

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.	)	

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Meda Pharmaceuticals Inc. (“Meda”) and Cipla Ltd. (“Cipla”) (collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, against defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”). This action relates to Apotex’s submission of Abbreviated New Drug Application (“ANDA”) No. 207712 to the U.S. Food and Drug Administration (“FDA”). ANDA No. 207712 seeks approval to market a 137 mcg strength azelastine hydrochloride and 50 mcg strength fluticasone propionate combination nasal spray (“Generic Product”)—a generic version of Plaintiff Meda’s proprietary DYMISTA® drug product—before the expiration of Plaintiff Cipla’s U.S. Patent Nos. 8,163,723 (“the ’723 patent”), 8,168,620 (“the ’620 patent”), and 9,259,428 (“the ’428 patent”), all of which cover the DYMISTA® drug product, and for all of which Meda is the exclusive licensee in the United States.

## PARTIES

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

3. Cipla is a publicly held company organized and existing under the laws of India, and having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India.

4. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, and having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, and having its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. As part of its business, upon information and belief, Apotex Inc., directly or through agents (including Apotex Corp.), regularly files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, Apotex Inc., directly or through agents (including Apotex Corp.), regularly files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“Paragraph IV certification”) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of the U.S. patents that cover them.

Upon information and belief, Apotex Inc.'s ordinary business operations include litigating and filing claims in the courts of the United States, including the United States District Court for the District of Delaware, regarding the infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of ANDAs filed by Apotex.

7. Upon information and belief, Apotex Inc. manufactures drug products for the purpose of sale within the United States, including in Delaware, by Apotex Corp.

8. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent and distributor, and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in Delaware. Upon information and belief, Apotex Inc. derives substantial revenue from services or things used or consumed in the State of Delaware. Apotex Inc. has stated on its website that "Apotex Inc. serves a marketplace of over 115 countries, and is committed to the growth on a global basis through affiliates such as Apotex Corp. in the United States of America."

### **JURISDICTION AND VENUE**

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Apotex Corp. is a Delaware corporation with a registered agent in Delaware (The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801); it is registered with the Delaware Board of Pharmacy as a

“Distributor/Manufacturer CSR” and “Pharmacy – Wholesale” pursuant to 24 Del. C. § 2540; it is in the business of marketing drug products, which it distributes and sells throughout the United States, including in Delaware; it derives substantial revenue from services or things used and/or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; and, upon receiving FDA approval, it intends to offer to sell and sell the Generic Product described in ANDA No. 207712 in the United States, including in Delaware.

12. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other reasons, upon information and belief, Apotex Inc. has had persistent and continuous contacts with this judicial district. It is in the business of manufacturing drug products which it manufactures, distributes, sells and/or offers to sell, primarily through Apotex Corp., throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in the State of Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA cases without contesting jurisdiction in this District, including by availing itself of this forum by filing counterclaims; it has, directly or through an agent, filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Generic Product described in ANDA No. 207712 in the United States, including in Delaware; upon receiving FDA approval, it intends to offer to sell and sell, primarily through Apotex Corp., a Delaware corporation, the Generic Product described in ANDA No. 207712 throughout the United States, including in Delaware; and Apotex Corp., acting as Apotex Inc.’s agent and/or alter ego, regularly does and solicits business in Delaware and is engaged in a persistent, continuous and systematic course of

conduct in Delaware in which it distributes, sells, and offers to sell Apotex Inc.'s drug products in Delaware and derives substantial revenue from services or things used or consumed in the State of Delaware on behalf of Apotex Inc.

13. By letter dated October 20, 2014, Apotex sent notice of its ANDA submission and Paragraph IV certification to Meda and Cipla ("the Notice Letter"), affirmatively challenging the validity and infringement of the '723 and '620 patents. Meda and Cipla's receipt of the Notice Letter triggered the 45-day statutory deadline for Meda and Cipla to initiate an infringement lawsuit that would invoke the automatic 30-month stay of FDA approval of ANDA No. 207712 in accordance with the Hatch-Waxman framework. 35 U.S.C. § 355(j)(5)(B)(iii). Apotex's submission of ANDA No. 207712 with Paragraph IV certifications to the '723 and '620 patents and its act of sending the Notice Letter are tortious acts with real and injurious consequences giving rise to this infringement action. And because Meda is a Delaware corporation, these injuries and consequences are suffered in Delaware. Apotex, therefore, has purposefully directed its activities towards the State of Delaware, where Meda is incorporated. And because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Apotex reasonably anticipated being haled into court in Delaware.

14. Apotex's Notice Letter listed the law firm of Wilson Sonsini Goodrich & Rosati P.C. ("WSGR") as the agent in the United States authorized to accept service of process for Apotex Inc. relating to ANDA 207712, which is the subject of the present action. WSGR maintains an office in Delaware, at 222 Delaware Avenue, Suite 800, Wilmington, Delaware, 19801.

15. Upon information and belief, Apotex Corp. and Apotex Inc. have on multiple occasions consented to personal jurisdiction in patent infringement actions in this District,

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