Robert M. Goodman
C. Brian Kornbrek
Thomas K. Murphy III
**GREENBAUM ROWE SMITH & DAVIS LLP**
75 Livingston Avenue
Roseland, NJ 07068
(973) 577-1770

*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.,<br><br>Plaintiffs,<br><br>v.<br><br>DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., PAR PHARMACEUTICAL, INC., and WATSON LABORATORIES, INC.,<br><br>Defendants. | Civil Action No. _____<br><br>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. ("Par"), Watson Laboratories, Inc. ("Watson"), Dr. Reddy's Laboratories, Inc. ("DRL Inc."), and Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") (collectively, "Defendants") 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 principle place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

5. Upon information and belief, Defendant Watson is a Nevada corporation having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

6. 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.

7. 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.

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

**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. 9,402,805 ("the '805 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 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).

12. 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); *Alcon Pharm. Ltd. et al. v. Par Pharm., Inc.*, 3:15-cv-07240-PGS-DEA (D.I. 13) (D.N.J. Dec. 21, 2015) (counterclaims filed by Par); *Biomarin Pharm. Inc. v. Par Pharm., Inc.*, 3:15-cv-01706 (D.I. 12) (D.N.J. Mar. 31, 2015) (same); *Supernus Pharms., Inc. v. Par Pharm. Cos.*, 2:15-cv-00326 (D.I. 17) (D.N.J. Mar. 12, 2015) (same).

13. 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, "generic version of Plaintiffs' Ciprodex Product"), including within this judicial district.

14. 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.

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

16. Upon information and belief, Par plans to sell a generic version of Plaintiffs' Ciprodex product in New Jersey, list a generic version of Plaintiffs' Ciprodex product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of a generic version of Plaintiffs' Ciprodex product in New Jersey.

17. Upon information and belief, Par has a network of independent wholesalers and distributors with which it contracts to market drugs in New Jersey. Upon information and belief, Par plans to direct sales of a generic version of Plaintiffs' Ciprodex product into New Jersey through this network.

18. This Court has personal jurisdiction over Watson by virtue of its widespread and continuous contacts with the State of New Jersey. Among other things, upon information and belief, Watson has a principal place of business in New Jersey.

19. Upon information and belief, Watson 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.*, *Alcon Pharm. Ltd. et al. v. Watson Labs., Inc.*, 3:16-cv-00101-PGS-DEA (D.I. 27) (D.N.J. Feb. 18, 2016) (counterclaims filed by Watson); *United Therapeutics Corp. v. Watson Labs., Inc.*, 3:15-cv-05723 (D.I. 10) (D.N.J. Sept. 1, 2015) (same); *Senju Pharm. Co. v. Watson Labs., Inc.*, 1:15-cv-05591 (D.I. 11) (D.N.J. Nov. 4, 2015) (same).

20. Upon information and belief, ANDA No. 208638 was prepared and filed by Watson with the intention of seeking to market a generic version of Plaintiffs' Ciprodex product, including within this judicial district.

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

22. Upon information and belief, Watson receives Medicaid reimbursements from drugs sold in New Jersey.

23. Upon information and belief, Watson plans to sell a generic version of Plaintiffs' Ciprodex product in New Jersey, list a generic version of Plaintiffs' Ciprodex product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of a generic version of Plaintiffs' Ciprodex product in New Jersey.

24. Upon information and belief, Watson has a network of independent wholesalers and distributors with which it contracts to market drugs in New Jersey. Upon information and belief, Watson plans to direct sales of a generic version of Plaintiffs' Ciprodex product into New Jersey through this network.

25. This Court has personal jurisdiction over both DRL Inc. and DRL Ltd. by virtue of their widespread and continuous contacts with the State of New Jersey. Among other things, upon information and belief, DRL Inc. has a principal place of business in New Jersey and is registered to do business in New Jersey under Business I.D. No. 0100518911. Upon information and belief, DRL Inc. is also a registered manufacturer and wholesaler of drugs in New Jersey, with Registration No. 5002312.

26. 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 Labs., Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Labs., Ltd., et al. v. AstraZeneca AB, et al.*, 08 Civ. 2496 (D.N.J. 2008).

27. 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 Labs., Ltd., et al. v. Eli Lilly and Co.*, 09 Civ. 0192 (D.N.J. 2009); *Dr. Reddy's Labs., 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 Labs., Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3521 (D.N.J. 2001); *Dr. Reddy's Labs., Ltd., et al. v. AAIPharma, Inc.*, 01 Civ. 3522 (D.N.J. 2001).

28. 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.

29. 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.

30. Upon information and belief, ANDA No. 205548 was prepared and filed by DRL Inc. and DRL Ltd. with the intention of seeking to market a generic version of Plaintiffs' Ciprodex product, including within this judicial district.

31. 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.

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

33. Upon information and belief, DRL Inc. and DRL Ltd. plan to sell a generic version of Plaintiffs' Ciprodex product in New Jersey, list a generic version of Plaintiffs' Ciprodex product on New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of a generic version of Plaintiffs' Ciprodex product in New Jersey.

34. 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.

35. 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 the Dr. Reddy's 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.

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

**Regulatory Requirements for New and Generic Drugs**

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

38. 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).

39. 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).

40. 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**

41. 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 trade name 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.

42. U.S. Patent No. 9,402,805 issued on August 2, 2016. The '805 Patent is listed in the FDA's Orange Book—formally known as *Approved Drug Products With Therapeutic Equivalence Evaluations*—in connection with NDA No. 021537. U.S. Patent Nos.

6,284,804 ("the '804 Patent") and 6,359,016 ("the '016 Patent") are also listed in the Orange Book in connection with NDA No. 021537.

43. Alcon Pharmaceuticals is the owner of the '805 Patent. Alcon Research has an exclusive license to manufacture Alcon's Ciprodex Product under the '805 Patent. Alcon Laboratories is an authorized distributor of Alcon Research and is authorized to sell and distribute Alcon's Ciprodex Product under the '805 Patent.

**Defendant Par's ANDA No. 204424**

44. 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 version of Plaintiffs' Ciprodex product.

45. Upon information and belief, on or around August 20, 2015, Par sent Plaintiff Alcon Pharmaceuticals a letter representing that Par had submitted to FDA ANDA No. 204424 with a paragraph IV certification for the '804 and the '016 Patents.

46. On October 1, 2015, Plaintiffs filed a complaint for patent infringement against Par for infringement of the '804 and the '016 Patents. That lawsuit is pending in this Court as *Alcon Pharmaceuticals Ltd. v. Par Pharmaceutical, Inc.*, No. 3:5-cv-07240 (PGS) (DEA).

47. Upon information and belief, on or around August 25, 2016, Par sent Plaintiffs a letter representing that Par had submitted to FDA an amendment to ANDA No.

204424 with a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for the '805 Patent.

48. Upon information and belief, the indications set forth in the proposed labeling submitted in ANDA No. 204424 for Par's generic version of Plaintiffs' Ciprodex product are for the treatment of acute otitis media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *staphylococcus aureus*, *streptococcus pneumoniae*, *haemophilus influenzae*, *moraxella catarrhalis*, and *pseudomonas aeruginosa*, and/or the treatment of acute otitis externa in pediatric (age 6 months and older), adult and elderly patients due to *staphylococcus aureus* and *pseudomonas aeruginosa*, i.e., at least one of the same indications as set forth in the approved labeling for Alcon's Ciprodex product.

49. 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 Plaintiffs' Ciprodex product before the expiration of the '805 Patent, listed in the Orange Book for NDA No. 021537. Hence, Par's purpose in submitting ANDA No. 204424 is to market products described therein before expiration of the '805 Patent.

**Defendant Watson's ANDA No. 208638**

50. Upon information and belief, on or before November 25, 2015, Watson submitted to FDA an ANDA (ANDA No. 208638) 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 version of Plaintiffs' Ciprodex product.

51. Upon information and belief, on or around November 25, 2015, Watson sent Plaintiff Alcon Research a letter representing that Watson had submitted to FDA ANDA No. 208638 with a paragraph IV certification for the '804 and the '016 Patents.

52. On January 7, 2016, Plaintiffs filed a complaint for patent infringement against Watson for infringement of the '804 and the '016 Patents. That lawsuit is pending in this Court as *Alcon Pharmaceuticals Ltd. v. Watson Laboratories, Inc.*, No. 2:16-cv-00101 (PGS) (DEA).

53. Upon information and belief, the indications set forth in the proposed labeling submitted in ANDA No. 208638 for Watson's generic version of Plaintiffs' Ciprodex product are for the treatment of acute otitis media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *staphylococcus aureus*, *streptococcus pneumoniae*, *haemophilus influenzae*, *moraxella catarrhalis*, and *pseudomonas aeruginosa*, and/or the treatment of acute otitis externa in pediatric (age 6 months and older), adult and elderly patients due to *staphylococcus aureus* and *pseudomonas aeruginosa*, i.e., at least one of the same indications as set forth in the approved labeling for Alcon's Ciprodex product.

54. Upon information and belief, 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 version of Plaintiffs' Ciprodex product before the expiration of the '805 Patent, listed in the Orange Book for NDA No. 021537. Hence, Watson's purpose in submitting ANDA No. 208638 is to market products described therein before expiration of the '805 Patent.

**The Dr. Reddy's Defendants' ANDA No. 205548**

55. Upon information and belief, on or before June 11, 2015, the Dr. Reddy's Defendants 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 version of Plaintiffs' Ciprodex product.

56. Upon information and belief, on or around June 11, 2015, the Dr. Reddy's Defendants sent Plaintiffs Alcon Laboratories and Alcon Pharmaceuticals a letter representing that the Dr. Reddy's Defendants had submitted to FDA ANDA No. 205548 with a paragraph IV certification for the '804 and the '016 Patents.

57. On July 24, 2015, Plaintiffs filed a complaint for patent infringement against Dr. Reddy's Defendants for infringement of the '804 and the '016 Patents. That lawsuit is pending in this Court as *Alcon Pharmaceuticals v. Dr. Reddy's Laboratories, Inc.*, No. 3:15-cv-05756 (PGS) (DEA).

58. Upon information and belief, the indications set forth in the proposed labeling submitted in ANDA No. 205548 for the Dr. Reddy's Defendants' generic version of Plaintiffs' Ciprodex product are for the treatment of acute otitis media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *staphylococcus aureus*, *streptococcus pneumoniae*, *haemophilus influenzae*, *moraxella catarrhalis*, and *pseudomonas aeruginosa*, and/or the treatment of acute otitis externa in pediatric (age 6 months and older), adult and elderly patients due to *staphylococcus aureus* and *pseudomonas aeruginosa*, i.e., at least one of the same indications as set forth in the approved labeling for Alcon's Ciprodex product.

59. Upon information and belief, the purpose of the ANDA and paragraph IV certifications will be to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of a generic version of Plaintiffs' Ciprodex product before the

expiration of the '805 Patent, listed in the Orange Book for NDA No. 021537. Hence, the Dr. Reddy's Defendants' purpose in submitting ANDA No. 205548 is to market products described therein before expiration of the '805 Patent.

**Count 1: Infringement of the '805 Patent by Par**

60. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 59 above.

61. United States Patent No. 9,402,805, entitled "METHOD OF TREATING MIDDLE EAR INFECTIONS," was duly and legally issued by the United States Patent and Trademark Office on August 2, 2016. Plaintiff Alcon Pharmaceuticals is the owner of the '805 Patent. Plaintiff Alcon Research is an exclusive licensee under the '805 Patent. A true and complete copy of the '805 Patent is attached hereto as Exhibit B.

62. 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 version of Plaintiffs' Ciprodex product before the expiration of the '805 Patent.

63. Par's manufacture, use, offer for sale, or sale of such product would infringe at least claim 1 of the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

64. Upon information and belief, if approved, the generic version of Plaintiffs' Ciprodex product for which approval is sought in 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 at least claim 1 of the '805 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 '805 Patent.

65. Par's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic version of Plaintiffs' Ciprodex product for which approval is sought in ANDA No. 204424 would actively induce and contribute to infringement of the '805 Patent, and Par would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

66. Upon information and belief, as part of the ANDA No. 204424 filing, Par purportedly provided written certification to FDA that the claims of the '805 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Par's generic version of Plaintiffs' Ciprodex product.

67. Par gave written notice of its certification of invalidity, unenforceability, and/or non-infringement of the '805 Patent, alleging that all claims of the '805 Patent are invalid and that some of the claims of the '805 Patent would not be infringed by Par's generic version of Plaintiffs' 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 '805 Patent.

68. Par has infringed the '805 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 version of Plaintiffs' Ciprodex product prior to the expiration of the '805 Patent. Moreover, if Par commercially uses, offers for sale, or sells its generic version of Plaintiffs' Ciprodex product, or induces or contributes to such conduct, it would further infringe the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

70. Plaintiffs will be irreparably harmed if Par is not enjoined from infringing or actively inducing or contributing to infringement of the '805 Patent. Plaintiffs do not have an adequate remedy at law.

**Count 2: Infringement of the '805 Patent by Watson**

71. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 70 above.

72. United States Patent No. 9,402,805, entitled "METHOD OF TREATING MIDDLE EAR INFECTIONS," was duly and legally issued by the United States Patent and Trademark Office on August 2, 2016. Plaintiff Alcon Pharmaceuticals is the owner of the '805 Patent. Plaintiff Alcon Research is an exclusive licensee under the '805 Patent. A true and complete copy of the '805 Patent is attached hereto as Exhibit B.

73. Upon information and belief, Watson submitted ANDA No. 208638 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Plaintiffs' Ciprodex product before the expiration of the '805 Patent.

74. Watson's manufacture, use, offer for sale, or sale of such product would infringe at least claim 1 of the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

75. Upon information and belief, if approved, the generic version of Plaintiffs' Ciprodex product for which approval is sought in ANDA No. 208638 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 at least claim 1 of the '805 Patent. Upon information and belief, this infringement will occur at Watson's behest, with its

intent, knowledge, and encouragement, and Watson will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '805 Patent.

76. Watson's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic version of Plaintiffs' Ciprodex product for which approval is sought in ANDA No. 208638 would actively induce and contribute to infringement of the '805 Patent, and Watson would be liable as an infringer under 35 U.S.C. § 271(b) and/or (c).

77. Watson has infringed the '805 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 208638 and seeking FDA approval of ANDA No. 208638 to market a generic version of Plaintiffs' Ciprodex product prior to the expiration of the '805 Patent. Moreover, if Watson commercially uses, offers for sale, or sells its generic version of Plaintiffs' Ciprodex product, or induces or contributes to such conduct, it would further infringe the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

79. Plaintiffs will be irreparably harmed if Watson is not enjoined from infringing or actively inducing or contributing to infringement of the '805 Patent. Plaintiffs do not have an adequate remedy at law.

**Count 3: Infringement of the '805 Patent by the Dr. Reddy's Defendants**

80. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 79 above.

81. United States Patent No. 9,402,805, entitled "METHOD OF TREATING MIDDLE EAR INFECTIONS," was duly and legally issued by the United States Patent and

Trademark Office on August 2, 2016. Plaintiff Alcon Pharmaceuticals is the owner of the '805 Patent. Plaintiff Alcon Research is an exclusive licensee under the '805 Patent. A true and complete copy of the '805 Patent is attached hereto as Exhibit B.

82. Upon information and belief, the Dr. Reddy's Defendants submitted ANDA No. 205548 to FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of Plaintiffs' Ciprodex product before the expiration of the '805 Patent.

83. The Dr. Reddy's Defendants' manufacture, use, offer for sale, or sale of such product would infringe at least claim 1 of the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

84. Upon information and belief, if approved, the generic version of Plaintiffs' Ciprodex product for which approval is sought in 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 at least claim 1 of the '805 Patent. Upon information and belief, this infringement will occur at the Dr. Reddy's Defendants' behest, with their intent, knowledge, and encouragement, and the Dr. Reddy's Defendants will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '805 Patent.

85. The Dr. Reddy's Defendants' manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic version of Plaintiffs' Ciprodex product for which approval is sought in ANDA No. 205548 would actively induce and

contribute to infringement of the '805 Patent, and the Dr. Reddy's Defendants would be liable as infringers under 35 U.S.C. § 271(b) and/or (c).

86. The Dr. Reddy's Defendants have infringed the '805 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 205548 and seeking FDA approval of ANDA No. 205548 to market a generic version of Plaintiffs' Ciprodex product prior to the expiration of the '805 Patent. Moreover, if the Dr. Reddy's Defendants commercially use, offer for sale, or sell their generic version of Plaintiffs' Ciprodex product, or induce or contribute to such conduct, they would further infringe the '805 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

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

88. Plaintiffs will be irreparably harmed if the Dr. Reddy's defendants are not enjoined from infringing or actively inducing or contributing to infringement of the '805 Patent. Plaintiffs do not have an adequate remedy at law.

**Prayer for Relief**

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Defendants have infringed the '805 Patent 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 (Par), ANDA No. 208638 (Watson), and ANDA No. 205548 (the Dr. Reddy's Defendants) is not earlier than the expiration date of the '805 Patent, or any later expiration of exclusivity for the '805 Patent to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Defendants and their 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 '805 Patent, including the products described in ANDA No. 204424 (Par), ANDA No. 208638 (Watson), and ANDA No. 205548 (the Dr. Reddy's Defendants);

D. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 204424 (Par), ANDA No. 208638 (Watson), and ANDA No. 205548 (the Dr. Reddy's Defendants), or inducing or contributing to such conduct, would constitute infringement of the '805 Patent by Defendants 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 7, 2016

Respectfully submitted,

*/s/ Robert M. Goodman*

Robert M. Goodman
C. Brian Kornbrek
Thomas K. Murphy III
**GREENBAUM ROWE SMITH & DAVIS LLP**
75 Livingston Avenue
Roseland, NJ 07068
(973) 577-1770

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

*Of Counsel:*
Christopher N. Sipes
Keith A. Teel
Christopher T. Zirpoli
Chanson Chang
Ashley M. Kwon
Christopher G. Higby
**COVINGTON & BURLING LLP**
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

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

Plaintiffs, by their undersigned counsel, hereby certify that the same Reference Listed Drug, parties, and accused products at issue in this action are the subject of three other actions currently pending in this District, captioned *Alcon Pharmaceuticals Ltd. et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 3:15-cv-07240-PGS-DEA; *Alcon Pharmaceuticals Ltd. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 3:15-cv-05756-PGS-DEA, and *Alcon Pharmaceuticals Ltd. et al. v. Watson Laboratories, Inc.*, Civil Action No. 3:16-cv-00101-PGS-DEA. All three related actions have been consolidated under *In re: Ciprodex*, Civil Action No. 15-cv-5756-PGS-DEA, for discovery purposes only.

Dated: October 7, 2016

Respectfully submitted,

*/s/ Robert M. Goodman*

Robert M. Goodman
C. Brian Kornbrek
Thomas K. Murphy III
**GREENBAUM ROWE SMITH & DAVIS LLP**
75 Livingston Avenue
Roseland, NJ 07068
(973) 577-1770

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

*Of Counsel:*
Christopher N. Sipes
Keith A. Teel
Christopher T. Zirpoli
Chanson Chang
Ashley M. Kwon
Christopher G. Higby
**COVINGTON & BURLING LLP**
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000