UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA INC.,

Petitioner

v.

MONOSOL RX, LLC,

Patent Owner

U.S. Patent No. 8,017,150

Case IPR2016: Unassigned

DECLARATION OF NANDITA DAS, Ph.D.

1. My name is Nandita Das. I have been retained by counsel for Petitioner Teva Pharmaceuticals USA, Inc. ("Teva"). I understand that Teva is petitioning for *inter partes* review of U.S. Patent No. 8,017,150 (the "'150 patent"), which is owned by MonoSol RX, LLC. I further understand that Teva will request that the United States Patent and Trademark Office ("USPTO") cancel certain claims of the '150 patent as unpatentable. I submit this expert declaration, which addresses and supports Teva's petition.

I. Qualifications and Background

A. Education and Experience; Prior Testimony

2. Currently, I am an Associate Professor of Pharmaceutics at Butler University with over 15 years of experience teaching pharmaceutical sciences. I have been on the faculty at Butler University since 2004 with a full-time campus-based tenure-track faculty position since 2005. I was granted tenure and promoted to Associate Professor in Spring 2012. Prior to my time at Butler University, I was an Assistant Professor of Pharmaceutics at Idaho State University, previous to which I taught as an Adjunct Professor at Nova Southeastern University while working full time as a licensed pharmacist in the state of Florida. A copy of my curriculum vitae and list of publications is attached as Ex. 1047.

3. I received a B.Pharm. in Pharmacy from Banaras Hindu University in India in 1988, achieving first rank among my classmates.

4. I received an M.Pharm. in Pharmaceutics from Banaras Hindu University in 1990. My research focused on controlled release dosage forms.

5. I received a Ph.D. in Pharmaceutical Sciences from the University of Pittsburgh in 1995. My research focused on the kinetics of solid-state microcalorimetry.

6. From 1993-1995, I completed my doctoral research work as a graduate scholar with SmithKline Beecham Pharmaceuticals, studying microcalorimetry under the mentorship of Dr. Theodore D. Sokoloski, Ph.D.

7. From 1995-1998, I worked as a commercial pharmacist, managing a community pharmacy.

8. My business address is College of Pharmacy & Health Sciences, Butler University, 4600 Sunset Avenue, Indianapolis, IN 46208-3485.

9. Among the numerous research grants I have received, from August 2002 through July 2006, I conducted a study on the use of mucadhesive buprenorphine in opioid addiction therapy for the National Institute of Health's National Institute on Drug Abuse.

10. In 2004, I published an article on the development of mucoadhesive dosage forms of buprenorphine for sublingual delivery in *Drug Delivery – The Journal of Delivery and Targeting of Therapeutic Agents*, Volume 11 (2004).

11. I have also researched, as part of my work during my time at Idaho State University, mucoadhesive properties of polymers used in sublingual drug delivery.

12. I also co-authored a paper regarding drugs used in the treatment of addiction for the *Indian Journal of Pharmacy Practice*, Volume 5, Issue 4 (2012).

13. I have authored or co-authored over 70 articles, abstracts, papers and book chapters and am a named inventor on one domestic patent. I have also appeared at 6 conferences on topic areas of present interest, including mucoadhesive sublingual delivery systems for buprenorphine.

14. I am a member of various professional societies, including the American Association of Pharmaceutical Scientists and the American Association of Colleges of Pharmacy. I am also a peer reviewer for five scientific and medical journals.

B. Bases for Opinion and Materials Considered

15. Exhibit 1048 includes a list of the materials I considered, in addition to my experience, education, and training, in providing the opinions contained herein.

C. Scope of Work

16. I have been retained by Teva as a technical expert in this matter to provide various opinions regarding the ’150 patent. I receive $400 per hour for my services and $500 per hour for deposition testimony. No part of my compensation is dependent upon my opinions given or the outcome of this case. I do not have any other current or past affiliation as an expert witness or consultant with Teva. I do not have any current or past affiliation with MonoSol RX, LLC, or any of the named inventors on the ’150 patent.

II. Summary of Opinions

17. I understand that Teva is challenging the validity of claims 1, 4-10, and 13-18 of the ’150 patent (“the Challenged Claims”).

18. In reaching these opinions, I have reviewed the ’150 patent as well as portions of the file history of the ’150 patent. I have also reviewed references and articles, which I describe in greater detail below, and the materials listed in Exhibit 1048 attached hereto. I have also relied upon my education, background, and experience in reaching the conclusions and in forming the opinions set forth herein.

19. To summarize, for the reasons set forth below, it is my opinion that the Challenged Claims of the’150 patent are obvious in view of the prior art, including art that discloses the use of hydrophilic cellulosic polymers and both

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