

**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

PLAINTIFFS' PROPOSED FINDINGS OF FACT

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I. THE PARTIES.

A. Meda.

1. Meda Pharmaceuticals Inc. (“Meda”)¹ is the exclusive licensee of the Patents-in-Suit and is a corporation organized and existing under the laws of Delaware. D.I. 135, Ex. 1 at ¶¶ 1, 20-21 (“Uncontested Facts”). On May 1, 2012, Meda received approval from the U.S. Food and Drug Administration (“FDA”) to market Dymista[®], a 137 mcg azelastine hydrochloride/50 mcg fluticasone propionate combination nasal spray, described in New Drug Application No. 202236. Uncontested Facts at ¶¶ 27-28.

B. Cipla.

2. Cipla Ltd. (“Cipla”) is a publicly held company organized and existing under the laws of India. Uncontested Facts at ¶ 2. Cipla is the owner of the Patents-in-Suit: U.S. Patent No. 8,168,620 B2 (“the ’620 patent”) and U.S. Patent No. 9,259,428 B2 (“the ’428 patent”) (collectively, “Patents-in-Suit”). Uncontested Facts at ¶ 18.

C. Apotex.

3. Apotex Inc. is a corporation organized and existing under the laws of Canada. Uncontested Facts at ¶ 3. Apotex Corp. is a corporation organized and existing under the laws of Delaware. Uncontested Facts at ¶ 4. Apotex Inc. and Apotex Corp. (collectively, “Apotex”) filed ANDA No. 207712 seeking to make and market a generic version of Dymista[®]. D.I. 93, at ¶ 1.

II. THE PATENTS-IN-SUIT.

4. On May 1, 2012, the U.S. Patent and Trademark Office (“Patent Office”) issued the ’620 patent, entitled “Combination of Azelastine and Steroids,” which expires on February 24, 2026. Uncontested Facts at ¶¶ 9, 12. The ’428 patent, entitled “Combination of Azelastine and

¹ Meda had two predecessor companies, Carter-Wallace and MedPointe, but Plaintiffs will refer to each of these companies as “Meda” for convenience.

Fluticasone for Nasal Administration,” issued on February 16, 2016 and expires on June 13, 2023. Uncontested Facts at ¶¶ 13, 16. The Patent Office issued a Certificate of Correction for the ’428 patent on May 3, 2016, which corrected typographical and other inadvertent errors made by the Patent Office. Uncontested Facts at ¶ 17. The Patents-in-Suit have an earliest filing date of June 14, 2002. Uncontested Facts at ¶ 19; Tr. 167:22-23 (Schleimer); Tr. 238:5-7 (Donovan).

5. Amar Lulla and Geena Malhotra are the named inventors of the Patents-in-Suit. Uncontested Facts at ¶¶ 10, 14, 18.

6. The Patents-in-Suit are directed to allergic rhinitis (“AR”), (Tr. 426:11-22 (Kaliner)), a common condition that afflicts millions of people in the United States that is defined as inflammation of the membranes lining the nose, characterized by nasal congestion, rhinorrhea (i.e., runny nose), sneezing, and itching of the nose. Tr. 148:18-149:7 (Schleimer); Tr. 427:22-428:1 (Kaliner); *see* PTX0022.00003-4; PTX0326.00017.

III. THE PATENTS-IN-SUIT ISSUED OVER APOTEX’S REFERENCES.

7. The ’620 patent was filed with the Patent Office as Application No. 10/518,016, which is a 35 U.S.C. § 371 national stage application of PCT/GB03/02557. PTX0001.00001. During prosecution of the ’620 patent, the patent examiner issued three Office Actions. PTX0005.09527-48; PTX0005.09850-69; PTX0005.10864-82.

8. The Patent Office considered the disclosures of Cramer (PTX0062) to be the closest prior art, (PTX0005.09866, 10050; PTX0007.09941, 09983), and therefore, every Office Action issued by the Patent Office during prosecution of the ’620 patent identified Cramer as the primary reference. PTX0005.09527-48; PTX0005.09850-69; PTX0005.10864-82. The Patent Office thrice considered the Cramer reference, and dozens of other references Apotex re-asserts

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