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

MEDA PHARMACEUTICALS, INC. and CIPLA LTD.	)	Civil Action No. 14-1453 (LPS)
Plaintiffs,	)	CIVII TECCOII TO. 11 1 133 (EI 5)
v.	)	
APOTEX, INC. and APOTEX CORP.	)	
Defendants	)	

EXPERT REPORT OF MAUREEN D. DONOVAN, PH.D.



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- 1. I, Maureen Donovan, have been retained by Defendants Apotex, Inc., and Apotex Corp. as an expert to analyze certain aspects 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 formulated certain opinions about those patents and their asserted claims. My opinions are set forth in this report, and I expect to testify about them at trial if asked to do so.
- 3. The basis for my opinions includes the documents and other materials cited in this report, my education, and my years of experience, teaching, and researching in the relevant field.
- 4. I reserve the right to amend or supplement my opinions in light of evidence presented by or on behalf of Meda Pharmaceuticals and Cipla Ltd., or in connection with additional information that may be made available to me in the future.
- 5. In addition to the information, materials and opinions discussed in this report, I may use demonstrative exhibits at trial to the extent useful for explaining and understanding the opinions I set forth in this report.
- 6. I may testify at trial about background scientific concepts related to my opinions to the extent that is useful for understanding my opinions.
- 7. I am being compensated for my time on this matter at a rate of \$250/hour for general document and background review, \$400/hour for preparing reports, and \$600/hour for testifying at trial or depositions. Those are my standard consulting rates. My compensation is in no way dependent on the outcome of this case.
- 8. In the past five years, I have been deposed only once, in *Sanofi Aventis v. Sandoz et al.*, but I was not a testifying expert at trial.

#### I. PERSONAL BACKGROUND

9. I am a Professor in the Division of Pharmaceutics at the University of Iowa



College of Pharmacy. I have more than 25 years of experience working and consulting in the field of pharmaceutics. My *curriculum vitae* is attached to this report as Exhibit A.

- 10. I am an expert in pharmaceutics. I received my Bachelor of Science in Pharmacy from the University of Minnesota College of Pharmacy in 1983 and my Ph.D. in Pharmaceutics from the University of Michigan in 1989.
- 11. My professional experience includes working as a Staff Pharmacist for Clark Professional Pharmacy from 1986 until 1989 and as a Visiting Scholar for SmithKline Beecham Pharmaceuticals in 1991. From 1989 through the present, I have held various positions at the University of Iowa College of Pharmacy. Specifically, in the Division of Pharmaceutics, I was an Assistant Professor from 1989 until 1996, and an Associate Professor from 1996 until 2008. I was promoted to the position of a Professor in 2008 in the College of Pharmacy, and I currently hold this position. From 2008 until 2013, I was the Division Head for the Division of Pharmaceutics. In 2013, I became the Associate Dean for Undergraduate Programs at the College of Pharmacy, and I currently hold this position.
- 12. I have over 25 years of experience in pharmaceutical research and development including actively teaching drug delivery, pharmaceutical preformulation, and compounding to pharmacy students and graduate students, and directing research programs focused on drug absorption, nasal drug delivery, and alternative routes of drug delivery and delivery systems.
- 13. I have published numerous articles, book chapters, and abstracts in the area of pharmaceutics, drug absorption, drug delivery, and materials characterization. I also belong to several professional societies for pharmaceutical science and technology, including the American Association of Pharmaceutical Scientists and the Controlled Release Society.
  - 14. In addition to my knowledge, education, and experience in the field of



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