IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
APOTEX INC. and APOTEX CORP.,	)	
	)	
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, that arises out of Apotex Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of PAZEO® ophthalmic solution, a drug product containing olopatadine hydrochloride, prior to the expiration of U.S. Patent No. 8,791,154 (the "'154 patent").

2. By letter dated August 26, 2016 (the "Notice Letter"), Apotex Corp. notified Alcon that Apotex Inc. had submitted to the FDA an ANDA, No. 209015, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of a generic 0.7 % w/v olopatadine ophthalmic solution ("Apotex's ANDA Product") prior to the expiration of the '154 patent. Upon information and belief, Apotex's ANDA Product is a drug product that is a generic version of PAZEO® ophthalmic solution, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

3. Plaintiff Alcon Research, Ltd. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134.

4. Upon information and belief, defendant Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States.

5. Upon information and belief, defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic versions of branded pharmaceutical products throughout the United States in concert with its subsidiary, Apotex Corp.

6. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

7. Apotex's Notice Letter states that Apotex Corp. is the agent in the United States authorized to accept service of process for Apotex Inc.

8. Upon information and belief, and consistent with their practice with respect to other generic products, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit ANDA No. 209015.

9. Upon information and belief, Apotex Inc. and Apotex Corp. contemplate that upon approval of ANDA No. 209015, Apotex Inc. will manufacture Apotex's ANDA

Product and Apotex Corp. will directly or indirectly market, sell, and distribute Apotex's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Apotex's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Apotex Corp. participated in, assisted, and cooperated with Apotex Inc. in the acts complained of herein. Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex."

10. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 209015, Apotex Inc. and Apotex Corp. will act in concert to distribute and sell Apotex's ANDA Product throughout the United States, including within Delaware.

11. Upon information and belief, following any FDA approval of ANDA No. 209015, Apotex Inc. and Apotex Corp. know and intend that Apotex's ANDA Product will be distributed and sold throughout the United States, including in Delaware.

JURISDICTION AND VENUE

12. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391 and 1400(b), and 2201 and 2202.

13. This Court has personal jurisdiction over Apotex Inc. and Apotex Corp.

14. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., 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, Apotex Inc., itself and through its subsidiary Apotex Corp., 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. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

15. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, it has purposely 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, Apotex Corp. 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. In addition, upon information and belief, Apotex Corp. is qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware.

16. Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. Defendants, for example, issued a press release in May 2011 stating that "Apotex Corp. is the US Company that markets the products of Apotex, Inc." Apotex Resumes Shipping to the U.S., *available at* http://www.apotex.com/global/about/press/20110510.asp (last visited Sept. 13, 2016).

17. Apotex has previously 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 branded pharmaceutical companies' patents by filing a certification 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), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

18. Upon information and belief, Apotex, with knowledge of the Hatch-Waxman Act process, directed the Notice Letter to, *inter alia*, Alcon Research, Ltd., an entity incorporated in Delaware, and alleged in the Notice Letter that Alcon's patents are invalid. Upon information and belief, Apotex knowingly and deliberately challenged Apotex'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. Moreover, upon information and belief, Apotex knew that two other Hatch-Waxman Act infringement actions relating to the same patent have been brought in Delaware and consolidated.

19. Because Alcon Research, Ltd. is a corporation incorporated in Delaware, Alcon suffers injury and consequences from Apotex's filing of ANDA No. 209015, challenging Alcon's patent rights, in Delaware. Upon information and belief, Apotex knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Apotex 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.

20. In addition, this Court has personal jurisdiction over Apotex because Apotex Inc. and Apotex Corp. regularly engage in patent litigation concerning FDA-approved branded drug products in this District, do not contest personal jurisdiction in this district, and have availed themselves of the jurisdiction of this Court by filing claims or counterclaims

affirmatively seeking relief in other prior actions in this district. *See, e.g.*, *Warner Chilcott Company, LLC and Hoffman-La Roche, Inc. v. Apotex Inc. and Apotex Corp.*, C.A. No. 10-1111-LPS, D.I. 11 (D. Del. Jan. 31, 2011); *Pfizer Inc. et al. v. Apotex, Inc. and. Apotex Corp.*, C.A. No. 11-606-GMS, D.I. 10 (D. Del. Oct. 3, 2011); *Senju Pharmaceutical Co., Ltd. et al. v. Apotex Inc. and Apotex Corp.*, C.A. No. 12-159-SLR, D.I. 9 (D. Del. Mar. 16, 2012); *Alcon Pharmaceuticals and Alcon Research Ltd. v. Apotex Inc. and Apotex Corp.*, C.A. No. 12-960-SLR, D.I. 6 (D. Del. July 23, 2012); *Pfizer Inc., et al. v. Apotex Inc. and Apotex Corp.*, C.A. No. 12-809-SLR, D.I. 18 (D. Del. Aug. 27, 2012); *UCB Inc., et al. v. Apotex Corp., et al.*, C.A. No. 13-1209-LPS, D.I. 12 (D. Del. Sept. 9, 2013); *Pfizer Inc., et al. v. Apotex Inc. and Apotex Corp.*, C.A. No. 13-1613-SLR, D.I. 8 (D. Del. Sept. 27, 2013); *Meda Pharms., Inc., et al. v. Apotex Inc. and Apotex Corp.*, C.A. No. 14-1453-LPS, D.I. 93 (D. Del. Mar. 9, 2016); *Salix Pharms., Inc. v. Apotex Inc. and Apotex Corp.*, C.A. No. 15-880-GMS, D.I. 15 (D. Del. Mar. 14, 2016).

21. Upon information and belief, if ANDA No. 209015 is approved, Apotex will manufacture, market, and/or sell Apotex's ANDA Product within the United States, including in Delaware, consistently with Apotex's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Apotex 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, Apotex's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware.

22. Upon information and belief, if ANDA No. 209015 is approved, Apotex will directly or indirectly market and distribute Apotex's ANDA Product in Delaware. Upon information and belief, Apotex'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 Apotex's ANDA Product is approved before the patent expires.

23. Upon information and belief, Apotex derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Apotex and/or for which Apotex Inc. or Apotex Corp. is the named applicant on approved ANDAs. Upon information and belief, various products for which Apotex Inc. or Apotex Corp. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

COUNT I
(Infringement of the '154 Patent)

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

25. The '154 patent, entitled "High Concentration Olopatadine Ophthamalic Composition" (Exhibit A hereto), was duly and legally issued on July 29, 2014, to Alcon Research, Ltd., as assignee of Daniel A. Gamache, Laman Alani, Malay Ghosh, Francisco Javier Galan, Nuria Carreras Perdiguer, and Onkar N. Singh.

26. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

27. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount

sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least 0.5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

28. Alcon owns the '154 patent.

29. Alcon will be substantially and irreparably damaged by infringement of the '154 patent.

30. PAZEO® ophthalmic solution, and the use of PAZEO® ophthalmic solution, are covered by one or more claims of the '154 patent, and the '154 patent has been listed in connection with that drug product in the FDA's Orange Book.

31. In its Notice Letter, Apotex notified Plaintiff that Apotex Inc. had submitted to the FDA ANDA No. 209015. The purpose of the submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product prior to the expiration of the '154 patent.

32. In the Notice Letter, Apotex also notified Plaintiff that, as part of its ANDA, Apotex 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, *inter alia*, the '154 patent. Upon information and belief, Apotex submitted ANDA No. 209015 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '154 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product.

33. Apotex's ANDA Product and the use of Apotex's ANDA Product are covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

34. Apotex has knowledge of the '154 patent.

35. Apotex's submission of ANDA No. 209015 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product before the expiration of the '154 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 209015.

37. The manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

38. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product in accordance with, and as directed by Apotex's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

39. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

40. Upon information and belief, Apotex knows that Apotex's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '154 patent, that Apotex's ANDA Product is not a staple article or commodity of commerce, and that

Apotex's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 209015.

41. Notwithstanding Apotex's knowledge of the claims of the '154 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's ANDA Product with its product labeling following upon FDA approval of ANDA No. 209015 prior to the expiration of the '154 patent.

42. The foregoing actions by Apotex constitute and/or will constitute infringement of the '154 patent, active inducement of the '154 patent, and contribution to the infringement by others of the '154 patent.

43. Upon information and belief, Apotex has acted with full knowledge of the '154 patent and without a reasonable basis for believing that it would not be liable for infringement of the '154 patent, active inducement of the '154 patent, and/or contribution to the infringement by others of the '154 patent.

44. Unless Apotex is enjoined from infringing the '154 patent, actively inducing infringement of the '154 patent, and contributing to the infringement by others of the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

COUNT II
(Declaratory Judgment of Infringement of the '154 Patent)

45. Alcon incorporates each of the preceding paragraphs 1-44 as if fully set forth herein.

46. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Alcon on

the one hand and Apotex on the other regarding Apotex's infringement, active inducement of infringement, and contribution to the infringement by others of the '154 patent.

47. The '154 patent claims, *inter alia*, an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% olopatadine dissolved in the solution, PEG having a molecular weight of 300 to 500, polyvinylpyrrolidone, hydroxypropyl-γ-cyclodextrin, benzalkonium chloride, and water.

48. The '154 patent also claims, *inter alia*, a method of treating at least one ocular allergy symptom in humans by topically applying to the eye of a human an amount sufficient to treat at least one ocular allergy symptom of an aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising at least 0.67 w/v% but no greater than 1.0 w/v% olopatadine dissolved in the solution; 2.0 w/v% to 6.0 w/v% PEG having a molecular weight of 300 to 500; 2.0 w/v% to 6.0 w/v% polyvinylpyrrolidone; at least 0.5 w/v% but no greater than 2.0 w/v% cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin; HP-β-cyclodextrin and combinations thereof; and water.

49. In the Notice Letter, Apotex notified Plaintiff that Apotex Inc. had submitted ANDA No. 209015 to the FDA. The purpose of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's ANDA Product prior to the expiration of the '154 patent.

50. In the Notice Letter, Apotex also notified Plaintiff that, as part of its ANDA, Apotex 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).

51. Upon information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product immediately and imminently upon approval of ANDA No. 209015.

52. Apotex's ANDA Product and use of Apotex's ANDA Product is covered by one or more claims of the '154 patent, including at least claim 1 and claim 12.

53. The manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

54. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product in accordance with, and as directed by, Apotex's proposed product labeling would infringe one or more claims of the '154 patent, including at least Claim 1 and Claim 12.

55. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '154 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

56. Upon information and belief, Apotex knows that Apotex's ANDA Product and its product labeling are especially made or adapted for use in infringing the '154 patent, that Apotex's ANDA Product is not a staple article or commodity of commerce, and that Apotex's ANDA Product and its product labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '154 patent immediately and imminently upon approval of ANDA No. 209015.

57. Notwithstanding Apotex's knowledge of the claims of the '154 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or

import Apotex's ANDA Product with its product labeling following FDA approval of ANDA No. 209015 prior to the expiration of the '154 patent.

58. The foregoing actions by Apotex will constitute infringement of, active inducement of infringement of, and contribute to the infringement by others of the '154 patent.

59. Upon information and belief, Apotex has acted with full knowledge of the '154 patent and without a reasonable basis for believing that it would not be liable for infringement of the '154 patent, active inducement of infringement of the '154 patent, and contribution to the infringement by others of the '154 patent.

60. Unless Apotex is enjoined from infringing, inducing infringement of, and contributing to the infringement by others of, the '154 patent, Alcon will suffer irreparable injury. Alcon has no adequate remedy at law.

61. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent.

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that United States Patent No. 8,791,154 has been infringed under 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of its ANDA No. 209015;

(b) A judgment providing that the effective date of any FDA approval of commercial manufacture, use, or sale of Apotex's ANDA Product, or any other drug product that infringes or the use of which infringes United States Patent No. 8,791,154 be not earlier than the latest of the expiration dates of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex's ANDA Product, or any other drug product covered by or whose use is covered by United States Patent No. 8,791,154, prior to the expiration of United States Patent No. 8,791,154, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Product, or any other drug product which is covered by or whose use is covered by United States Patent No. 8,791,154, prior to the expiration of United States Patent No. 8,791,154, will infringe, induce the infringement of, and contribute to the infringement by others of, that patent;

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

(f) Costs and expenses in this action;

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

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