

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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

**PLAINTIFFS MEDA AND CIPLA'S ANSWER TO COUNTERCLAIMS TO FIRST  
AMENDED COMPLAINT**

Plaintiffs and Counterclaim-Defendants Meda Pharmaceuticals Inc. ("Meda") and Cipla Ltd. ("Cipla") (collectively, "Counterclaim-Defendants"), by their attorneys, answer the Counterclaims of Defendants Apotex Inc. and Apotex Corp (collectively "Apotex"), as set forth in Apotex's Answer and Counterclaims to First Amended Complaint, using the same paragraph numbers as in Apotex's Counterclaims as follows:

1. Counterclaim-Plaintiff Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Counterclaim-Plaintiff Apotex Inc. is a corporation organized and existing under the laws of the Canada, having a place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

**Answer:** Upon information and belief, admitted.

2. On information and belief, Counterclaim-Defendant Meda is a corporation organized and existing under the laws of the Delaware, having a principal place of business at 265 Davidson Avenue, Suite 300, Somerset, New Jersey 08873-4120.

**Answer:** Admitted.

3. On information and belief, Counterclaim-Defendant Cipla is a corporation organized and existing under the laws of India and having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India.

**Answer:** Admitted.

4. This is a counterclaim for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties.

**Answer:** Paragraph 4 contains no allegations of fact to which a response is required. To the extent a response is required, Counterclaim-Defendants deny the allegations of paragraph 4.

5. The Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**Answer:** Paragraph 5 contains no allegations of fact to which a response is required. To the extent a response is required, Counterclaim-Defendants deny the allegations of paragraph 5.

6. Venue is proper in this district under 28 U.S.C. §§ 1391 (b) and (c), 1400(b), and because Counterclaim-Defendants have consented to venue in this Court by filing the instant action in this jurisdiction.

**Answer:** Paragraph 6 contains no allegations of fact to which a response is required. To the extent a response is required, Counterclaim-Defendants admit that they filed the instant action in this jurisdiction. They deny the remaining allegations of paragraph 6.

7. Counterclaim-Plaintiffs Apotex submitted Abbreviated New Drug Application (“ANDA”) No. 207712 to the Food and Drug Administration (“FDA”) seeking approval of generic nasal spray containing 137 mcg of the active ingredient azelastine hydrochloride and containing 50 mcg of the active ingredient fluticasone propionate combination nasal spray (“Apotex’s ANDA product”).

**Answer:** Upon information and belief, admitted.

8. Upon information and belief, FDA lists Meda as the holder of New Drug Application (“NDA”) No. 202236.

**Answer:** Admitted.

9. On information and belief, NDA No. 202236 covers DYMISTA®, Counterclaim-Defendants’ 137 mcg azelastine hydrochloride and 50 mcg fluticasone propionate nasal spray product.

**Answer:** Admitted.

10. On information and belief, the ’723 patent and ’620 patent are both listed in the FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (the “Orange Book”) for the product DYMISTA®. On information and belief, the ’428 patent will be listed in the Orange Book for the product DYMISTA® within thirty days of its issuance.

**Answer:** Admitted. Counterclaim-Defendants note that the ’428 patent has been listed in the Orange Book for the product DYMISTA®.

11. Counterclaim-Defendant Meda has alleged in the instant action that it is the exclusive licensee of the ’723 patent, ’620, and ’428 patents.

**Answer:** Admitted.

12. On information and belief, Counterclaim-Defendant Cipla is the present owner of the '723 patent, '620, and '428 patents.

**Answer:** Admitted.

13. Counterclaim-Plaintiff Apotex sent Counterclaim-Defendants a letter dated October 20, 2014 notifying Counterclaim-Defendants of its paragraph IV certification that the claims of the '723 patent, and the '620 patent are invalid and/or will not be infringed by the product that is the subject of ANDA No. 207712. The Notice Letter included an offer of confidential access (“the Notice Letter”).

**Answer:** The Notice Letter referenced in paragraph 13 speaks for itself and is the best evidence of its contents. To the extent a response is required, Counterclaim-Defendants admit that they received a letter dated October 20, 2014 notifying them of Apotex’s paragraph IV certification. Counterclaim-Defendants admit that Notice Letter included an offer of confidential access. Counterclaim-Defendants deny the remaining allegations of paragraph 13.

14. On December 2, 2014, Counterclaim-Defendants filed an action against Counterclaim-Plaintiff Apotex for infringement of the '723 patent, and the '620 patent. On February 26, 2016, Counterclaim-Defendants filed an amended complaint alleging infringement of the '428 patent.

**Answer:** Admitted.

15. As a consequence of the foregoing, there is an actual and justiciable controversy between Counterclaim-Plaintiff Apotex and Counterclaim-Defendants Meda and Cipla as to whether the claims of the '723, '620, and '428 patents are invalid and whether those claims are

being infringed or will be infringed by Apotex's ANDA No. 207712 or by the manufacture, use, or sale of the product described therein.

**Answer:** Paragraph 15 contains no allegations of fact to which a response is required. To the extent a response is required, Counterclaim-Defendants deny the allegations of paragraph 15.

### **COUNT I**

#### **(Declaration of Invalidity of the '723 Patent)**

16. Counterclaim-Plaintiff Apotex re-alleges and incorporates the allegations of paragraphs 1-15 as if fully set forth herein.

**Answer:** Paragraph 16 contains no allegations of fact to which a response is required. To the extent a response is required, Counterclaim-Defendants incorporate the answers to paragraph 1-15 fully.

17. Counterclaim-Defendants allege ownership of and exclusive license to the '723 patent and have brought claims against Counterclaim-Plaintiff Apotex alleging infringement of the '723 patent.

**Answer:** Cipla owns the '723 patent. Meda is the exclusive licensee to the '723 patent. Counterclaim-Defendants have brought claims against Apotex alleging infringement of the '723 patent. Counterclaim-Defendants deny the remaining allegations in paragraph 17.

18. One or more claims of the '723 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

**Answer:** Denied.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.