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

ALCON PHARMACEUTICALS LTD., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Plaintiffs, v. PAR PHARMACEUTICAL, INC., Defendant.	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 Par Pharmaceutical, Inc. ("Defendant" or "Par") 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 Par is a Delaware corporation having a place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

Jurisdiction and Venue

5. 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").

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

7. This Court has personal jurisdiction over Par by virtue of its widespread and continuous contacts with the State of New Jersey. Among other things, upon information and belief, Par 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 is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration Nos. 5001143 (manufacturer) and 5004032 (manufacturer and wholesaler).

8. Upon information and belief, Par has a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

9. Upon information and belief, Par 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 claims and counterclaims in this Court. *See, e.g.*, *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, 1:13-cv-04000 (D.I. 1) (D.N.J. June 27, 2013) (claims filed by Par); *Biomarin Pharm. Inc. v. Par Pharm., Inc.*, 3:15-cv-01706 (D.I. 12) (D.N.J. Mar. 31, 2015) (counterclaims filed by Par); *Supernus Pharms., Inc. v. Par Pharm. Cos.*, 2:15-cv-00326 (D.I. 17) (D.N.J. Mar. 12, 2015) (same).

10. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 204424 was prepared and filed by Par with the intention of seeking to market a generic version of Plaintiffs' CIPRODEX® product (hereinafter, the "Generic Ciprodex Product"), including within this judicial district.

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

12. Upon information and belief, Par receives Medicaid reimbursements from drugs sold in New Jersey.

13. Upon information and belief, Par plans 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.

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 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 for purposes of 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. 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 (hereinafter, "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.

20. 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.

21. 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. 204424

22. Upon information and belief, on or before August 20, 2015, Par submitted to FDA an ANDA (ANDA No. 204424) 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.

23. Upon information and belief, Par sent Plaintiffs a letter dated August 20, 2015 (the "Notice Letter"). The Notice Letter represented that Par had submitted to FDA ANDA No. 204424 with a paragraph IV certification for the '804 and '016 Patents.

24. 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.

25. In the Notice Letter, Par offered confidential access to portions of ANDA No. 204424 on terms and conditions set forth therein (the "Offer of Confidential Access"). Par requested that Plaintiffs accept the Offer of Confidential Access before receiving access to ANDA No. 204424. The Offer of Confidential Access contained unreasonable restrictions, above and beyond those that would apply under a typical protective order.

26. 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."

27. Plaintiffs have negotiated with Par to procure a copy of ANDA No. 204424 under restrictions "as would apply had a protective order been issued." These negotiations have been unsuccessful.

28. Plaintiffs are not aware of any other means of obtaining information regarding Par'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 Par'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: Infringement of the '804 Patent

29. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 28 above.

30. 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.

31. Upon information and belief, Par submitted ANDA No. 204424 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.

32. Par'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).

33. Upon information and belief, if approved, the Generic Ciprodex Product for which approval is sought in Par's ANDA No. 204424 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 Par's behest, with its intent, knowledge, and encouragement, and Par will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '804 Patent.

34. Par'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. 204424 would actively induce and contribute to infringement of the '804 Patent, and Par would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

35. Upon information and belief, as part of the ANDA filing, Par 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 Par's Generic Ciprodex Product.

36. Par 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 Par's Generic Ciprodex Product, and informing Plaintiffs that Par 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.

37. Par has infringed the '804 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204424 with a paragraph IV certification and seeking FDA approval of ANDA No. 204424 to market a Generic Ciprodex Product prior to the expiration of the '804 Patent. Moreover, if Par 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).

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

39. Plaintiffs will be irreparably harmed if Par 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: Infringement of the '016 Patent

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

41. 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.

42. Upon information and belief, Par submitted ANDA No. 204424 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.

43. Par'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).

44. Upon information and belief, if approved, the Generic Ciprodex Product for which approval is sought in Par's ANDA No. 204424 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 Par's behest, with its intent, knowledge, and encouragement, and Par will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '016 Patent.

45. Par'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. 204424 would actively induce and contribute to infringement of the '016 Patent, and Par would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

46. Upon information and belief, as part of the ANDA filing, Par 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 Par's Generic Ciprodex Product.

47. Par 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 Par's Generic Ciprodex Product, and informing Plaintiffs that Par 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.

48. Par has infringed the '016 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 204424 with a paragraph IV certification and seeking FDA approval of ANDA No. 204424 to market a Generic Ciprodex Product prior to the expiration of the '016 Patent. Moreover, if Par 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).

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

50. Plaintiffs will be irreparably harmed if Par 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 Par 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. 204424 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 Par 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. 204424;

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204424, or inducing or contributing to such conduct, would constitute infringement of the '804 and '016 Patents by Par 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: October 1, 2015

Respectfully submitted,

/s/ Robert M. Goodman

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify that the same product and patents at issue in this action are the subject of one other action currently pending in this District, captioned *Alcon Pharmaceuticals Ltd. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 3:15-cv-05756-PGS-DEA.

Dated: October 1, 2015

Respectfully submitted,

/s/ Robert M. Goodman

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