

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD., )  
 )  
 Plaintiff, )  
 )  
 v. ) C.A. No. \_\_\_\_\_  
 )  
 BARR 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, that arises out of the submission by defendant Barr Laboratories, Inc. (“Barr”) 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 (“TRAVATAN Z<sup>®</sup>”) prior to the expiration of U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253.

**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 Barr is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

## **JURISDICTION AND VENUE**

4. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 1391, and 1400(b). Barr is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Barr is a resident and citizen of the State of Delaware and has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law, and Barr is in the business of marketing pharmaceutical products, which it distributes and sells throughout the United States, including in Delaware.

## **BACKGROUND**

5. TRAVATAN Z<sup>®</sup> is an ophthalmic solution for topical administration to the eye. The active ingredient in TRAVATAN Z<sup>®</sup> is travoprost. TRAVATAN Z<sup>®</sup> is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication.

6. U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253 have been listed in connection with TRAVATAN Z<sup>®</sup> in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly (and hereinafter) known as the "Orange Book."

7. By letter dated June 24, 2009 (the "Notice Letter"), Barr notified Alcon that Barr had submitted to the FDA an ANDA, No. 91-411, for Barr's travoprost ophthalmic solution, 0.004% sterile, ionic buffered ("Barr's ANDA Product"). Barr's ANDA Product is a drug product that is a generic version of TRAVATAN Z<sup>®</sup>, and on information and belief, Barr's

ANDA Product contains the same ingredients, or equivalents thereof, in the same amounts, or equivalent amounts, as TRAVATAN Z<sup>®</sup>.

8. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), for each claim of U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253 that Barr believes would not be infringed by the making, using, offering for sale, sale, or importation of Barr's ANDA Product, Barr was required to provide in its Notice Letter a full and detailed explanation of why each such claim is or would not be infringed.

9. Barr did not assert in its Notice Letter that the making, using, offering for sale, sale, or importation of Barr's ANDA Product would not infringe one or more claims of each of U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253.

10. The purpose of Barr's submission of ANDA No. 91-411 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product prior to the expiration of U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253.

11. In the Notice Letter, Barr also notified Alcon that, as part of its ANDA No. 91-411, Barr 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 U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253. Upon information and belief, Barr submitted ANDA No. 91-411 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that U.S. Patent Nos. 5,510,383, 5,889,052, 6,503,497, and 6,849,253 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Barr's ANDA Product.

**COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,510,383**

12. Alcon incorporates each of the preceding paragraphs 1–11 as if fully set forth herein.

13. United States Patent No. 5,510,383 (“the ’383 patent”), entitled “Use of Cloprostenol, Fluprostenol and Their Salts and Esters to Treat Glaucoma and Ocular Hypertension” (Exhibit A hereto), was duly and legally issued on April 23, 1996, to Alcon Laboratories, Inc., as assignee of John E. Bishop, Louis DeSantis, Jr., and Verney L. Sallee, and is incorporated herein by reference.

14. Alcon Laboratories, Inc.’s interest in the ’383 patent has been subsequently assigned to Alcon Research, Ltd.

15. Alcon will be substantially and irreparably damaged by infringement of the ’383 patent.

16. Barr has knowledge of the ’383 patent.

17. Barr’s submission of ANDA No. 91-411 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA Product prior to the expiration of the ’383 patent was an act of infringement of the ’383 patent under 35 U.S.C. § 271(e)(2)(A).

18. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product would infringe one or more claims of the ’383 patent.

19. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

20. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '383 patent.

21. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '383 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

22. Upon information and belief, Barr knows that Barr's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '383 patent, and that Barr's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Barr plans and intends to, and will, contribute to infringement of the '383 patent immediately and imminently upon approval of ANDA No. 91-411.

23. The foregoing actions by Barr constitute and/or will constitute infringement of the '383 patent, active inducement of infringement of the '383 patent, and contribution to the infringement by others of the '383 patent.

24. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '383 patent, actively inducing infringement of the '383 patent, and contributing to the infringement by others of the '383 patent.

25. Unless Barr is enjoined from infringing the '383 patent, actively inducing infringement of the '383 patent, and contributing to the infringement by others of the '383 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT II – INFRINGEMENT OF U.S. PATENT NO. 5,889,052**

26. Alcon incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. United States Patent No. 5,889,052 (“the ’052 patent”), entitled “Use of Cloprostenol and Fluprostenol Analogues to Treat Glaucoma and Ocular Hypertension” (Exhibit B hereto), was duly and legally issued on March 30, 1999, to Alcon Laboratories, Inc., as assignee of Peter G. Klimko, John E. Bishop, Verney L. Sallee, and Paul W. Zinke, and is incorporated herein by reference.

28. Alcon Laboratories, Inc.’s interest in the ’052 patent has been subsequently assigned to Alcon Research, Ltd.

29. Alcon will be substantially and irreparably damaged by infringement of the ’052 patent.

30. Barr has knowledge of the ’052 patent.

31. Barr’s submission of ANDA No. 91-411 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA Product prior to the expiration of the ’052 patent was an act of infringement of the ’052 patent under 35 U.S.C. § 271(e)(2)(A).

32. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product would infringe one or more claims of the ’052 patent.

33. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

34. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '052 patent.

35. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '052 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

36. Upon information and belief, Barr knows that Barr's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '052 patent, and that Barr's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Barr plans and intends to, and will, contribute to infringement of the '052 patent immediately and imminently upon approval of ANDA No. 91-411.

37. The foregoing actions by Barr constitute and/or will constitute infringement of the '052 patent, active inducement of infringement of the '052 patent, and contribution to the infringement by others of the '052 patent.

38. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '052 patent, actively inducing infringement of the '052 patent, and contributing to the infringement by others of the '052 patent.

39. Unless Barr is enjoined from infringing the '052 patent, actively inducing infringement of the '052 patent, and contributing to the infringement by others of the '052 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT III – INFRINGEMENT OF U.S. PATENT NO. 6,503,497**

40. Alcon incorporates each of the preceding paragraphs 1–39 as if fully set forth herein.

41. United States Patent No. 6,503,497 (“the ’497 patent”), entitled “Use of Borate-Polyol Complexes in Ophthalmic Compositions” (Exhibit C hereto), was duly and legally issued on Jan. 7, 2003, to Alcon Manufacturing, Ltd., as assignee of Masood Chowhan and Nissanke L. Dassanayake, and is incorporated herein by reference.

42. Alcon Manufacturing, Ltd.’s interest in the ’497 patent has been subsequently assigned to Alcon Research, Ltd.

43. Alcon will be substantially and irreparably damaged by infringement of the ’497 patent.

44. Barr has knowledge of the ’497 patent.

45. Barr’s submission of ANDA No. 91-411 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA Product prior to the expiration of the ’497 patent was an act of infringement of the ’497 patent under 35 U.S.C. § 271(e)(2)(A).

46. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product would infringe one or more claims of the ’497 patent.

47. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

48. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '497 patent.

49. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '497 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

50. The foregoing actions by Barr constitute and/or will constitute infringement of the '497 patent and active inducement of infringement of the '497 patent.

51. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '497 patent and actively inducing infringement of the '497 patent.

52. Unless Barr is enjoined from infringing the '497 patent and actively inducing infringement of the '497 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 6,849,253**

53. Alcon incorporates each of the preceding paragraphs 1–52 as if fully set forth herein.

54. United States Patent No. 6,849,253 (“the '253 patent”), entitled “Use of Borate-Polyol Complexes in Ophthalmic Compositions” (Exhibit D hereto), was duly and legally issued on Feb. 1, 2005, to Alcon Manufacturing, Ltd., as assignee of Masood Chowhan and Nissanke L. Dassanayake, and is incorporated herein by reference.

55. Alcon Manufacturing, Ltd.'s interest in the '253 patent has been subsequently assigned to Alcon Research, Ltd.

56. Alcon will be substantially and irreparably damaged by infringement of the '253 patent.

57. Barr has knowledge of the '253 patent.

58. Barr's submission of ANDA No. 91-411 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA Product prior to the expiration of the '253 patent was an act of infringement of the '253 patent under 35 U.S.C. § 271(e)(2)(A).

59. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product would infringe one or more claims of the '253 patent.

60. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

61. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '253 patent.

62. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '253 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

63. The foregoing actions by Barr constitute and/or will constitute infringement of the '253 patent and active inducement of infringement of the '253 patent.

64. Upon information and belief, Barr acted without a reasonable basis for believing that it would not be liable for infringing the '253 patent and actively inducing infringement of the '253 patent.

65. Unless Barr is enjoined from infringing the '253 patent and actively inducing infringement of the '253 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT V – INFRINGEMENT OF U.S. PATENT NO. 5,631,287**

66. Alcon incorporates each of the preceding paragraphs 1–65 as if fully set forth herein.

67. United States Patent No. 5,631,287 (“the '287 patent”), entitled “Storage-Stable Prostaglandin Compositions” (Exhibit E hereto), was duly and legally issued on May 20, 1997, to Alcon Laboratories, Inc., as assignee of L. Wayne Schneider, and is incorporated herein by reference.

68. Alcon Laboratories, Inc.’s interest in the '287 patent has been subsequently assigned to Alcon Research, Ltd.

69. Alcon will be substantially and irreparably damaged by infringement of the '287 patent.

70. Barr has knowledge of the '287 patent.

71. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product would infringe one or more claims of the '287 patent.

72. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr’s ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

73. Upon information and belief, the use of Barr’s ANDA Product in accordance with and as directed by Barr’s proposed labeling for that product would infringe one or more claims of the '287 patent.

74. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '287 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

75. The foregoing actions by Barr will constitute infringement of the '287 patent and active inducement of infringement of the '287 patent.

76. Upon information and belief, Barr lacks a reasonable basis for believing that it would not be liable for infringing the '287 patent and actively inducing infringement of the '287 patent.

77. Unless Barr is enjoined from infringing the '287 patent and actively inducing infringement of the '287 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

**COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 6,011,062**

78. Alcon incorporates each of the preceding paragraphs 1–77 as if fully set forth herein.

79. United States Patent No. 6,011,062 (“the '062 patent”), entitled “Storage-Stable Prostaglandin Compositions” (Exhibit F hereto), was duly and legally issued on Jan. 4, 2000, to Alcon Laboratories, Inc., as assignee of L. Wayne Schneider, Rajan Bawa, and Alan L. Weiner, and is incorporated herein by reference.

80. Alcon Laboratories, Inc.’s interest in the '062 patent has been subsequently assigned to Alcon Research, Ltd.

81. Alcon will be substantially and irreparably damaged by infringement of the '062 patent.

82. Barr has knowledge of the '062 patent.

83. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product would infringe one or more claims of the '062 patent.

84. Upon information and belief, Barr will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Barr's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 91-411.

85. Upon information and belief, the use of Barr's ANDA Product in accordance with and as directed by Barr's proposed labeling for that product would infringe one or more claims of the '062 patent.

86. Upon information and belief, Barr plans and intends to, and will, actively induce infringement of the '062 patent when ANDA No. 91-411 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

87. The foregoing actions by Barr will constitute infringement of the '062 patent and active inducement of infringement of the '062 patent.

88. Upon information and belief, Barr lacks a reasonable basis for believing that it would not be liable for infringing the '062 patent and actively inducing infringement of the '062 patent.

89. Unless Barr is enjoined from infringing the '062 patent and actively inducing infringement of the '062 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

WHEREFORE, Alcon requests the following relief:

(a) A judgment that Barr has infringed the '383, '052, '497, '253, '287, and '062 patents;

(b) A judgment ordering that the effective date of any FDA approval for Barr to make, use, offer for sale, sell, market, distribute, or import Barr's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '383, '052, '497, or '253 patent, be not earlier than the latest of the expiration dates of the '383, '052, '497, and '253 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Barr, and all persons acting in concert with Barr, from making, using, selling, offering for sale, marketing, distributing, or importing Barr's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '383, '052, '497, '253, '287, or '062 patent, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the '383, '052, '497, '253, '287, and '062 patents, inclusive of any extension(s) and additional period(s) of exclusivity;

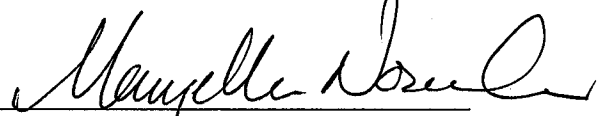
(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Barr's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '383, '052, '497, '253, '287, or '062 patent, prior to the latest of the expiration dates of the '383, '052, '497, '253, '287, and '062 patents, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '383, '052, '497, '253, '287, or '062 patent;

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

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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July 13, 2009  
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