Paper No.\_\_\_\_\_

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC. Petitioner

v.

RB PHARMACEUTICALS LIMITED Patent Owner

> US Patent No. 8,475,832 Issue Date: July 2, 2013

Title: SUBLINGUAL AND BUCCAL FILM COMPOSITIONS

Inter Partes Review No. Unassigned

## DECLARATION BY MAUREEN REITMAN, SC.D. UNDER 37 CFR § 1.132

Sir/Madam:

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>. I, Maureen Reitman, do hereby make the following declaration:

1. I am a Principal and the Director of the Polymer Science and Materials Chemistry Practice at Exponent. I hold two academic degrees: (1) a Bachelor of Science in Materials Science and Engineering from the Massachusetts Institute of Technology (MIT), and (2) a Doctor of Science in Materials Science and Engineering, with a thesis in the field of polymers, from MIT. I have been practicing in the field of polymer science and engineering for more than 20 years as a researcher at MIT, in a variety of technical roles at the 3M Company, and as a consultant with Exponent. I provide consulting engineering services in all aspects of polymer science and engineering including, but not limited to material selection, product design and development, mechanical and chemical testing, failure analysis, polymer chemistry, polymer physics, and polymer processing. My specialties include formulation, processing and performance evaluation of polymeric materials, including films, coatings, adhesives and transdermal drug delivery systems. I have been directly involved in product development, product line extensions, transfer of new products to manufacturing, qualification of

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alternative materials and manufacturing equipment, evaluating field performance, and assessing intellectual property. I am a past chairman and continue to serve as a member of the board of directors of the Medical Plastics Division of the Society of Plastics Engineers. My *curriculum vitae* is provided in Appendix A.

- While Exponent is being paid for my time, I am not an employee of, nor do I have any financial interest in, BioDelivery Sciences International, Inc.
- **3.** I have been asked to measure the pH of Suboxone® tablets.
- 4. <u>Materials/Methods</u>. 8 mg Suboxone® tablets were used in this experiment. An EL20 pH meter from Mettler Toledo was used according to manufacturer instructions to measure the pH of the Suboxone ® tablets in deionized water.
- 5. <u>pH of Suboxone® tablets</u>. In order to measure the pH of the 8 mg Suboxone® tablets, the tablets were dissolved in both 1.5 mL and 3 mL of deionized water. The pH of the 8 mg tablets was measured to be 3.5 in both 1.5 mL and 3 mL of deionized water.
- I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and

belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application or any patents issued thereon.

Dated: January 6, 2014

Maureen Reitman, Sc.D.



Exponent 17000 Science Drive Suite 200 Bowie, Maryland 20715

telephone 301-291-2500 facsimile 301-291-2599 www.exponent.com

### Maureen T. F. Reitman, Sc.D. Principal and Practice Director

#### **Professional Profile**

Dr. Maureen Reitman is a Principal and the Director of Exponent's Polymer Science and Material Chemistry practice. Her expertise includes polymer and composite technology, mechanics of materials, adhesion science, fiber mechanics, history and technology of plastics, and material failure analysis. She is skilled in the development and use of testing tools and methods and has applied them to plastic, rubber, textile, metal, glass, ceramic, and composite materials and systems. She is experienced in major aspects of product development, including materials selection, formulation, scale-up, end-use testing, failure analysis, certification procedures and issues related to intellectual property.

Dr. Reitman has conducted research in the areas of packaging and barrier materials; paints and coatings; plastic pipes; transdermal drug delivery; adhesives, sealants, and encapsulants; molding compounds; high temperature resins; nanoparticles; fibers and textiles; protective coatings and finishes; polymer chemical resistance; plastic insulation; connectors and splices; plastic packaging; medical devices; environmental effects on durability; and product aging. She has used her expertise to solve a broad range of problems related to coatings, fibers, films, and extruded and molded products, and their use in the telecom, electronics, electrical, transportation, construction, fire protection, medical, and consumer products markets.

Dr. Reitman is a member of the Board of Directors of the Medical Plastics Division of the Society of Plastics Engineers and an active member of two Underwriters Laboratories Standard Technical Panels, addressing Polymeric Materials (UL 94, UL 746, UL 1694) and Appliance Wiring (UL758).

Prior to joining Exponent, Dr. Reitman worked for the 3M Company in both research and management roles. Her activities included technology identification, materials selection and qualification, product development, customer support, program management, acquisition integration, intellectual property analysis, and patent litigation support.

#### Academic Credentials and Professional Honors

DOCKE

Sc.D., Materials Science and Engineering/ Program in Polymer Science and Technology, Massachusetts Institute of Technology, 1993
B.S., Materials Science and Engineering, Massachusetts Institute of Technology, 1990

National Academy of Engineering Frontiers of Engineering, 2009; Tau Beta Pi; Sigma Xi John Wulff Award; Carl Loeb Fellowship; NCAA Postgraduate Scholarship; Malcolm G. Kispert Award; GTE Academic All-American

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