

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

**PLAINTIFFS MEDA AND CIPLA'S
OPENING CLAIM CONSTRUCTION BRIEF**

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INTRODUCTION

Plaintiffs Meda Pharmaceuticals Inc. and Cipla Ltd. (together, “Plaintiffs”) submit this Opening Claim Construction Brief to address disputed patent claim terms in this patent infringement action. There are two patents in suit: U.S. Patent Nos. 8,163,723 (“the ’723 patent”) and 8,168,620 (“the ’620 patent”). They are directed to a single-dosage formulation for the simultaneous administration of two active pharmaceutical ingredients: azelastine and fluticasone. The commercial embodiments of the patents—Meda’s Dymista® (which is marketed in the U.S. and in numerous other countries) and Cipla’s Duonase (which is marketed in India) are groundbreaking, highly-successful nasal spray products indicated for the treatment of allergic rhinitis.

The parties dispute the meaning of only two claim terms in this action: **condition(s)** and **administration**. As discussed below, Plaintiffs’ construction follows the plain and ordinary meaning of each term, as read in the context of the patents and their prosecution histories. Defendants, Apotex Inc. and Apotex Corp. (together, “Apotex”), on the other hand, propose constructions that ignore both the plain meaning of the terms and the clear context of the patents.

Plaintiffs maintain that “condition” means a disease-condition “resulting in or causing allergic reactions,” consistent with the subject matter of the patents. Apotex wants this Court to construe “condition” to mean *any* “disease or illness” (*e.g.*, cancer), disregarding the patents’ intrinsic record and teachings. Similarly, Plaintiffs maintain that “administration” is clear on its face and requires no specialized construction. “Administration” simply means “application” or “to apply” as it relates to pharmaceuticals. In contrast, Apotex retreats from this simplicity, and advances a special definition for “administration” that: (i) finds no support in the intrinsic record; and (ii) is in fact directly at odds with the patents’ prosecution histories. In each instance,

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