UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. and
DR. REDDY'S LABORATORIES, INC.
Petitioners,
v.

MONOSOL RX, LLC
Patent Owner.

Patent No. 8,603,514

DECLARATION OF BOZENA MICHNIAK-KOHN, PH.D.

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I, Bozena Michniak-Kohn, declare as follows:

I. QUALIFICATIONS

1. My name is Bozena Michniak-Kohn. I am a tenured Professor of Pharmaceutics in the Ernest Mario School of Pharmacy at Rutgers-The State University of New Jersey. I have been employed by Rutgers-The State University of New Jersey, initially as a tenured Associate Professor, and finally a full Professor, since 2005. In February 2011, I founded the Center for Dermal Research (CDR) at Rutgers-The State University of New Jersey and have served as the Director of the CDR since that time. In addition, I served all this time as the Director of the Laboratory for Drug Delivery at the NJ Center for Biomaterials, at Rutgers-The State University of New Jersey. I received my Ph.D in Pharmacology from De Montfort University in 1980.

2. In 2016 I was appointed to the Board of Directors of the International Pharmaceutical Excipients Council of the Americas Foundation. I have also been a member of the Editorial Board for the Journal of Drug Research and Development since 2014.

3. I currently serve as the Academic Chair of the Transdermal section of the Non-Invasive Macromolecule Consortium Working Group of the Catalent Applied Drug Delivery Institute (since 2014) and am a member of the faculty of the National Institute for Pharmaceutical Technology and Education (since 2014).

4. I am the recipient of several awards and honors including the award of Fellow status of the American Association of Pharmaceutical Scientists, in July 2008.

5. My research interests and experience focus on the optimization of topical, transdermal and transmucosal drug delivery, including sublingual drug delivery as well as the design and development of oral edible and transdermal drug containing polymer films.

6. I have authored numerous publications related to drug delivery and formulation including *Drying of biocompatible polymer films loaded with poorly water soluble drugs nano-*

particles via low temperature forced convection, Int. J. Pharm. (2013), 445, 93-103; *Preparation and characterization of hydroxypropyl methyl cellulose films containing stable BCS Class II drug nanoparticles for pharmaceutical applications*, J. Pharmaceutics (2012), 423, 4960508; *Synthesis and immobilization of microscale drug particles in polymeric films*, (2011), Colloids and Surfaces B.: Bionterfaces (2011), 86(1), 181-188; and *Preparation and characterization of hydroxypropyl methyl cellulose films containing stable BCS Class II drug nanoparticles for pharmaceutical applications*, J. Pharmaceutics (2012), 423, 4960508.

7. A summary of my education, experience, publications, patents, award and honors is provided in my CV, a copy of which is separately submitted as EX1003.

II. SCOPE OF WORK

8. I understand Mylan Technologies, Inc. ("Mylan") has filed a petition for *inter partes* review challenging claims of U.S. Patent No. 8,603,514 ("the '514 patent"). I have reviewed and considered Mylan's IPR petition and the accompanying Declaration of Graham Buckton, Ph.D.. Applying my independent judgment and expertise, and after having independently reviewed and analyzed all of the materials that Dr. Buckton considered, and after having done the additional work of fact checking and considering whether potential counterarguments may exist, I have come to the same conclusions as Dr. Buckton regarding the obviousness of the '514 patent. I agree with the analysis in his declaration as set forth below. For the sake of efficiency, given that I agree with Dr. Buckton's analysis, I have adopted much of the language and organization from his declaration rather than needlessly rewriting passages. The opinions in this declaration are mine.

9. I am being compensated at the rate of $650.00/hour for my time in this matter and I have no financial interest in the outcome.

III. OVERVIEW OF THE '514 PATENT

10. The '514 patent is entitled "Uniform Films For Rapid Dissolve [sic] Dosage Form Incorporating Taste-Masking Compositions." The first page of the patent states that an application for the '514 patent (U.S. Application No. 11/775,484, "the '484 application") was filed on July 10, 2007 and claims priority to several applications. The patent states that the '484 application is a continuation-in-part of U.S. Application No. 10/768,809 ("the '809 application). The '809 application is itself a continuation-in-part application of PCT/US02/32594, PCT/US02/32542, and PCT/US02/32575, which were all filed on October 11, 2002. The earliest claimed priority date of the '484 application is October 12, 2001, the filing date of U.S. Provisional Application No. 60/328,868 ("the '868 application").

11. I am informed that a federal judge has found that the '514 patent is only entitled to the benefit of U.S. Provisional Application No. 60/414,276 ("the '276 application") filed on September 27, 2002. For the purposes of my declaration and the prior art presented in the grounds herein, however, I have assumed that the applicable date is the earliest priority date claimed in the '514 patent, October 12, 2001. However, the outcome of my opinions does not depend on which of these dates is used.

12. The claims of the '514 patent are generally directed to drug delivery film compositions made of water-soluble or water-swellable polymers. Independent claim 62 of the '514 patent recites the following:

> 62. A drug delivery composition comprising:
>
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active;

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