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.	)	

APOTEX INC. AND APOTEX CORP.'S ANSWER AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") by and through their undersigned counsel, file this Answer and respond to each of the allegations of plaintiffs Meda Pharmaceuticals Inc. and Cipla Ltd. (collectively "Plaintiffs") as follows:

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.

ANSWER: Paragraph 1 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the Complaint purports to relate to an action for patent infringement under the patent laws of the United States, Title 35, United States Code, against Apotex. Apotex admits that Apotex submitted ANDA No. 207712 to the FDA and seeks approval to market a 137 mcg strength azelastine hydrochloride and 50 mcg strength fluticasone propionate combination nasal spray. Apotex lacks knowledge or information sufficient to form a belief as to the truth of whether the '723 patent, '620 patent, and '428 cover the DYMISTA® drug

product or whether Meda is the exclusive licensee in the United States for all of the patents. To the extent not expressly admitted, Apotex denies the allegations of paragraph 1.

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.

ANSWER: Apotex admits that publically available documents indicate that 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. To the extent not expressly admitted, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 and therefore denies them.

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.

ANSWER: Apotex admits that publically available documents indicate that 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. To the extent not expressly admitted, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 and therefore denies them.

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.

ANSWER: Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada and that it has an office located at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. To the extent not expressly admitted, Apotex denies the allegations of paragraph 4.

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.

ANSWER: Apotex admits that Apotex Corp. is a corporation organized and existing under the laws of Delaware and that it has an office located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. To the extent not expressly admitted, Apotex denies the allegations of paragraph 5.

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.

ANSWER: Apotex admits that Apotex Inc. is in the business of manufacturing, marketing and selling generic drug products. Apotex further admits that as part of its business, Apotex has filed ANDAs with the FDA seeking approval of proposed generic drug products. Apotex further admits that it has filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act. Apotex further admits it has been involved in litigation regarding claims related to its generic drug products in the courts of the United States, including the United States District Court for the District of Delaware. To the extent not expressly admitted, Apotex denies the allegations of paragraph 6.

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.

ANSWER: Apotex admits that Apotex Inc. manufactures drug products. Apotex admits that Apotex Corp. sells drug products within the United States. To the extent not expressly admitted, Apotex denies the allegations of paragraph 7.

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."

ANSWER: Apotex admits that Apotex Corp. sells drug products within the United States. The Apotex public website speaks for itself and is the best evidence of its contents. To the extent not expressly admitted, Apotex denies the allegations of paragraph 8.

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.

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent a response is required, Apotex admits that paragraph 9 cites the patent laws of the United States generally and that this Court has subject matter jurisdiction.

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

ANSWER: Paragraph 10 contains conclusions of law for which no response is required. To the extent a response is required, Apotex does not contest venue for purposes of this litigation only.

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.

ANSWER: Paragraph 11 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 11.

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.

ANSWER: Paragraph 12 contains conclusions of law for which no response is required. To the extent that a response is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. To the extent not expressly admitted, Apotex denies the remaining allegations of paragraph 12.

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