IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDA PHARMACEUTICALS, INC. and CIPLA LTD.	)	
Plaintiff,	)	Civil Action No. 1:14-cv-01453-LPS
v.	)	
APOTEX, INC. and APOTEX CORP.	)	
Defendant.	)	

EXPERT REPORT OF RAMPRAKASH GOVINDARAJAN, PH.D.

I. INTRODUCTION

1. My name is Ramprakash Govindarajan, Ph.D. As detailed in my current *curriculum vitae*, which is attached to this declaration as Appendix A, I became Director of Preformulation at the University of Iowa Pharmaceuticals in 2015. I am also a Clinical Assistant Professor at the College of Pharmacy, University of Iowa.

2. I obtained my Ph.D in Pharmaceutics from the University of Mumbai in 2002. After that, I was a Research Associate in Pharmaceutics at the University of Minnesota until 2006. From 2006 to 2015, I worked in various product development roles at GlaxoSmithKline.

3. Throughout my career, I have had experience conducting experiments similar to the one described in this report, including making pharmaceutical formulations.

4. I have never testified as an expert witness or prepared an expert report in connection with litigation. A list of all my publications from the last 18 years is included in my *curriculum vitae*.

5. I have rendered all services in this case as an independent consultant. Apotex has compensated me for these services at in the amount of $8,500. If additional testimony is required of me, I will be compensated at a rate of $250/hour. My compensation does not depend on the the opinions formed in this Report or the outcome of this litigation.

6. If called to testify, I am prepared to testify regarding the results of my experiment as reported in this report and the attached documents. I am also prepared to testify about the methods I used and the research I conducted in obtaining those results.

II. SUMMARY OF WORK

7. Apotex retained me to formulate the composition in "Example III" of EP 0780127 ("Cramer") (attached as Appendix B). To make the formulation, I was directed to follow any instructions or guidance included in the document. To the extent the Cramer reference did not

expressly provide information I needed to formulate, I was directed to proceed as an ordinarily skilled pharmaceutical formulator would have proceeded in June 2002 after reading Cramer. I was directed not to take any steps or use any equipment that was not known and readily available to an ordinarily skilled pharmaceutical formulator in 2002. Cramer was the only document given to me by Apotex's counsel.

8. I was not told what outcome(s) to try to obtain, or what outcome would be helpful to Apotex or their opponent in this litigation. I have not reviewed any patent asserted in this litigation.

9. If I was able to make a pharmaceutical formulation as described in Example III in Cramer, I was asked to make the following observations:

a. Observe whether Example III forms a suspension, solution, or something else.
    i. If Example 3 does form a suspension, observe whether that suspension settles.
        1. If it settles, observe whether it is difficult to re-suspend.
        2. If it settles, opine on whether the settling is unacceptable for a pharmaceutical product.
b. Measure the osmolality in mOsm/kg.
c. Put the resulting composition in a nasal pump with a suitable actuator. Observe if the composition comes out as a spray, a jet, or something else.

10. I was asked to record my work and the above observations/experimental results.

III. RESULTS AND OBSERVATIONS

11. The laboratory notebook entries reflecting the work I did are attached as Exhibit C.

12. I prepared three batches of the formulation in Example III during the formulation process. I conducted my final testing and made my final observations using Batch 1345-011. My laboratory notebook records the steps I took to make each batch, as well as the ingredient and equipment I used. I am prepared to discuss each of those steps if asked to do so, and I incorporate the contents of my lab notebook to this report as if set forth herein.

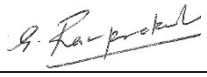
13. I concluded that Cramer Example III is a suspension that would be acceptable as a pharmaceutical product. There was some settling, but no settling or sedimentation in the product that would make it pharmaceutically unacceptable.

14. I further concluded that the product could be delivered as a fine spray using a nasal spray pump. I took two videos of the mist produced by Batch 1345-011 when actuated in a nasal pump with a suitable actuator. Those videos are attached as Appendix D and Appendix E.

15. I also took osmolality measurements as requested. I determined that Batch 1345-011 had an osmolality of 529 mOsm/kg.

IV. DECLARATION

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge.

Date: 29 - June - 2016 Signed: 

Dr. Ramprakash Govindarajan

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