



## Meda and Cipla sue Apotex to enforce Dymista® patents

Meda Pharmaceuticals Inc. and Cipla Ltd. today announced that they sued Apotex Inc. and Apotex Corp. ("Apotex") in Federal District Court in Delaware to enforce the Orange-Book listed patents covering Dymista (azelastine HCl/fluticasone propionate) Nasal Spray in response to Apotex's submission to the US Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA"), and accompanying Paragraph IV certification, seeking approval to market a generic version of Meda's Dymista prior to expiration of the Dymista patents.

The Complaint was filed within 45 days of receiving Apotex's Paragraph IV certification notice, thus triggering an automatic stay preventing the FDA from approving Apotex's ANDA for 30 months from receipt of the notice, unless ordered otherwise by a district court. Meda has the exclusive licenses to U.S. Patent Nos. 8,163,723 and 8,168,620 covering the Dymista composition and its approved uses, which does not expire until 2026. Meda holds the New Drug Application ("NDA") to manufacture and market Dymista in the US for the treatment of seasonal allergic rhinitis.

*"Meda will vigorously enforce the Dymista patent rights against Apotex and any other company who challenges these patents",* said Dr. Jörg-Thomas Dierks, CEO of Meda.

Meda and Cipla are jointly represented by attorneys from Sterne, Kessler, Goldstein & Fox P.L.L.C. and Ashby & Geddes, PA.

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Meda AB discloses the information provided herein pursuant to the Securities Markets Act and/or the Financial Instruments Trading Act. The information was submitted for publication on December 3, 2014, at 8:00 CET.

**MEDA AB (publ)** is a leading international specialty pharma company. Meda's products are sold in more than 150 countries worldwide and the company is represented by its own organizations in over 60 countries. The Meda share is listed under Large Cap on Nasdaq Stockholm. Find out more, visit [www.meda.se](http://www.meda.se).

**About Cipla Limited**

Cipla is a global pharmaceutical company which uses cutting edge technology and innovation to meet the everyday needs of all patients. For more than 70 years, Cipla has emerged as one of the most respected pharmaceutical names in India as well as across more than 150 countries. Cipla's portfolio includes over 1500 products in various therapeutic categories with one quality standard globally. Cipla's turnover in 2013/14 was 1.7 billion USD.

Whilst delivering a long-term sustainable business, Cipla recognises its duty to provide affordable medicines. Cipla's emphasis on access for patients was recognized globally for the pioneering role played in HIV/AIDS treatment as the first pharmaceutical company to provide a triple combination anti-retroviral (ARV) in Africa at less than one dollar a day and thereby treating many millions of patients since 2001.

Cipla's research and development focuses on developing innovative products and drug delivery systems and has given India and the world many 'firsts' for instance Triomune. In a tightly regulated environment, the company's manufacturing facilities have approvals from all the main regulators including US FDA, UKMHRA, WHO, MCC, ANVISA, and PMDA which means the company provides one universal standard both domestically and internationally.