IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-129 (LPS) (SRF)
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

AMENDED COMPLAINT

Plaintiff Alcon Research, Ltd. ("Alcon"), by its attorneys, for its Amended 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 defendant's submission 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 ILEVRO® (nepafenac ophthalmic suspension) 0.3% ("ILEVRO") prior to the expiration of U.S. Patent Nos. 7,947,295 ("the '295 patent"), 8,921,337 ("the '337 patent"), and 9,662,398 ("the '398 patent").

2. By letter dated January 19, 2016 (the "First Notice Letter"), Watson Laboratories, Inc. ("Watson") notified Alcon that Watson had submitted to the FDA an ANDA, No. 208816, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic nepafenac ophthalmic suspension, 0.3% ("Watson's ANDA Product") prior to the expiration of the '295 patent and the '337 patent. Watson's ANDA Product is a drug

product that is a generic version of ILEVRO, containing the same or equivalent ingredients in the same or equivalent amounts.

3. The '398 patent issued on May 30, 2017, on U.S. Application No. 14/539,996. That application is a continuation of the application that resulted in the '337 patent. By letter dated June 9, 2017 (the "Second Notice Letter"), Watson notified Alcon that Watson had submitted to the FDA an amendment to ANDA No. 208816 seeking approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product in the United States prior to the expiration of the '398 patent.

PARTIES

4. Plaintiff Alcon Research, Ltd. 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.

5. Upon information and belief, defendant Watson is a corporation organized and existing under the laws of the State of Nevada having a 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 is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Watson is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

JURISDICTION

6. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Watson.

8. Watson is subject to personal jurisdiction in Delaware because, among other things, Watson 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 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 Alcon's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, Watson earns revenue from the distribution in Delaware of generic pharmaceutical products that are manufactured by Watson or for which Watson is the named applicant on approved ANDAs. Upon information and belief, Watson is a party 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 is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

9. In addition, upon information and belief, Watson's ANDA No. 208816 seeks FDA approval to sell Watson's ANDA product throughout the United States, including in Delaware, prior to the expiration of the '295, '337, and '398 patents, and thus seeks FDA approval to engage in conduct that will infringe Alcon's patent rights throughout the United States, including in Delaware. Moreover, upon information and belief, Watson knowingly 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 Alcon's patents by filing certifications 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). Watson has previously used

the process contemplated by 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 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.

10. Upon information and belief, Watson, with knowledge of the Hatch-Waxman Act process, directed the First and Second Notice Letters to Alcon Research, Ltd., an entity incorporated in Delaware, and alleged in the First and Second Notice Letters 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.

11. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Watson's filing of ANDA No. 208816, which challenges 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.

12. In addition, this Court has personal jurisdiction over Watson because Watson regularly engages 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; *Fresenius Kabi USA, LLC v. Watson Labs, Inc.*, C.A. No. 14-161; *Sanofi v. Watson Labs, Inc.,* C.A. No. 14-265; *Depomed, Inc. v. Watson,*

Inc. – Florida, C.A. No. 13-342. In addition, Watson has affirmatively sought transfer of patent litigation concerning FDA-approved branded drug products to this District. *See* Mot. to Transfer, *Bayer Pharma AG v. Watson Labs., Inc.*, C.A. Nos. 14-01804, 14-02065 (D.N.J. Apr. 17, 2014).

13. Watson 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.*, *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; *Novartis Pharma Corp. v. Actavis, Inc.*, C.A. No. 13-371.

14. Upon information and belief, if ANDA No. 208816 is approved, Watson will manufacture, market, and/or sell Watson's ANDA Product within the United States, including in Delaware, consistent 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.

15. Upon information and belief, if ANDA No. 208816 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.

16. 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 is the named applicant on approved ANDAs. Upon information and belief, various products for which Watson is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

17. For the above reasons, it would not be unfair or unreasonable for Watson to litigate this action in this District, and there is personal jurisdiction over Watson here.

BACKGROUND

18. ILEVRO is an ophthalmic suspension for topical administration to the eye. The active ingredient in ILEVRO is nepafenac. ILEVRO is indicated for the treatment of pain and inflammation associated with cataract surgery.

19. The ’295 patent, entitled “Ophthalmic Compositions Containing a Synergistic Combination of Two Polymers,” was duly and legally issued on May 4, 2011. Alcon Research, Ltd. is the assignee of and owns the ’295 patent. A true and correct copy of the ’295 patent is attached hereto as Exhibit A.

20. The ’337 patent, entitled “Carboxyvinyl Polymer-Containing Nanoparticle Suspensions,” was duly and legally issued on December 30, 2014. Alcon Research, Ltd. is the assignee of and owns the ’337 patent. A true and correct copy of the ’337 patent is attached hereto as Exhibit B.

21. The ’398 patent, entitled “Carboxyvinyl Polymer-Containing Nanoparticle Suspensions,” was duly and legally issued on May 30, 2017. Alcon Research, Ltd. is the assignee of and owns the ’398 patent. A true and correct copy of the ’398 patent is attached hereto as Exhibit C.

22. The ’295, ’337, and ’398 patents have been listed in connection with ILEVRO in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, maintained by the FDA, commonly known as the “Orange Book.”

23. The purpose of Watson’s submission of ANDA No. 208816 was to obtain 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 ’295, ’337, and ’398 patents. 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 ’295, ’337, and ’398 patents.

COUNT I
(Infringement of U.S. Patent No. 7,947,295)

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

25. Upon information and belief, Watson’s ANDA Product falls within the scope of or is equivalent to a composition falling within the scope of one or more claims of the ’295 patent, including claim 10 and claims 13 through 20.

26. 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 ’295 patent, including claim 10 and claims 13 through 20.

27. Upon information and belief, Watson filed as a part of ANDA No. 208816 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 ’295 patent, asserting that the claims of the ’295 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson’s ANDA Product.

28. Watson's submission of ANDA No. 208816 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 '295 patent was an act of infringement of the '295 patent under 35 U.S.C. § 271(e)(2)(A).

29. 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. 208816.

30. Upon information and belief, Watson has knowledge of the claims of the '295 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. 208816.

31. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '295 patent when ANDA No. 208816 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

32. The foregoing actions by Watson constitute and/or will constitute infringement of the '295 patent and active inducement of infringement of the '295 patent.

33. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '295 patent and without a reasonable basis for believing that it would not be liable for infringing the '295 patent and actively inducing infringement of the '295 patent.

34. Alcon will be substantially and irreparably damaged by infringement of the '295 patent. Accordingly, unless Watson is enjoined from infringing the '295 patent and actively inducing infringement of the '295 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

35. The Court should declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by the '295 patent, will infringe and induce the infringement of that patent.

COUNT II
(Infringement of U.S. Patent No. 8,921,337)

36. Alcon incorporates each of the preceding paragraphs 1–35 as if fully set forth herein.

37. Upon information and belief, Watson's ANDA Product falls within the scope of or is equivalent to a composition falling within the scope of each of the claims of the '337 patent.

38. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe each of the claims of the '337 patent.

39. Upon information and belief, Watson filed as a part of ANDA No. 208816 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 '337 patent, asserting that the claims of the '337 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

40. Watson's submission of ANDA No. 208816 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 '337 patent was an act of infringement of the '337 patent under 35 U.S.C. § 271(e)(2)(A).

41. 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. 208816.

42. Upon information and belief, Watson has knowledge of the claims of the '337 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. 208816.

43. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '337 patent when ANDA No. 208816 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. The foregoing actions by Watson constitute and/or will constitute infringement of the '337 patent and active inducement of infringement of the '337 patent.

45. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '337 patent and without a reasonable basis for believing that it would not be liable for infringing the '337 patent and actively inducing infringement of the '337 patent.

46. Alcon will be substantially and irreparably damaged by infringement of the '337 patent. Accordingly, unless Watson is enjoined from infringing the '337 patent and actively inducing infringement of the '337 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

47. The Court should declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by the '337 patent, will infringe and induce the infringement of that patent.

COUNT III
(Infringement of U.S. Patent No. 9,662,398)

48. Alcon incorporates each of the preceding paragraphs 1–47 as if fully set forth herein.

49. Upon information and belief, Watson's ANDA Product falls within the scope of or is equivalent to a composition falling within the scope of each of the claims of the '398 patent.

50. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Watson's ANDA Product would infringe each of the claims of the '398 patent.

51. Upon information and belief, Watson filed as an amendment to ANDA No. 208816 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 '398 patent, asserting that the claims of the '398 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Product.

52. Watson's submission of ANDA No. 208816 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Watson's ANDA Product was an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

53. 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. 208816.

54. Upon information and belief, Watson has knowledge of the claims of the '398 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. 208816.

55. Upon information and belief, Watson plans and intends to, and will, actively induce infringement of the '398 patent when ANDA No. 208816 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

56. The foregoing actions by Watson constitute and/or will constitute infringement of the '398 patent and active inducement of infringement of the '398 patent.

57. Upon information and belief, Watson has acted, and will continue to act, with full knowledge of the '398 patent and without a reasonable basis for believing that it would not be liable for infringing the '398 patent and actively inducing infringement of the '398 patent.

58. Alcon will be substantially and irreparably damaged by infringement of the '398 patent. Accordingly, unless Watson is enjoined from infringing the '398 patent and actively inducing infringement of the '398 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

59. The Court should declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Watson's ANDA Product, or any other drug product which is covered by or whose use is covered by the '398 patent, will infringe and induce the infringement of that patent.

WHEREFORE, Alcon requests the following relief:

(a) A judgment that Watson has infringed the '295 patent and will infringe and actively induce infringement of the '295 patent;

(b) A judgment that Watson has infringed the '337 patent and will infringe and actively induce infringement of the '337 patent;

(c) A judgment that Watson has infringed the '398 patent and will infringe and actively induce infringement of the '398 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 '295, '337, or '398 patents, be not earlier than the latest of the expiration dates of the '295, '337, and '398 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 '295, '337, or '398 patents, or the inducement of any of the foregoing, prior to the latest of the expiration date of the '295, '337, and '398 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 '295 patent, prior to the expiration date of the '295 patent, will infringe and/or actively induce infringement of the '295 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 '337 patent, prior to the expiration date of the '337 patent, will infringe and/or actively induce infringement of the '337 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 '398 patent, prior to the expiration date of the '398 patent, will infringe and/or actively induce infringement of the '398 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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