IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC., AND ACTAVIS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Alcon Research, Ltd. ("Alcon"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Watson's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of PAZEO® ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 8,791,154 (the "'154 patent").

2. By letter dated November 3, 2015 (the "Notice Letter"), Watson Laboratories, Inc. notified Alcon that it had submitted to the FDA an ANDA, No. 208637, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic olopatadine ophthalmic solution ("Watson's ANDA Product") prior to the expiration of the '154 patent. Upon information and belief, Watson's ANDA Product is a drug product that is

a generic version of PAZEO®, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

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

4. Upon information and belief, defendant Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880, and a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson Laboratories is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, and relies on contributions from Actavis, Inc. and Actavis Pharma, Inc. Upon information and belief, Watson Laboratories is a wholly owned subsidiary of Actavis, Inc.

5. Upon information and belief, defendant Actavis, Inc. ("Actavis"), formerly known as Watson Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries.

6. Upon information and belief, defendant Actavis Pharma, Inc. ("Actavis Pharma"), formerly known as Watson Pharma, Inc., is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris

Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, and relies on contributions from Watson Laboratories and Actavis. Upon information and belief, Actavis Pharma is a wholly owned subsidiary of Actavis.

7. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma operate as an integrated, unitary generic pharmaceutical business. Upon information and belief, Watson Laboratories, Actavis, and/or Actavis Pharma share common employees, officers, and directors. Upon information and belief, Watson Laboratories, Actavis Pharma, and Actavis are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Watson's ANDA Product, and enter into agreements with each other that are closer than arm's length. Upon information and belief, Actavis and Actavis Pharma participated in, assisted, and cooperated with Watson Laboratories in the acts complained of herein. Except where otherwise noted, Watson Laboratories, Actavis Pharma, and Actavis are referred to collectively herein as "Watson."

8. Upon information and belief, and consistent with their practice with respect to other generic products, Watson Laboratories, Actavis and Actavis Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 208637, the ANDA at issue in this litigation. For instance, by letter dated November 3, 2015, Watson Laboratories directed Alcon to send any written notice regarding confidential access concerning ANDA No. 208637 to Brian Anderson, Esq., Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Mr. Anderson is Vice

President, Intellectual Property – Global Generics at Actavis. Upon information and belief, Actavis directed Watson Laboratories to submit ANDA No. 208637.

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 208637, Watson Laboratories, Actavis, and Actavis Pharma will act in concert to distribute and sell Watson's ANDA Product throughout the United States, including within Delaware.

JURISDICTION AND VENUE

10. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391 and 1400(b), and 2201 and 2202.

11. This Court has personal jurisdiction over Watson Laboratories, Actavis, and Actavis Pharma.

12. Watson Laboratories is subject to personal jurisdiction in Delaware because, among other things, Watson Laboratories has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Watson Laboratories develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, Watson Laboratories earns revenue from the distribution in Delaware by Actavis Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Actavis and/or Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic

pharmaceutical products. Upon information and belief, such agreements are at less than arm's length. Upon information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

13. Actavis is subject to personal jurisdiction in Delaware because, among other things, Actavis, itself and through its wholly-owned subsidiaries Watson Laboratories and Actavis Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Actavis, itself and through its wholly-owned subsidiaries Watson Laboratories and Actavis Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, Actavis has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other subsidiaries, Watson Laboratories and Actavis Pharma. Upon information and belief, Actavis earns revenue from the distribution in Delaware by Actavis Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

14. Actavis Pharma is subject to personal jurisdiction in Delaware because, among other things, Actavis Pharma has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Actavis Pharma, acting as the agent of Actavis and Watson Laboratories, distributes and sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson

Laboratories is the named applicant on approved ANDAs. Upon information and belief, Actavis Pharma and/or Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are at less than arm's length. In addition, Actavis Pharma is subject to personal jurisdiction in Delaware because, upon information and belief, Actavis Pharma is incorporated in Delaware and has appointed a registered agent in Delaware for service of process. Upon information and belief, Actavis Pharma is registered, under 24 Del. C. § 2540, to distribute Watson's generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

15. In addition, Watson has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. Upon information and belief, Watson, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to Alcon Research, Ltd., an entity incorporated in Delaware, and alleged in the Notice Letter that Alcon's patents are invalid. Upon information and belief, Watson knowingly and deliberately challenged Alcon's patent rights, and knew when it did so that it was triggering a forty-five day period for Alcon to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Watson's filing of ANDA No. 208637, challenging Alcon's patent rights, in Delaware. Upon information and belief, Watson knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Watson has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Alcon, a Delaware corporation, that it would be sued in Delaware for patent infringement.

18. In addition, this Court has personal jurisdiction over Watson because Watson Laboratories, Actavis, and Actavis Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this District and do not contest personal jurisdiction in this district. *See, e.g.*, *Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268 (Watson Laboratories and Actavis); *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161 (Watson Laboratories and Actavis); *Sanofi v. Watson Labs, Inc.,* C.A. No. 14-265 (Watson Laboratories, Actavis, and Actavis Pharma (as Watson Pharma, Inc.)); *Depomed, Inc. v. Watson Laboratories, Inc. – Florida*, C.A. No. 13-342 (Actavis and Actavis Pharma (as Watson Pharma, Inc.)).

19. Watson Laboratories, Actavis, and Actavis Pharma have also purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268 (Watson Laboratories); *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161 (Watson Laboratories); *Kissei Pharma Co. v. Hetero USA Inc.*, C.A. No. 13-1091 (Watson Laboratories and Actavis); *Kissei Pharma Co. v. Sandoz Inc.*, C.A. No. 13-1092 (Watson

Laboratories and Actavis); *Novartis Pharma Corp. v. Actavis, Inc.*, C.A. No. 13-371 (Watson Laboratories, Actavis, and Actavis Pharma (as Watson Pharma, Inc.)).

20. Upon information and belief, if ANDA No. 208637 is approved, Watson will manufacture, market, and/or sell Watson's ANDA Product within the United States, including in Delaware, consistently with Watson's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Watson regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Watson's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

21. Upon information and belief, if ANDA No. 208637 is approved, Watson will directly or indirectly market and distribute Watson's ANDA Product in Delaware. Upon information and belief, Watson's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Alcon's patent in the event that Watson's ANDA Product is approved before the patent expires.

22. Upon information and belief, Watson derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Watson and/or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

COUNT I
Infringement of the ’154 Patent

23. Alcon incorporates each of the preceding paragraphs 1-22 as if fully set forth herein.

24. The ’154 patent, entitled “High Concentration Olopatadine Ophthamalic Composition” (Exhibit A hereto), was duly and legally issued on July 29, 2014, to Alcon Research, Ltd., as assignee of Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisco Javier Galan, Nuria Carreras Perdiguer, and Onkar N. Singh.

25. The ’154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

26. The ’154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least .5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

27. Alcon owns the ’154 patent.

28. Alcon will be substantially and irreparably damaged by infringement of the ’154 patent.

29. PAZEO®, and the use of PAZEO®, are covered by one or more claims of the '154 patent, and the '154 patent has been listed in connection with that drug product in the FDA's Orange Book.

30. In its Notice Letter, Watson notified Plaintiff that Watson Laboratories had submitted to the FDA ANDA No. 208637. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product prior to the expiration of the '154 patent.

31. In the Notice Letter, Watson also notified Plaintiff that, as part of its ANDA, Watson had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to, *inter alia*, the '154 patent. Upon information and belief, Watson submitted ANDA No. 208637 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '154 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Watson's ANDA Product.

32. Watson's ANDA Product and the use of Watson's ANDA Product are covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

33. In the Notice Letter, Watson did not contest the infringement of claims 1-6, 8-10 and 12-27 of the '154 patent.

34. Watson has knowledge of the '154 patent.

35. Watson's submission of ANDA No. 208637 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Watson's ANDA Product before the expiration of the '154 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 208637.

37. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

38. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product in accordance with, and as directed by. Watson's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

39. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. Upon information and belief, Watson knows that Watson's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '154 patent, that Watson's ANDA Product is not a staple article or commodity of commerce, and that Watson's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 208637.

41. Notwithstanding Watson's knowledge of the claims of the '154 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following upon FDA approval of ANDA No. 208637 prior to the expiration of the '154 patent.

42. The foregoing actions by Watson constitute and/or will constitute infringement of the '154 patent, active inducement of the '154 patent, and contribution to the infringement by others of the '154 patent.

43. Upon information and belief, Watson has acted with full knowledge of the '154 patent and without a reasonable basis for believing that it would not be liable for infringement of the '154 patent, active inducement of the '154 patent, and/or contribution to the infringement by others of the '154 patent.

44. Unless Watson is enjoined from infringing the '154 patent, actively inducing infringement of the '154 patent, and contributing to the infringement by others of the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II
Declaratory Judgment of Infringement of the '154 Patent

45. Alcon incorporates each of the preceding paragraphs 1-44 as if fully set forth herein.

46. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on the one hand and Watson on the other regarding Watson's infringement, active inducement of infringement, and contribution to the infringement by others of the '154 patent.

47. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% olopatadine

dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

48. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least .67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least .5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

49. In the Notice Letter, Watson notified Plaintiff that Watson Laboratories had submitted ANDA No. 208637 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product prior to the expiration of the '154 patent.

50. In the Notice Letter, Watson also notified Plaintiff that, as part of its ANDA, Watson had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

51. Upon information and belief, Watson will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product immediately and imminently upon approval of ANDA No. 208637.

52. Watson's ANDA Product and use of Watson's ANDA Product is covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

53. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

54. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product in accordance with, and as directed by, Watson's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

55. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

56. Upon information and belief, Watson knows that Watson's ANDA Product and its product labeling are especially made or adapted for use in infringing the '154 patent, that Watson's ANDA Product is not a staple article or commodity of commerce, and that Watson's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Watson plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 208637.

57. Notwithstanding Watson's knowledge of the claims of the '154 patent, Watson has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Watson's ANDA Product with its product labeling following FDA approval of ANDA No. 208637 prior to the expiration of the '154 patent.

58. The foregoing actions by Watson will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the '154 patent.

59. Upon information and belief, Watson has acted with full knowledge of the '154 patent and without a reasonable basis for believing that it would not be liable for infringement of the '154 patent, active inducement of infringement of the '154 patent, and contribution to the infringement by others of the '154 patent.

60. Unless Watson is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

61. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that United States Patent No. 8,791,154 has been infringed under 35 U.S.C. § 271(e)(2) by Watson's submission to the FDA of its ANDA No. 208637;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Watson's ANDA Product, or any other drug product that infringes or the use of which infringes United States Patent No. 8,791,154 be not earlier than the latest of the expiration dates of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Watson's ANDA Product, or any other drug product covered by or whose use is covered by United States Patent No. 8,791,154, prior to the

expiration of United States Patent No. 8,791,154, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, prior to the expiration of United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action;

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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