IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

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 the filing by Watson Laboratories, Inc. ("Watson Laboratories") 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. 9,533,053 (the "'053 patent").

2. By letter dated February 13, 2017 (the "Notice Letter"), Watson Laboratories 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 '053 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 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, developing, manufacturing, marketing, and selling generic versions of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

5. 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.

6. This Court has personal jurisdiction over Watson Laboratories.

7. 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 and sale in Delaware 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, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

8. Upon information and belief, if ANDA No. 208637 is approved, Watson Laboratories will directly or indirectly manufacture, market, and/or sell Watson's ANDA Product within the United States, including in Delaware, consistently with Watson Laboratories' practices for the manufacturing, marketing and distribution of other generic pharmaceutical products. Upon information and belief, Watson Laboratories 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 Laboratories' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

9. Upon information and belief, if ANDA No. 208637 is approved, Watson Laboratories 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 '053 patent expires.

10. Upon information and belief, Watson Laboratories derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware,

and which are manufactured by Watson Laboratories 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.

11. In addition, Watson Laboratories 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.

12. Upon information and belief, Watson Laboratories, 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 patent is invalid. Upon information and belief, Watson Laboratories 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.

13. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Watson Laboratories' filing of ANDA No. 208637, challenging Alcon's patent rights, in Delaware. Upon information and belief, Watson Laboratories knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Watson Laboratories 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.

14. In addition, this Court has personal jurisdiction over Watson Laboratories because it regularly engages in patent litigation concerning FDA-approved branded drug products in this District and does not contest personal jurisdiction. *See, e.g.*, *Alcon Research, Ltd. v. Watson Labs., Inc.*, C.A. No. 15-1159; *Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268; *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161; *Sanofi v. Watson Labs, Inc.,* C.A. No. 14-265.

15. Watson Laboratories has also purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Alcon Research, Ltd. v. Watson Labs., Inc.*, C.A. No. 15-1159; *Takeda Pharma. U.S.A., Inc. v. Watson Labs., Inc.*, C.A. No. 14-268; *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161; *Kissei Pharma Co. v. Hetero USA Inc.*, C.A. No. 13-1091; *Kissei Pharma Co. v. Sandoz Inc.*, C.A. No. 13-1092; *Novartis Pharma Corp. v. Actavis, Inc.*, C.A. No. 13-371.

COUNT I – INFRINGEMENT OF THE ’053 PATENT

16. Alcon incorporates each of the preceding paragraphs 1–15 as if fully set forth herein.

17. The ’053 patent, entitled “High Concentration Olopatadine Ophthalmic Composition” (Exhibit A hereto), was duly and legally issued on January 3, 2017, to Alcon Research, Ltd., as assignee of Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisco Javier Galan, Nuria Carreras Perdiguer, and Onkar N. Singh.

18. The ’053 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising: at least 0.67 w/v%

olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin, and hydroxypropyl-γ-cyclodextrin; and water.

19. The ’053 patent also claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising: at least 0.67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; benzalkonium chloride; hydroxypropylmethyl cellulose; and water.

20. Alcon owns the ’053 patent.

21. Alcon will be substantially and irreparably damaged by infringement of the ’053 patent.

22. PAZEO®, and the use of PAZEO®, are covered by one or more claims of the ’053 patent, and the ’053 patent has been listed in connection with that drug product in the FDA’s Orange Book.

23. In its Notice Letter, Watson Laboratories notified Plaintiff that it 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 ’053 patent.

24. In the Notice Letter, Watson Laboratories also notified Plaintiff that, as part of its ANDA, Watson Laboratories 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 ’053 patent. Upon information and belief, Watson Laboratories 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 '053 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.

25. Watson's ANDA Product and the use of Watson's ANDA Product are covered by one or more claims of the '053 patent, including at least claim 1 and claim 8.

26. In the Notice Letter, Watson did not contest the infringement of claims 1–13 of the '053 patent.

27. Watson Laboratories has knowledge of the '053 patent.

28. Watson Laboratories' 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 '053 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, Watson Laboratories 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.

30. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

31. 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 Laboratories' proposed product labeling would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

32. Upon information and belief, Watson Laboratories plans and intends to, and will, actively induce infringement of the '053 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

33. Notwithstanding Watson Laboratories' knowledge of the claims of the '053 patent, Watson Laboratories 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 '053 patent.

34. The foregoing actions by Watson Laboratories constitute and/or will constitute infringement, and active inducement of infringement, of the '053 patent.

35. Upon information and belief, Watson Laboratories has acted with full knowledge of the '053 patent and without a reasonable basis for believing that it would not be liable for infringement of the '053 patent and/or active inducement of infringement of the '053 patent.

36. Unless Watson Laboratories is enjoined from infringing the '053 patent and actively inducing infringement of the '053 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '053 PATENT

37. Alcon incorporates each of the preceding paragraphs 1–36 as if fully set forth herein.

38. 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 Laboratories on the other regarding Watson Laboratories' infringement, and active inducement of infringement, of the '053 patent.

39. The ’053 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising: at least 0.67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin, and hydroxypropyl-γ-cyclodextrin; and water.

40. The ’053 patent also claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising: at least 0.67 w/v% olopatadine dissolved in the solution; PEG having a molecular weight of 200 to 800; polyvinylpyrrolidone; a cyclodextrin selected from the group consisting of hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; benzalkonium chloride; hydroxypropylmethyl cellulose; and water.

41. In the Notice Letter, Watson Laboratories notified Plaintiff that it 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 ’053 patent.

42. In the Notice Letter, Watson Laboratories also notified Plaintiff that, as part of its ANDA, Watson Laboratories 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).

43. Upon information and belief, Watson Laboratories 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.

44. Watson’s ANDA Product and use of Watson’s ANDA Product is covered by one or more claims of the ’053 patent, including at least claim 1 and claim 8.

45. The manufacture, use, sale, offer for sale, or importation of Watson's ANDA Product would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

46. 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 Laboratories' proposed product labeling would infringe one or more claims of the '053 patent, including at least Claim 1 and Claim 8.

47. Upon information and belief, Watson Laboratories plans and intends to, and will, actively induce infringement of the '053 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

48. Notwithstanding Watson Laboratories' knowledge of the claims of the '053 patent, Watson Laboratories 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 '053 patent.

49. The foregoing actions by Watson Laboratories will constitute infringement of, and active inducement of infringement of, the '053 patent.

50. Upon information and belief, Watson Laboratories has acted with full knowledge of the '053 patent and without a reasonable basis for believing that it would not be liable for infringement of the '053 patent and/or active inducement of infringement of the '053 patent.

51. Unless Watson Laboratories is enjoined from infringing, and inducing infringement of, the '053 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

52. 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. 9,533,053, will infringe, and induce the infringement of, that patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that United States Patent No. 9,533,053 has been infringed under 35 U.S.C. § 271(e)(2) by Watson Laboratories' 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. 9,533,053 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 Laboratories, and all persons acting in concert with Watson Laboratories, 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. 9,533,053, prior to the expiration of United States Patent No. 9,533,053, 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. 9,533,053, prior to the expiration of United

States Patent No. 9,533,053, 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

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff Alcon Research, Ltd.

OF COUNSEL:

Adam L. Perlman
Thomas H.L. Selby
Christopher J. Mandernach
Joelle P. Justus
Christopher A. Suarez
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

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