

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

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MICRO LABS LIMITED and MICRO LABS	)	
USA 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 defendant Micro Labs 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”).

2. By letter dated December 2, 2013 (the “Notice Letter”), Micro Labs USA Inc. notified Alcon that Micro Labs Limited had submitted to the FDA an ANDA, No.021994, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic travoprost ophthalmic solution (“Micro Labs’ ANDA Product”), 0.004% prior to the

expiration of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Micro Labs' 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 Micro Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 27 Race Course Road, Bangalore 560 001, India.

5. Upon information and belief, defendant Micro Labs USA Inc. is a corporation organized and existing under the laws of the state of New Jersey, having its principal place of business at 104 Carnegie Ctr., Suite 216, Princeton, NJ 08540. Upon information and belief, Micro Labs USA Inc. is a wholly owned subsidiary of Micro Labs Limited.

6. Upon information and belief, Micro Labs Limited and Micro Labs USA Inc. are part of a vertically integrated and unified organization. Upon information and belief, Micro Labs Limited and Micro Labs USA Inc. will act in concert to manufacture, import, distribute, offer for sale and sell Micro Labs' ANDA Product throughout the United States, including within the State of Delaware.

7. Upon information and belief, Micro Labs Limited and Micro Labs USA Inc. 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.

8. Upon information and belief, the Notice Letter was signed by Dr. Kumara Sekar, Vice President, Regulatory Affairs, Micro Labs USA Inc., but stated that the FDA received ANDA 021994, the ANDA at issue in this litigation, from Micro Labs Limited. Upon information and belief, Micro Labs Limited and Micro Labs USA Inc. participated in, contributed to, aided, abetted and/or induced the submission by Micro Labs Limited to the FDA of ANDA No. 021994. Upon information and belief, Micro Labs USA Inc. is acting as the agent of Micro Labs Limited with respect to the filing of ANDA No. 021994.

9. Micro Labs Limited and Micro Labs USA Inc. are collectively referred to herein as "Micro Labs."

#### **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. Micro Labs Limited is subject to personal jurisdiction in this Court because, among other things, upon information and belief: (1) Micro Labs Limited itself and through its wholly owned subsidiary, Micro Labs USA Inc., 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; (2) Micro Labs Limited is a generic pharmaceutical company that, on its own and/or through its wholly owned subsidiary and agent, Micro Labs USA Inc., 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; (3) Micro Labs Limited earns revenue from the distribution in the State of Delaware by Micro Labs USA Inc. of generic pharmaceutical products that are manufactured by Micro Labs Limited and/or Micro Labs USA Inc., for which Micro Labs Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs; (4) following any FDA approval of Micro Labs' ANDA No. 021994, Micro Labs Limited, alone or in concert with Micro Labs USA Inc., intends to offer to sell and sell Micro Labs' ANDA Product throughout the United States and within the State of Delaware; (5) if Micro Labs Limited is permitted to sell Micro Labs' ANDA Product in the United States prior to the expiration of the '299, '630, and '941 patents, Micro Labs Limited will cause substantial injury to Alcon, a Delaware corporation, including on the basis of Micro Labs Limited's conduct in the State of Delaware; (6) Micro Labs Limited has induced and will induce Micro Labs USA Inc.'s acts of infringement in the State of Delaware; and (7) Micro Labs Limited controls and dominates Micro Labs USA Inc., and therefore the activities of Micro Labs USA Inc. in the State of Delaware are attributable to Micro Labs Limited.

12. Micro Labs USA Inc. is subject to personal jurisdiction in this Court because, among other things, upon information and belief, (1) Micro Labs USA Inc. 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; (2) Micro Labs USA Inc., on behalf of and as the agent of Micro Labs Limited, 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; (3) Micro Labs USA Inc. earns revenue from the distribution in the State of

Delaware of generic pharmaceutical products that are manufactured by Micro Labs Limited and/or Micro Labs USA Inc., for which Micro Labs Limited and/or one of its agents or wholly owned subsidiaries is the named applicant on approved ANDAs; (4) following any FDA approval of Micro Labs' ANDA No. 021994, Micro Labs USA Inc., alone or in concert with Micro Labs Limited, intends to offer to sell and sell Micro Labs' ANDA Product throughout the United States and within the State of Delaware; and (5) if Micro Labs USA Inc. is permitted to sell Micro Labs' ANDA Product in the United States prior to the expiration of the '299, '630, and '941 patents, Micro Labs USA Inc. will cause substantial injury to Alcon, a Delaware corporation, including on the basis of Micro Labs USA Inc.'s conduct in the State of Delaware.

### **BACKGROUND**

13. 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.

14. 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.

15. 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.

16. 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.

17. 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."

18. The purpose of Micro Labs' submission of ANDA No. 021994 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FFDCA") to engage in the commercial manufacture, use, and/or sale of Micro Labs' ANDA Product prior to the expiration dates of the '299 patent, the '630 patent, and the '941 patent. Upon information and belief, Micro Labs is seeking approval under the FFDCA to engage in the commercial manufacture, use, and/or sale of Micro Labs' ANDA Product prior to the expiration of the '299, '630, and '941 patents.

**COUNT I**

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

19. Alcon incorporates each of the preceding paragraphs 1–18 as if fully set forth herein.

20. Upon information and belief, Micro Labs' ANDA Product falls within the scope of one or more claims of the '299 patent.

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

22. Upon information and belief, Micro Labs filed as a part of ANDA No. 021994 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 '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 Micro Labs' ANDA Product.

23. Micro Labs' submission of ANDA No. 021994 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Micro Labs' 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).

24. Upon information and belief, Micro Labs will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Product immediately and imminently upon FDA approval of ANDA No. 021994.

25. Upon information and belief, Micro Labs has knowledge of the claims of the '299 patent. Notwithstanding this knowledge, Micro Labs has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Product immediately and imminently upon approval of ANDA No. 021994.

26. Upon information and belief, Micro Labs plans and intends to, and will, actively induce infringement of the '299 patent when ANDA No. 021994 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

27. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '299 patent and active inducement of infringement of the '299 patent.

28. Upon information and belief, Micro Labs 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.

29. Alcon will be substantially and irreparably damaged by infringement of the '299 patent. Accordingly, unless Micro Labs 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.

30. An actual case or controversy exists between Alcon and Micro Labs with respect to infringement of the '299 patent.

### **COUNT II**

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

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

32. Upon information and belief, Micro Labs' ANDA Product falls within the scope of one or more claims of the '630 patent.

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

34. Upon information and belief, Micro Labs filed as a part of ANDA No. 021994 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 Micro Labs ANDA Product.

35. Micro Labs' submission of ANDA No. 021994 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Micro Labs'



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).

36. Upon information and belief, Micro Labs will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs ANDA Product immediately and imminently upon FDA approval of ANDA No. 021994.

37. Upon information and belief, Micro Labs has knowledge of the claims of the '630 patent. Notwithstanding this knowledge, Micro Labs has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Product immediately and imminently upon approval of ANDA No. 021994.

38. Upon information and belief, Micro Labs plans and intends to, and will, actively induce infringement of the '630 patent when ANDA No. 021994 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '630 patent and active inducement of infringement of the '630 patent.

40. Upon information and belief, Micro Labs 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.

41. Alcon will be substantially and irreparably damaged by infringement of the '630 patent. Accordingly, unless Micro Labs 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.

42. An actual case or controversy exists between Alcon and Micro Labs with respect to infringement of the '630 patent.

**COUNT III**

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

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

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

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

46. Upon information and belief, Micro Labs filed as a part of ANDA No. 021994 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 '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 Micro Labs' ANDA Product.

47. Micro Labs' submission of ANDA No. 021994 for the purpose of obtaining approval to engage in the commercial manufacture, use, and/or sale of Micro Labs' 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).

48. Upon information and belief, Micro Labs will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Product immediately and imminently upon FDA approval of ANDA No. 021994.

49. Upon information and belief, Micro Labs has knowledge of the claims of the '941 patent. Notwithstanding this knowledge, Micro Labs has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Product immediately and imminently upon approval of ANDA No. 021994.

50. Upon information and belief, Micro Labs plans and intends to, and will, actively induce infringement of the '941 patent when ANDA No. 021994 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

51. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '941 patent and active inducement of infringement of the '941 patent.

52. Upon information and belief, Micro Labs 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.

53. Alcon will be substantially and irreparably damaged by infringement of the '941 patent. Accordingly, unless Micro Labs 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.

54. An actual case or controversy exists between Alcon and Micro Labs with respect to infringement of the '941 patent.

WHEREFORE, Alcon requests the following relief:

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

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

(c) A judgment that Micro Labs 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 Micro Labs to make, use, offer for sale, sell, market, distribute, or import Micro Labs' 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 Micro Labs, and all persons acting in concert with Micro Labs, from making, using, selling, offering for sale, marketing, distributing, or importing Micro Labs' 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 Micro Labs' 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 Micro Labs' 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 Micro Labs' 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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January 9, 2014

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*/s/ Maryellen Noreika*

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