IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS INC. and CIPLA LTD., Plaintiffs, v. APOTEX INC and APOTEX CORP., Defendants.	C.A. No. 14-1453-LPS REDACTED PUBLIC VERSION

PROPOSED JOINT PRETRIAL ORDER

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Redacted: November 10, 2016

On November 22, 2016, counsel for Plaintiffs[1] and Apotex[2] will participate in a pretrial conference before this Court pursuant to Rule 16 of the Federal Rules of Civil Procedure, Local Rule 16.3, and this Court's June 04, 2015 Oral Order (D.I. 28). Pursuant to Local Rule 16.3, Plaintiffs and Apotex hereby submit this proposed Joint Pretrial Order governing the bench trial of Civil Action No. 14-1453-LPS for the Court's approval. Trial is scheduled to begin on December 12, 2016.

Plaintiffs are represented by: Mark Fox Evens (mevens@skgf.com), Uma N. Everett (ueverett@skgf.com), Dennies Varughese (dvarughe@skgf.com), Rami Bardenstein (rbardenstein@skgf.com), Adam C. LaRock (alarock@skgf.com), Joshua I. Miller (jmiller@skgf.com), Josephine J. Kim (joskim@skgf.com), Stephanie Nguyen (snguyen@skgf.com) of Sterne, Kessler, Goldstein & Fox PLLC, 1100 New York Ave., N.W., Washington, DC 20005-3934, and Frederick L. Cottrell, III (Cottrell@rlf.com) and Selena Molina (molina@rlf.com) of Richards, Layton, Finger, 920 North King Street, Wilmington, DE 19801.

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[1] "Plaintiffs" when used hereinafter with reference to C.A. No. 14-1453-LPS, shall mean the Plaintiffs in that action, namely Meda Pharmaceuticals Inc. and Cipla Ltd.

[2] "Apotex" when used hereinafter with reference to C.A. No. 14-1453-LPS shall mean Apotex Inc. and Apotex Corp.

This Order will control the subsequent course of this action, unless modified by the Court to prevent manifest injustice.

I. Nature of the Case – Civil Action No. 14-1453-LPS

A. Nature of the Action

1. Plaintiffs brought this action for patent infringement against Apotex pursuant to the Hatch-Waxman Act, codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e). Plaintiff Meda makes and sells the drug product Dymista®—approved by the Food and Drug Administration for the relief of symptoms of seasonal allergic rhinitis—in the United States.

B. Plaintiffs' Complaints

2. On December 2, 2014, Plaintiffs brought the instant action against Apotex (D.I. 1) for infringing two patents—U.S. Patent Nos. 8,163,723 ("the '723 patent") and 8,168,620 ("the '620 patent")—based on Apotex's filing of Abbreviated New Drug Application ("ANDA") No. 207712 and accompanying certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that it intended to manufacture, sell or offer for sale its generic version of Dymista® ("Generic Product") prior to the expiration of those patents. In their Complaint, Plaintiffs alleged that Apotex infringed, contributed to, aided and abetted, and/or induced infringement of the '723 patent and the '620 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA and accompanying Paragraph IV certification. Plaintiffs further alleged that Apotex would infringe, contribute to or induce infringement under 35 U.S.C. § 271(a)-(c) if Apotex were to sell, offer for sale, manufacture, or import the products described in ANDA No. 207712.

3. On February 26, 2016, Plaintiffs filed a First Amended Complaint ("Amended Complaint") against Apotex (D.I. 90) that asserted a claim for infringement of newly issued U.S.

Patent No. 9,259,428 ("the '428 patent") based on Apotex's pending ANDA No. 207712. In their Amended Complaint, Plaintiffs repeated all allegations from their original Complaint and also alleged that Apotex infringed, contributed to, aided and abetted, and/or induced infringement of the '428 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA. Plaintiffs further alleged that Apotex would infringe, contribute to or induce infringement under 35 U.S.C. § 271(a)-(c) if Apotex were to sell, offer for sale, manufacture, or import the products described in ANDA No. 207712.

4. Plaintiffs are asserting claims 4, 29, and 42-44 of the '620 patent and claims 10, 11, 13, 15, 16, 23, 24, 26, and 29-30 of the '428 patent.

C. Apotex's Answers and Counterclaims

5. Apotex filed its Answer and Counterclaims to Plaintiffs' original Complaint on December 23, 2014 (D.I. 8) and to Plaintiffs' Amended Complaint on March 9, 2016 (D.I. 93). Apotex's Answer and Counterclaims to the original Complaint and to the Amended Complaint, taken together, assert defenses that each of the asserted patents—the '723 patent, '620 patent, and '428 patent—are invalid and not infringed, and that Plaintiffs' allegations failed to state a claim upon which relief can be granted. Apotex also alleged counterclaims for a declaration of noninfringement and invalidity of the '723 patent, the '620 patent, and the '428 patent.

D. Plaintiffs' Answers to Apotex's Counterclaims

6. On January 16, 2015, Plaintiffs filed their Answer to Apotex's Counterclaims to the Complaint (D.I. 12) and, on April 4, 2016, filed their Answer to Apotex's Answer and Counterclaims to the Amended Complaint (D.I. 93), denying that Apotex was entitled to any relief as asserted in its Counterclaims or otherwise.

E. Pending Motions

7. There are no pending motions in this action.

F. Stipulation to Infringement

8. The parties have stipulated that Apotex's Generic Product, described by ANDA No. 207712, literally infringes claims 4, 29, and 42-44 of the '620 patent; and claims 10, 11, 13, 15, 16, 23, 24, 26, and 29-30 of the '428 patent. (D.I. 104.)

G. Relief Sought by Plaintiffs

9. Plaintiffs request the following relief from the Court: a judgment that the asserted claims of the '620 and '428 patents are valid and enforceable; a judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Apotex's ANDA No. 207712 not be earlier than the latest of the expiration dates of the '620 and '428 patents, inclusive of any extension(s) and additional period(s) of exclusivity; a permanent injunction enjoining Apotex and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, Apotex's Generic Product for which approval is sought in ANDA No. 207712; a declaration under 28 U.S.C. § 2201 that if Apotex, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's Generic Product prior to patent expiry, it will constitute an act of direct and/or indirect infringement of the '620 and '428 patents; a finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285; an award of costs and expenses in this action; and any further and other relief as this Court determines to be just and proper.

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