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

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| MEDA PHARMACEUTICALS, INC. and CIPLA LTD. | ) | |
| Plaintiffs, | ) | Civil Action No. 14-1453 (LPS) |
| v. | ) | |
| APOTEX, INC. and APOTEX CORP. | ) | |
| Defendants. | ) | |

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

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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 submitted an opening expert report on June 30, 2016, opining that the asserted claims of the patents-in-suit are obvious. I reserve the right to reply to any expert report submitted by plaintiffs in response to my opening expert report.

3. I have been asked in addition to respond to the expert reports of Dr. Warner Carr and Dr. Michael Kaliner, submitted by plaintiffs on June 30, 2016, to the extent they opine that Dymista® met a long felt but unmet need, or had unexpected superior results.

4. 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.

5. 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.

6. My professional background and the bases for my opinions are set forth in my opening expert report.

## I. SUMMARY OF OPINIONS

7. *First*, it is my opinion that Dymista®, what Meda says is a commercial embodiment of the patents-in-suit, does not meet any long-felt but unmet need in the field of treatments for allergic rhinitis.

8. I understand from counsel that this "secondary consideration of non-obviousness" looks to whether demand existed for the patented invention, and that others tried but failed to satisfy that demand.

9. Here, Dymista® did not satisfy any long-felt and unmet need. As explained in my opening report, combination antihistamine/steroid therapies were known and practiced for the treatment of allergic rhinitis in the art before June 2002. Indeed, doctors prescribed both Astelin® (azelastine hydrochloride) and Flonase® (fluticasone propionate) to the same patient at the same time before that date. Opening Report ¶ 79; Accetta Tr., at 22:16-23:5; 55:16-56:13. Additionally, I have reviewed the expert report of Dr. James Wedner, MD, and note that he, too, prescribed both drugs and observed other doctors doing so. Report of H. James Wedner ¶¶ 12, 25, 26.

10. Thus, the only "need" Dymista could have satisfied was a desire by doctors or patients to combine the active ingredients of Astelin® and Flonase® into a single formulation for patient convenience. Yet, Drs. Carr and Kaliner have not shown that there was any particular long-felt or unmet need for such convenience.

11. I further understand from counsel that there was a so-called "blocking patent," which would have provided a strong disincentive for a person of ordinary skill in the art (a "POSA") to develop a combination azelastine hydrochloride and fluticasone propionate product. *See* Hettche, U.S. Patent No. 5,164,194 (covering "a sterile and stable aqueous solution of azelastine or one or more of its salts which can be used in the form of . . . a spray (preferably a nasal spray)") (expiring May 2011); *see also* Phillips, U.S. Patent No. 4,335,121 (covering intranasal corticosteroids) (expiring May 2004). In my opinion, the fact that others did not co-formulate azelastine and fluticasone before June 2002 relates to patent protection and not issues

of obviousness.

12. *Second*, it is my opinion that Dymista® does not exhibit any unexpected or surprising results in light of the closest prior art.

13. Here, the closest prior art is the sequential administration of an azelastine HCl drug (Astelin®) and a fluticasone propionate drug (Flonase®), which were prescribed together by doctors before June 2002. In my opinion, Dymista® produced the same results as azelastine HCl and fluticasone propionate, delivered together in two separate sprays. In fact, Drs. Kaliner and Carr have discussed no study comparing the results of Dymista® to this closest prior art. The only study comparing this prior art to azelastine monotherapy and fluticasone monotherapy suggests that the magnitude of improvement is at least the same as the magnitude of improvement with Dymista®. Moreover, as also explained, to the extent the monotherapies are the correct prior art comparison, the superiority of Dymista® is not unexpected at all, for the numerous reasons stated in my opening report.

14. Thus, and as also explained in my opening report, the only attributes Dymista® provides over the prior art are conveniences resulting from using a single nasal spray. But in my opinion a more convenient dosing form was obvious at the time, such increased convenience does not provide a meaningful advance in clinical care, this convenience did not meet any previously unfilled need of any patient population, and the results of the co-formulation were expected.

15. Lastly, as I also explain in my opening report, the handful of studies on combinations of oral antihistamines and a steroid on which Plaintiffs rely would not have deterred a POSA from combining an intranasal azelastine and intranasal fluticasone for a number of reasons—and the superior results from such a combination would be fully expected.

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