IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WATSON LABORATORIES, INC., ACTAVIS, INC., and ACTAVIS PHARMA, 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 and the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Alcon's TRAVATAN Z® (travoprost ophthalmic solution) 0.004% ("TRAVATAN Z") prior to the expiration of U.S. Patent Nos. 8,268,299 ("the '299 patent"), 8,323,630 ("the '630 patent"), and 8,388,941 ("the '941 patent").

2. By letter dated April 17, 2014 (the "Notice Letter"), Watson Laboratories, Inc. ("Watson Laboratories") notified Alcon that Watson Laboratories had submitted to the FDA an ANDA, No. 206048, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution, 0.004% ("Watson's ANDA Product") prior to the expiration of the '299 patent, the '630 patent, and the '941 patent.

Upon information and belief, Watson's ANDA Product is a drug product that is a generic version of TRAVATAN Z, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

3. Plaintiff Alcon is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and 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 92878.

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 with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

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.

7. Upon information and belief, Watson Laboratories and Actavis Pharma are wholly owned subsidiaries of Actavis, Inc. Except where otherwise noted, Watson Laboratories, Actavis Pharma, and Actavis, Inc. are referred to collectively herein as "Watson."

8. Upon information and belief, Watson Laboratories' preparation and submission of ANDA No. 206048 was done at the direction, under the control, and for the direct

benefit of Actavis. Upon information and belief, Actavis directed Watson Laboratories to submit ANDA No. 206048.

9. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 206048, Actavis, Watson Laboratories, and Actavis Pharma will act in concert to distribute and sell the product that is the subject of ANDA No. 206048 throughout the United States and within Delaware. Upon information and belief, following any FDA approval of ANDA No. 206048, Watson knows and intends that the product will be distributed and sold in the United States and within Delaware.

JURISDICTION AND VENUE

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

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

12. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma have had persistent and continuous contacts with this judicial district, including developing, manufacturing, and/or distributing pharmaceutical products that are sold in this judicial district.

13. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce

for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Watson Laboratories, Actavis, and Actavis Pharma have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

14. Upon information and belief, Watson Laboratories, Actavis, and/or Actavis Pharma have overlapping officers, directors, and employees.

15. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma operate as an integrated, unitary generic pharmaceutical business. Upon information and belief, Actavis organizes its operations into at least three distinct operating segments: Actavis Pharma, Actavis Specialty Brands, and Anda Distribution.

16. Upon information and belief, Actavis's "Actavis Pharma" segment is responsible for developing, manufacturing, marketing, and selling generic copies of branded pharmaceutical products for the U.S. market, and relies on contributions from Watson Laboratories, Actavis, and Actavis Pharma.

17. Upon information and belief, Watson Laboratories, Actavis, and Actavis Pharma are agents of each other and/or operate in concert as integrated parts of Actavis's "Actavis Pharma" segment.

18. 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.

19. 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.

20. On 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.

21. On information and belief, Actavis and/or 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. On information and belief, various products for which Watson Laboratories is the named applicant on approved ANDAs are available at retail pharmacies in Delaware. On information and belief, Actavis Pharma, Actavis, and Watson Laboratories will manufacture, market, and/or sell within the United States the generic product described in Watson's ANDA No. 206048 if FDA approval is granted. If ANDA No. 206048 is approved, the generic product would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

22. On information and belief, Actavis, Watson Laboratories, and Actavis Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA

of ANDA No. 206048, the ANDA at issue in this litigation. For instance, by letter dated April 22, 2014, Watson Laboratories directed Plaintiff to send any written notice regarding confidential access concerning ANDA No. 206048 to Brian Anderson, Esq. Morris Corporate Center III, 400 Interpace Parkway, Parsipanny, NJ 07054. On information and belief, Mr. Anderson is Senior Counsel – Intellectual Property at Actavis. Although submitted on behalf of Watson Laboratories, the letter addressed to Plaintiffs and dated April 22, 2014 was sent under the letterhead of "Actavis."

23. Upon information and belief, 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.*, No. 14-268 (Watson Laboratories and Actavis); *Fresenius Kabi USA, LLC v. Watson Labs., Inc.*, No. 14-161 (Watson Laboratories and Actavis); *Sanofi v. Watson Labs., Inc.*, No. 14-265 (Watson Laboratories, Actavis, and Actavis Pharma (as Watson Pharma, Inc.)); *Depomed, Inc. v. Watson Laboratories, Inc. – Florida*, No. 13-342-SLR (Actavis and Actavis Pharma (as Watson Pharma, Inc.)).

24. Additionally, Watson Laboratories, Actavis, and Actavis Pharma have 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.*, No. 14-268 (Watson Laboratories); *Fresenius Kabi USA, LLC v. Watson Labs., Inc.*, No. 14-161 (Watson Laboratories); *Merck & Co. v. Watson Labs. Inc.*, No. 05-658; *Kissei Pharma. Co. v. Hetero USA Inc.*, No. 13-1091 (Watson Laboratories and Actavis); *Kissei Pharma. Co. v. Sandoz Inc.*, No. 13-1092 (Watson Laboratories and Actavis); *Novartis Pharma. Corp. v. Actavis, Inc.*, No. 13-371 (Watson Laboratories, Actavis, and Actavis Pharma (as Watson Pharma, Inc.)).

BACKGROUND

25. TRAVATAN Z is an ophthalmic solution for topical administration to the eye. The active ingredient in TRAVATAN Z is travoprost. TRAVATAN Z is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

26. The '299 patent, entitled "Self Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on September 18, 2012. Alcon Research, Ltd. is the assignee of and owns the '299 patent. A true and correct copy of the '299 patent is attached hereto as Exhibit A and is incorporated herein by reference.

27. The '630 patent, entitled "Self-Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on December 4, 2012. Alcon Research, Ltd. is the assignee of and owns the '630 patent. A true and correct copy of the '630 patent is attached hereto as Exhibit B and is incorporated herein by reference.

28. The '941 patent, entitled "Self Preserved Aqueous Pharmaceutical Compositions," was duly and legally issued on March 5, 2013. Alcon Research, Ltd. is the assignee of and owns the '941 patent. A true and correct copy of the '941 patent is attached hereto as Exhibit C and is incorporated herein by reference.

29. The '299 patent, '630 patent, and '941 patent have each been listed in connection with TRAVATAN Z in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, maintained by the FDA, commonly known as the "Orange Book."

30. The purpose of Watson's submission of ANDA No. 206048 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration

dates of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Watson is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '299, '630, and '941 patents.

COUNT I
(Infringement of U.S. Patent No. 8,268,299)

31. Alcon incorporates each of the preceding paragraphs 1–30 as if fully set forth herein.

32. Upon information and belief, Watson's ANDA Product falls within the scope of one or more claims of the '299 patent.

33. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe one or more claims of the '299 patent.

34. Upon information and belief, Watson filed as a part of ANDA No. 206048 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '299 patent, asserting that the claims of the '299 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

35. Watson's submission of ANDA No. 206048 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '299 patent was an act of infringement of the '299 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 FDA approval of ANDA No. 206048.

37. Upon information and belief, Watson has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to 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. 206048.

38. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 206048 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing actions by Watson constitute and/or will constitute infringement of the '299 patent and active inducement of infringement of the '299 patent.

40. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '299 patent and without a reasonable basis for believing that it would not be liable for infringing the '299 patent and actively inducing infringement of the '299 patent.

41. Alcon will be substantially and irreparably damaged by infringement of the '299 patent. Accordingly, unless Watson is enjoined from infringing the '299 patent and actively inducing infringement of the '299 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

42. An actual case or controversy exists between Alcon and Watson with respect to infringement of the '299 patent.

COUNT II
(Infringement of U.S. Patent No. 8,323,630)

43. Alcon incorporates each of the preceding paragraphs 1–42 as if fully set forth herein.

44. Upon information and belief, Watson's ANDA Product falls within the scope of one or more claims of the '630 patent.

45. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe one or more claims of the '630 patent.

46. Upon information and belief, Watson filed as a part of ANDA No. 206048 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '630 patent, asserting that the claims of the '630 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

47. Watson's submission of ANDA No. 206048 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '630 patent was an act of infringement of the '630 patent under 35 U.S.C. § 271(e)(2)(A).

48. 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 FDA approval of ANDA No. 206048.

49. Upon information and belief, Watson has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to 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. 206048.

50. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 206048 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. The foregoing actions by Watson constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '630 patent.

52. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '630 patent and without a reasonable basis for believing that it would not be liable for infringing the '630 patent and actively inducing infringement of the '630 patent.

53. Alcon will be substantially and irreparably damaged by infringement of the '630 patent. Accordingly, unless Watson is enjoined from infringing the '630 patent and actively inducing infringement of the '630 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

54. An actual case or controversy exists between Alcon and Watson with respect to infringement of the '630 patent.

COUNT III
(Infringement of U.S. Patent No. 8,388,941)

55. Alcon incorporates each of the preceding paragraphs 1–54 as if fully set forth herein.

56. Upon information and belief, Watson's ANDA Product falls within the scope of one or more claims of the '941 patent. In addition, upon information and belief, the manufacture of Watson's ANDA Product falls within the scope of one or more claims of the '941 patent.

57. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe one or more claims of the '941 patent.

58. Upon information and belief, Watson filed as a part of ANDA No. 206048 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '941 patent, asserting that the claims of the '941 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

59. Watson's submission of ANDA No. 206048 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product prior to the expiration of the '941 patent was an act of infringement of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

60. 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 FDA approval of ANDA No. 206048.

61. Upon information and belief, Watson has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Watson has continued to assert its intent to 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. 206048.

62. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 206048 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

63. The foregoing actions by Watson constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '941 patent.

64. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '941 patent and without a reasonable basis for believing that it would not be liable for infringing the '941 patent and actively inducing infringement of the '941 patent.

65. Alcon will be substantially and irreparably damaged by infringement of the '941 patent. Accordingly, unless Watson is enjoined from infringing the '941 patent and actively inducing infringement of the '941 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

66. An actual case or controversy exists between Alcon and Watson with respect to infringement of the '941 patent.

WHEREFORE, Alcon requests the following relief:

(a) A judgment that Watson has infringed the '299 patent and will infringe and actively induce infringement of the '299 patent;

(b) A judgment that Watson has infringed the '630 patent and will infringe and actively induce infringement of the '630 patent;

(c) A judgment that Watson has infringed the '941 patent and will infringe and actively induce infringement of the '941 patent;

(d) A judgment ordering that the effective date of any FDA approval for Watson to make, use, offer for sale, sell, market, distribute, or import Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, be not earlier than the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A preliminary and permanent injunction enjoining Watson, and all persons acting in concert with Watson, from making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299, '630, or '941 patents, or the inducement of any of the foregoing, prior to the latest of the expiration dates of the '299, '630, and '941 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(f) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '299 patent, prior to the expiration date of the '299 patent, will infringe and/or actively induce infringement of the '299 patent;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '630 patent, prior to the expiration date of the '630 patent, will infringe and/or actively induce infringement of the '630 patent;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Watson's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '941 patent, prior to the expiration date of the '941 patent, will infringe and/or actively induce infringement of the '941 patent;

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

(j) An award of Alcon's costs and expenses in this action; and

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

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May 20, 2014