

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
WOCKHARDT LIMITED, WOCKHARDT	)	
BIO AG, and WOCKHARDT USA, LLC,	)	
	)	
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 Wockhardt 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<sup>®</sup> (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”).

**PARTIES**

2. 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.

3. Upon information and belief, defendant Wockhardt Limited is an Indian corporation having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

4. Upon information and belief, defendant Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. Upon information and belief, Wockhardt Bio AG is a wholly owned subsidiary of Wockhardt Limited. Upon information and belief, Wockhardt Bio AG was formerly known as Wockhardt EU Operations (Swiss) AG.

5. Upon information and belief, defendant Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054. Upon information and belief, Wockhardt USA, LLC is an indirect, wholly owned subsidiary of Wockhardt Bio AG and Wockhardt Limited.

6. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC, are collectively referred to herein as “Wockhardt.”

#### **JURISDICTION AND VENUE**

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

8. Wockhardt Limited is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt Limited itself and through its wholly owned subsidiaries, Wockhardt Bio AG and Wockhardt USA, LLC, has purposely availed itself of the benefits and protections of Delaware’s laws such that it should reasonably anticipate being haled into court in this District.

9. Upon information and belief, Wockhardt Limited is a generic pharmaceutical company that, on its own and/or through its wholly owned subsidiaries and agents, Wockhardt Bio AG and Wockhardt USA, LLC, 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.

10. Upon information and belief, Wockhardt Limited earns revenue from the distribution in the State of Delaware by Wockhardt USA, LLC of generic pharmaceutical products that are manufactured by Wockhardt Bio AG and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

11. Wockhardt Limited is subject to jurisdiction in the State of Delaware on the basis of its inducement of Wockhardt Bio AG's and/or Wockhardt USA, LLC's acts of infringement in the State of Delaware.

12. Wockhardt Limited is subject to personal jurisdiction in the State of Delaware because, on information and belief, it controls and dominates Wockhardt Bio AG and Wockhardt USA, LLC, and therefore the activities of Wockhardt Bio AG and Wockhardt USA, LLC in this District are attributable to Wockhardt Limited.

13. Wockhardt Bio AG is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt Bio AG has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in this District.

14. Upon information and belief, Wockhardt Bio AG, on behalf of and as the agent of Wockhardt Limited and/or through Wockhardt USA, LLC, develops, manufactures, markets, sells, and/or offers to sell generic pharmaceutical products 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.

15. Upon information and belief, Wockhardt Bio AG earns revenue from the distribution in the State of Delaware by Wockhardt USA, LLC of generic pharmaceutical products that are manufactured by Wockhardt Bio AG and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

16. Wockhardt Bio AG is subject to jurisdiction in the State of Delaware on the basis of its inducement of Wockhardt USA, LLC's acts of infringement in the State of Delaware.

17. Wockhardt USA, LLC is subject to personal jurisdiction in this Court because, among other things, upon information and belief, Wockhardt USA, LLC, has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in this District.

18. Upon information and belief, Wockhardt USA, LLC, on behalf of and as the agent of Wockhardt Limited and Wockhardt Bio AG, develops, manufactures, imports, markets, offers for sale, and/or sells generic pharmaceutical products throughout the United States, including in the State of Delaware and therefore transacts business within the State of

Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

19. Upon information and belief, Wockhardt USA, LLC earns revenue from the distribution in the State of Delaware of generic pharmaceutical products that are manufactured by Wockhardt Bio AG and/or Wockhardt USA, LLC, for which Wockhardt Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs.

20. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC are part of a vertically integrated and unified organization. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC will act in concert to manufacture, import, distribute, offer for sale and sell the products that are the subject of ANDA No. 205664 ("Wockhardt's ANDA Product") throughout the United States, including within the State of Delaware.

21. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and/or Wockhardt USA, LLC share common employees, officers and directors, and have entered into one or more contracts for the manufacture, importation, distribution, offer for sale, and/or sale of generic pharmaceutical products throughout the United States, including in the State of Delaware, which were not negotiated at arm's length.

22. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC participated in, contributed to, aided, abetted and/or induced the submission by Wockhardt Bio AG to the U.S. Food and Drug Administration ("FDA") of ANDA No. 205664, the ANDA at issue in this litigation.

23. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC have each previously consented to personal jurisdiction in this District. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC have affirmatively availed themselves of the Courts of this District by asserting counterclaims in previous litigation in the District of Delaware.

### **BACKGROUND**

24. 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.

25. 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.

26. 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.

27. 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.

28. 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."

29. By letter dated November 7, 2013 (the "Notice Letter"), Wockhardt USA, LLC notified Alcon that Wockhardt Bio AG had submitted to the FDA an ANDA, No. 205664, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution, 0.004% prior to the expiration of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Wockhardt'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.

30. The purpose of Wockhardt's submission of ANDA No. 205664 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to engage in the commercial manufacture, use, and/or sale of Wockhardt's ANDA Product prior to the expiration dates of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Wockhardt is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Wockhardt'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, Wockhardt'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 Wockhardt's ANDA Product would infringe one or more claims of the '299 patent.

34. Upon information and belief, Wockhardt filed as a part of ANDA No. 205664 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCIA, 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 Wockhardt's ANDA Product.

35. Wockhardt's submission of ANDA No. 205664 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Wockhardt'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, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon FDA approval of ANDA No. 205664.

37. Upon information and belief, Wockhardt has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Wockhardt has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 205664.

38. Upon information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 205664 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.



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

40. Upon information and belief, Wockhardt 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 Wockhardt 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 Wockhardt 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, Wockhardt'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 Wockhardt's ANDA Product would infringe one or more claims of the '630 patent.

46. Upon information and belief, Wockhardt filed as a part of ANDA No. 205664 a certification 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 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 Wockhardt's ANDA Product.

47. Wockhardt's submission of ANDA No. 205664 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Wockhardt'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, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon FDA approval of ANDA No. 205664.

49. Upon information and belief, Wockhardt has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Wockhardt has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 205664.

50. Upon information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 205664 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

52. Upon information and belief, Wockhardt 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 Wockhardt 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 Wockhardt 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, Wockhardt'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 Wockhardt'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 Wockhardt's ANDA Product would infringe one or more claims of the '941 patent.

58. Upon information and belief, Wockhardt filed as a part of ANDA No. 205664 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FFDCFA, 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 Wockhardt's ANDA Product.

59. Wockhardt's submission of ANDA No. 205664 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Wockhardt'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, Wockhardt will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon FDA approval of ANDA No. 205664.

61. Upon information and belief, Wockhardt has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Wockhardt has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's ANDA Product immediately and imminently upon approval of ANDA No. 205664.

62. Upon information and belief, Wockhardt plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 205664 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

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

64. Upon information and belief, Wockhardt 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 Wockhardt 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 Wockhardt with respect to infringement of the '941 patent.

WHEREFORE, Alcon requests the following relief:

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

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

(c) A judgment that Wockhardt 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 Wockhardt to make, use, offer for sale, sell, market, distribute, or import Wockhardt'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 Wockhardt, and all persons acting in concert with Wockhardt, from making, using, selling, offering for sale, marketing, distributing, or importing Wockhardt'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 Wockhardt'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 Wockhardt'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 Wockhardt'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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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