

**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.

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Civil Action No. 1:14-cv-01453-LPS

EXPERT REPORT OF ROBERT P. SCHLEIMER, PH.D.

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A. The closest prior art to a single product combining azelastine and fluticasone for nasal administration is the simultaneous or sequential intranasal administration of azelastine and fluticasone.44

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1. I, Robert P. Schleimer, have been retained by Defendants Apotex, Inc., and Apotex Corp. as an expert to analyze certain claims of U.S. Patent Nos. 8,163,723 (“the ’723 patent”); 8,168,620 (“the ’620 patent”); and 9,259,428 (“the ’428 patent”), in connection with this lawsuit.

2. I have developed certain opinions about those patents and their asserted claims, which I set forth in this report. I expect to testify about them at trial if asked to do so. To form my opinions, I relied on documents and other materials cited in this report, my education, and my years of experience, teaching, and performing research in this field.

3. I reserve the right to amend or supplement my opinions in light of evidence presented by or on behalf of the plaintiffs, or in connection with additional information that may later be made available to me. At trial, I may use demonstrative exhibits if useful for explaining and understanding the opinions in this report, and I may testify about background scientific concepts related to pharmacology to explain as necessary the context of the claims.

4. I am being compensated for my time on this matter at a rate of \$400/hour for consulting and \$600/hour for testimony. Those are my standard consulting rates. My compensation is in no way dependent on the outcome of this case.

5. I have not given testimony or written an expert report in connection with litigation in the last five years.

I. PROFESSIONAL BACKGROUND

6. I am the Roy and Elaine Patterson Professor of Medicine and the Chief, Division of Medicine-Allergy-Immunology, at the Feinberg School of Medicine, Northwestern University.

7. I received my B.A. from the University of California at San Diego and my Ph.D. from the University of California at Davis. My Ph.D. is in Pharmacology-Toxicology and I have

received training as an Immuno-pharmacologist. My postdoctoral fellowship was at the Johns Hopkins University School of Medicine where I studied mechanisms of allergic diseases using both *in vitro* and *in vivo* approaches. The *in vivo* challenge models of human disease included nasal challenge of human subjects with allergen to assess allergic rhinitis mechanisms, bronchial challenges of human subjects with allergen to assess asthma mechanisms, and studies of the skin and sinuses. Between 1982 and 2004 I was on the faculty at Johns Hopkins, and since 2004 I have been on the faculty at Northwestern. During my time at Johns Hopkins and subsequently at Northwestern, allergic rhinitis has been one of the major allergic diseases I have studied.

8. I have published widely on the use of steroids and antihistamines. A Pubmed search of my publications reveals 61 papers for the search term “steroid” and 64 papers for the search term “histamine.” These are listed in my *curriculum vitae*, attached hereto as Exhibit A (current as of December 2015). I am recognized as an international expert in the study of the mechanisms of anti-inflammatory steroid actions in allergic disease.

9. I have taught Pharmacology and/or Allergy-Immunology at Northwestern Feinberg School of Medicine, Johns Hopkins School of Medicine, California State University at Chico, and the University of California at Davis. I have trained dozens of scientific investigators holding either the Ph.D. or M.D. degree, and many of my former trainees are now recognized as international experts in the mechanisms of allergic disease.

10. I also have significant experience outside of the academic setting. For instance, I have served as a full time member on three standing National Institutes of Health grant review committees—Lung Biology and Pathology (LBPA), Lung Cell and Molecular Immunology (LCMI), and the Specialized Center of Clinically Oriented Research (SCCOR). I have also served as a member and served as the Chairman for two NIH study sections (Lung Cell and

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