information and belief, DRL Ltd. 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 suit in this Court. *See, e.g., Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al.*, 08 Civ. 2496 (D.N.J. 2008); *Reddy Cheminor, Inc., et al. v. Eli Lilly and Co.*, 01 Civ. 3220 (D.N.J. 2001); *Dr. Reddy's Laboratories, Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3521 (D.N.J. 2001); *Dr. Reddy's Laboratories, Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3522 (D.N.J. 2001).

14. Upon information and belief, DRL Inc. acts as DRL Ltd.'s agent in the United States in developing, manufacturing, distributing, marketing, offering to sell, and/or selling generic drug products for sale and use throughout the United States.

15. Upon information and belief, DRL Inc. and DRL Ltd. act in concert to develop generic products and to seek approval from the United States Food and Drug Administration ("FDA") to sell generic products throughout the United States, including within this judicial district.

16. Upon information and belief, abbreviated new drug application ("ANDA") No. 205548 was prepared and filed by Dr. Reddy's with the intention of seeking to market a generic version of Plaintiffs' CIPRODEX® product (hereinafter, "Generic Ciprodex Product"), including within this judicial district.

17. Upon information and belief, DRL Inc. is registered to do business in New Jersey under Business I.D. No. 0100518911, and is registered as a manufacturer and wholesaler of drugs under Registration No. 5002312.

18. Upon information and belief, DRL Inc. is licensed by the New Jersey Department of Health and Senior Services to sell generic pharmaceutical products in New Jersey.

19. Upon information and belief, DRL Inc. and DRL Ltd., through DRL Inc., receive Medicaid reimbursements from drugs sold in New Jersey.

20. Upon information and belief, DRL Inc. and DRL Ltd. plan to sell a Generic Ciprodex Product in New Jersey, list a Generic Ciprodex Product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of a Generic Ciprodex Product in New Jersey.

21. By virtue of, *inter alia*, DRL Inc. being incorporated in New Jersey and maintaining a principal place of business in New Jersey, this Court has general personal jurisdiction over DRL Inc.

22. Upon information and belief by virtue of, *inter alia*, DRL Ltd.'s relationship with DRL Inc., its designation of Lee Banks of the Princeton, New Jersey office of DRL Inc. as its agent for acceptance of service of process, and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has general personal jurisdiction over DRL Ltd.

23. On information and belief, by virtue of Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, this Court has specific personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

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

Regulatory Requirements for New and Generic Drugs

25. A person wishing to market a new drug that has not previously been approved by the 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).

26. 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 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).

27. 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 for purposes of safety and effectiveness conclusions. 21 U.S.C. § 355(j).

28. 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

29. Alcon Pharmaceuticals is the current holder of NDA No. 021537, for a sterile otic suspension containing 0.3% ciprofloxacin and 0.1% dexamethasone, which was first approved by FDA on July 18, 2003. Alcon Laboratories markets the approved drug product under the tradename CIPRODEX®. Alcon's CIPRODEX® product ("Alcon's Ciprodex Product") is approved for the treatment of infections caused by susceptible isolates of certain microorganisms in the conditions of acute otitis media in pediatric patients with tympanostomy tubes and acute otitis externa in pediatric, adult, and elderly patients. A copy of the prescribing information for Alcon's Ciprodex Product approved in NDA No. 021537 is attached as Exhibit A.

30. The '804 and '016 Patents are listed in the FDA's Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 021537.

31. Alcon Pharmaceuticals is the owner of the '804 and '016 Patents. Alcon Research has an exclusive license to manufacture Alcon's Ciprodex Product under the '804 and '016 Patents. Alcon Laboratories is an authorized distributor of Alcon Research and is authorized to sell and distribute Alcon's Ciprodex Product under the '804 and '016 Patents.

ANDA No. 205548

32. Upon information and belief, on or before June 11, 2015, DRL Inc. and DRL Ltd. jointly submitted to FDA an ANDA (ANDA No. 205548) 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 a ciprofloxacin 0.3% and dexamethasone 0.1% sterile otic solution purportedly bioequivalent to Alcon's Ciprodex Product. 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 Ciprodex Product.

33. Upon information and belief, Dr. Reddy's sent Plaintiffs a letter dated June 11, 2015 (the "Notice Letter"). The Notice Letter represented that Dr. Reddy's had submitted to FDA ANDA No. 205548 with a paragraph IV certification for the '804 and '016 Patents.

34. 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 Ciprodex Product before the expiration of the '804 and '016 Patents, listed in the Orange Book for NDA No. 021537.

35. In the Notice Letter, DRL offered confidential access to portions of ANDA No. 205548 on terms and conditions set forth therein (the "Offer of Confidential Access"). DRL requested that Plaintiffs accept the Offer of Confidential Access before receiving access to ANDA No. 205548. The Offer of Confidential Access contained unreasonable restrictions, above and beyond those that would apply under a typical protective order.

36. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

37. Plaintiffs have negotiated with DRL to procure a copy of ANDA No. 205548 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful.

38. Plaintiffs are not aware of any other means of obtaining information regarding DRL's Generic Ciprodex Product. In the absence of such information, Plaintiffs are availing themselves of the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that DRL's Generic Ciprodex Product falls within the scope of the claim of the '804 Patent and one or more claims of the '016 Patent.

Count 1: Patent Infringement of the '804 Patent

39. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 38 above.

40. United States Patent No. 6,284,804, entitled "TOPICAL SUSPENSION FORMULATIONS CONTAINING CIPROFLOXACIN AND DEXAMETHASONE," was duly and legally issued by the United States Patent and Trademark Office on September 4, 2001. Plaintiff Alcon Pharmaceuticals is the owner of the '804 Patent. Plaintiff Alcon Research is an exclusive licensee under the '804 Patent. A true and complete copy of the '804 Patent is attached hereto as Exhibit B.

41. Upon information and belief, Dr. Reddy's submitted ANDA No. 205548 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a Generic Ciprodex Product before the expiration of the '804 Patent.

42. Dr. Reddy's manufacture, use, offer for sale, or sale of such product would infringe the claim of the '804 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

43. Upon information and belief, if approved, the Generic Ciprodex Product for which approval is sought in Dr. Reddy's ANDA No. 205548 will be administered to human patients for the treatment of acute otitis media in pediatric patients and/or acute otitis externa in pediatric, adult, and elderly patients, which administration would constitute direct infringement, either literally or under the doctrine of equivalents, of the claim of the '804 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 '804 Patent.

44. Dr. Reddy's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Generic Ciprodex Product for which approval is sought in ANDA No. 205548 would actively induce and contribute to infringement of the '804 Patent, and Dr. Reddy's would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

45. Upon information and belief, as part of the ANDA filing, Dr. Reddy's purportedly provided written certification to FDA that the claim of the '804 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Dr. Reddy's Generic Ciprodex Product.

46. Dr. Reddy's gave written notice of its certification of invalidity, unenforceability, and/or non-infringement of the '804 Patent, alleging that the claim of the '804 Patent is invalid, unenforceable, and/or would not be infringed by Dr. Reddy's Generic Ciprodex Product, and informing Plaintiffs that Dr. Reddy's seeks approval to engage in the commercial manufacture, use, and sale of a product bioequivalent to Alcon's Ciprodex Product prior to the expiration of the '804 Patent.

47. Dr. Reddy's has infringed the '804 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205548 with a paragraph IV certification and seeking FDA approval of ANDA No. 205548 to market a Generic Ciprodex Product prior to the expiration of the '804 Patent. Moreover, if Dr. Reddy's commercially uses, offers for sale, or sells its Generic Ciprodex Product, or induces or contributes to such conduct, it would further infringe the '804 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

49. Plaintiffs will be irreparably harmed if Dr. Reddy's is not enjoined from infringing or actively inducing or contributing to infringement of the '804 Patent. Plaintiffs do not have an adequate remedy at law.

Count 2: Patent Infringement of the '016 Patent

50. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 49 above.

51. United States Patent No. 6,359,016, entitled "TOPICAL SUSPENSION FORMULATIONS CONTAINING CIPROFLOXACIN AND DEXAMETHASONE," was duly and legally issued by the United States Patent and Trademark Office on March 19, 2002. Plaintiff Alcon Pharmaceuticals is the owner of the '016 Patent. Plaintiff Alcon Research is an exclusive licensee under the '016 Patent. A true and complete copy of the '016 Patent is attached hereto as Exhibit C.

52. Upon information and belief, Dr. Reddy's submitted ANDA No. 205548 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a Generic Ciprodex Product before the expiration of the '016 Patent.

53. Dr. Reddy's manufacture, use, offer for sale, or sale of such product would infringe the claims of the '016 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

54. Upon information and belief, if approved, the Generic Ciprodex Product for which approval is sought in Dr. Reddy's ANDA No. 205548 will be administered to human patients for the treatment of acute otitis media in pediatric patients and/or acute otitis externa in pediatric, adult, and elderly patients, which administration would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '016 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 '016 Patent.

55. Dr. Reddy's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Generic Ciprodex Product for which approval is sought in ANDA No. 205548 would actively induce and contribute to infringement of the '016 Patent, and Dr. Reddy's would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

56. Upon information and belief, as part of the ANDA filing, Dr. Reddy's purportedly provided written certification to FDA that the claims of the '016 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Dr. Reddy's Generic Ciprodex Product.

57. Dr. Reddy's gave written notice of its certification of invalidity, unenforceability, and/or non-infringement of the '016 Patent, alleging that claims of the '016 Patent are invalid, unenforceable, and/or would not be infringed by Dr. Reddy's Generic Ciprodex Product, and informing Plaintiffs that Dr. Reddy's seeks approval to engage in the commercial manufacture,

use, and sale of a product bioequivalent to Alcon's Ciprodex Product prior to the expiration of the '016 Patent.

58. Dr. Reddy's has infringed the '016 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205548 with a paragraph IV certification and seeking FDA approval of ANDA No. 205548 to market a Generic Ciprodex Product prior to the expiration of the '016 Patent. Moreover, if Dr. Reddy's commercially uses, offers for sale, or sells its Generic Ciprodex Product, or induces or contributes to such conduct, it would further infringe the '016 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

60. Plaintiffs will be irreparably harmed if Dr. Reddy's is not enjoined from infringing or actively inducing or contributing to infringement of the '016 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 '804 and '016 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. 205548 is not earlier than the expiration date of the '804 and '016 Patents, or any later expiration of exclusivity for the '804 and '016 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 ’804 and ’016 Patents, including the product described in ANDA No. 205548;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 205548, or inducing or contributing to such conduct, would constitute infringement of the ’804 and ’016 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: July 24, 2015

Respectfully submitted,

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