IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

APOTEX INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 16-cv-03145-WTL-MTD
	)	
ALCON RESEARCH, LTD.,	)	
ALCON LABORATORIES, INC., and	)	
ALCON PHARMACEUTICALS LTD.	)	
	)	
Defendants.	)	
	)	
(Proposed) Intervenor-Defendant.	)	
_____	)	

AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Comes now Plaintiff Apotex Inc. ("Apotex"), by counsel, hereby brings its Amended Complaint for Declaratory Judgment against Defendants Alcon Research, Ltd., Alcon Laboratories, Inc., and Alcon Pharmaceuticals Ltd. (collectively, "Alcon"), and alleges as follows:

INTRODUCTION

1. This declaratory judgment action seeking a declaration of non-infringement of United States Patent Nos. 6,995,186 (the "'186 Patent") and 7,402,609 (the "'609 Patent") (the '186 Patent and the '609 Patent are collectively referred to herein as the "Patents-In-Suit") to enable Apotex to bring its generic 0.2% olopatadine hydrochloride ophthalmic solution product ("Apotex's ANDA Product") to market at the earliest possible date under the applicable contractual, statutory and U.S. Food & Drug Administration ("FDA") regulatory provisions and to allow the public to enjoy the benefits of generic competitions for these products.

2. The ‘186 Patent will expire on May 12, 2024, inclusive of six months of pediatric exclusivity.

3. The ‘609 Patent will expire on December 19, 2022, inclusive of six months of pediatric exclusivity.

PARTIES

4. Plaintiff Apotex Inc. is a Canadian corporation having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. On information and belief, Defendant 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.

6. On information and belief, Defendant Alcon Laboratories, Inc. 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.

7. On information and belief, Defendant Alcon Pharmaceuticals, Ltd. Is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Route des Arsenaux 41, 1701 Fribourg, Switzerland.

JURISDICTION AND VENUE

8. This Amended Complaint arises under a contract (the “Settlement Agreement”) entered into between Apotex and the Defendants on July 17, 2013 regarding the Patents-in-Issue, and is based upon an actual controversy between the parties to declare that: Apotex is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import Apotex’s ANDA Product as described in Abbreviated New Drug Application No. 90-918, including any amendments or supplements thereto (“Apotex’s ANDA”) in the United States of America and its

territories and possessions, including the Commonwealth of Puerto Rico and District of Colombia (the "Territory") beginning on December 29, 2016, because Apotex's ANDA Product is a licensed product of Alcon as of December 29, 2016 and therefore does not infringe the Patents-In-Suit on or after that date.

9. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. § 1331, 1332, and 1338.

10. This Court has personal jurisdiction over the Defendants because they have consented to personal jurisdiction and venue in the courts of the State of Indiana.

BACKGROUND

11. In February of 2009, Alcon and Kyowa Hakko Kirin Co., Ltd. ("Kyowa") filed a Complaint in the United States District Court for the Southern District of Indiana, Case No. 1:09-cv-0102-RLY-TAB (the "Lawsuit"), against Apotex Inc. and Apotex Corp. (collectively, the "Apotex Defendants" and collectively with Alcon and Kyowa, the "Parties") alleging that the Apotex Defendants had engaged in patent infringement following the Apotex Defendants' filing of an Abbreviated New Drug Application ("ANDA") with FDA seeking approval to manufacture and sell a generic version of Pataday® ophthalmic solution, a drug containing olopatadine hydrochloride, prior to the expiration of certain patents owned by Alcon and Kyowa.

12. During the course of litigation, the Parties engaged in lengthy negotiations over the claims. The Parties ultimately reached a settlement agreement, and Apotex and Alcon executed the Settlement Agreement which forms the basis of this declaratory judgment action on July 17, 2013.

13. The Parties jointly filed a Stipulation of Dismissal of the Lawsuit without prejudice on July 19, 2013. By reason of clerical error, the District Court entered an order

dismissing the Lawsuit with prejudice on July 31, 2013. On November 1, 2016, the District Court corrected this error and entered an order dismissing the Lawsuit without prejudice. [Exhibit A, Order of Dismissal without Prejudice]

14. Upon information and belief, Barr Laboratories, Inc. ("Barr") has obtained final approval from FDA for its generic 0.2% olopatadine hydrochloride ophthalmic solution product (its "Generica Equivalent") and is eligible for a 180-day exclusivity period by FDA, under the Federal Food, Drug, and Cosmetic ("FD&C") Act 21 U.S.C. § 355(j)(5)(B)(iv). Exhibit B, FDA final approval letter to Barr Laboratories, Inc. dated July 15, 2015, as to ANDA No. 090848 for olopatadine hydrochloride ophthalmic solution, 0.2% ("Barr's Approval Letter"). Despite final FDA approval that permits Barr to launch its Generic Equivalent, Barr has yet to do so. Barr's 180-day exclusivity period bars final approval of all later-filed ANDAs that contain a Paragraph IV certification to each of the Patents-In-Suit, including Apotex's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

15. Barr's Approval Letter states that "Barr is eligible for 180 days of generic drug exclusivity for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Exhibit B at 2. On information and belief, Barr remains to this day eligible for the 180-day exclusivity period and has not triggered that period with the commercial marketing of its Generic Equivalent.

16. Apotex's ANDA has received tentative approval from FDA. A product that has tentative approval cannot be marketed or sold in the United States. *See* 21 C.F.R. § 314.105. Apotex's ANDA is not yet eligible to receive final FDA approval due to Barr's 180-day exclusivity period.

17. The Settlement Agreement between Alcon and Apotex provides that if a Generic Equivalent is not launched in the United States by July 1, 2016, Apotex may file a declaratory judgment action seeking a declaration that, effective on December 29, 2016, Apotex's ANDA Product does not infringe the Patents-In-Suit because it is, as of that date, a licensed product under the settlement.

18. Apotex desires to bring its Apotex ANDA Product to market and allow the public to enjoy the benefits of generic competition for these products at the earliest possible date under the applicable contractual, statutory, and FDA regulatory provisions.

19. Upon information and belief, the earliest possible date that Apotex can obtain final FDA marketing approval for Apotex's ANDA Product is upon the forfeiture of Barr's 180-day exclusivity period for its Generic Equivalent. Forfeiture of the 180-day period is possible where a court enters a final decision, from which no appeal (other than a petition to the Supreme Court for a writ of certiori) has been or can be taken, that the Patents-In-Suit are not infringed by Apotex's ANDA Product [21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA)], or where the court signs a consent judgment that enters a final judgment that includes a finding that the Patents-In-Suit are not infringed [21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB)].

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE PATENTS-IN-SUIT

20. Apotex repeats and realleges each of the allegations in paragraphs 1-20 as if fully set forth herein.

21. Apotex seeks a declaration that:

a. effective on December 29, 2016, Apotex's ANDA Product does not infringe the Patents-In-Suit because Apotex's ANDA Product is, as of that date, a licensed product under the terms of the Settlement Agreement; and

b. Alcon has waived its right to appeal regarding this matter, under the terms of the Settlement Agreement.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests the Court to enter judgment as follows:

A. Declaring that effective December 29, 2016, the claims of the Patents-In-Suit are not infringed by Apotex's ANDA Product because that produce is licensed;

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Apotex's ANDA 90-918 would not, if marketed on or after December 29, 2016, infringe or induce or contribute to the infringement by others of any claims of the Patents-In-Suit;

C. Declaring that Alcon has waived its right to appeal regarding this matter, thus the Court's order is a final decision from which no appeal can be taken by Alcon; and

D. Awarding Apotex such other relief that the Court deems just and proper under the circumstances.

Respectfully submitted,

/s/Jonathan G. Polak

Jonathan G. Polak (21954-49)
jpolak@taftlaw.com
Cristina Costa (31271-29)
ccosta@taftlaw.com
TAFT STETTINIUS & HOLLISTER LLP
One Indiana Square
Suite 3500
Indianapolis, IN 46204
(317) 713-3500
(317) 713-3699
Counsel for Plaintiff Apotex Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2016, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/Jonathan G. Polak