UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

RB PHARMACEUTICALS LIMITED
Patent Owner.

Case IPR2014-00325
Patent 8,475,832

DECLARATION OF PROFESSOR THOMAS P. JOHNSTON IN SUPPORT OF PATENT OWNER'S RESPONSE

1. I, Thomas P. Johnston, Ph.D., hereby declare as follows:

2. I have been retained by counsel for Patent Owner RB Pharmaceuticals Limited and its licensee, Reckitt Benckiser Pharmaceuticals Inc. ("RBP") as an expert in pharmaceutical science to address topics relevant to the subject matter of this *inter partes* review proceeding involving certain claims U.S. Patent No 8,475,832 (Ex. 1001; the "'832 patent"). I am being compensated at the rate of $400 per hour. My compensation is in no way dependent on the outcome of this case

I. SUMMARY OF QUALIFICATIONS

3. My *curriculum vitae* is Ex. 2004.

4. I am a tenured Full Professor of Pharmaceutics in the Division of Pharmaceutical Sciences at the University of Missouri-Kansas City School of Pharmacy.

5. I received a Bachelor of Science degree in Pharmacy and a Ph.D. in Pharmaceutics from the University of Minnesota in 1980 and 1987, respectively.

6. I held a joint-appointment as a Post-Doctoral Research Fellow from 1987-1988 in the Department of Pediatric Cardiology, the University of Michigan Medical School and the Department of Pharmaceutics, the University of Michigan College of Pharmacy.

7. I was an Associate Professor of Pharmaceutics in the Division of Pharmaceutical Sciences at the University of Missouri-Kansas City School of

Pharmacy from 1995 until I obtained my current position in 2008. From 1988 to 1994, I was an Assistant Professor of Pharmaceutics in the Department of Pharmaceutics and Pharmacodynamics at the University of Illinois College of Pharmacy.

8. I have presented scientific lectures at a number of institutions as well as to the United States Food and Drug Administration. These lectures have focused on dissolution, stability, pharmacokinetics, and *in vitro/in vivo* correlation of pharmaceuticals.

9. I was awarded the *Rho Cho Pharmacy Honor Society Faculty Member of the Year* award in March 2008. I was awarded *Outstanding Teacher of the Year* in November 2007 and 2013 at the University of Missouri-Kansas City and in May of 1994 and 1990 at the University of Illinois College of Pharmacy. In July 2002, I was designated as a *Master Instructor* in the field of pharmaceutics by the American Association of Colleges of Pharmacy. I was also cited as an *Outstanding Pharmaceutical Educator* at an American Association of Colleges of Pharmacy meeting in July 1994. My other scientific honors and awards are listed in my *curriculum vitae*, which also includes a list of my publications, presentations at scientific meetings, and professional and honorary memberships.

10. My research has resulted in more than 90 peer-reviewed published research papers, 10 book chapters and encyclopedia contributions, and

approximately 100 presentations at scientific meetings to national and international audiences.

11. Over the course of my career, I have 29 years of experience teaching and conducting pharmaceutical research, including a specialization in the oral transmucosal delivery of conventional and polypeptide drugs through the buccal mucosa.

12. I have contributed five book chapters that describe the anatomy and physiology of the oral cavity as it pertains to the administration of small molecule organic drug as well as peptidic compounds. In particular, I published a book devoted to buccal drug delivery: T.P. Johnston and P.P. Bhatt, Buccal Drug Delivery, Technomic Co., Lancaster, PA, pp. 1-315, 1996. Also, my most recent book chapter, which will be published in late 2014, or early 2015, is entitled, "Anatomy and physiology of the oral mucosa and its relevance to local and systemic oral mucosal drug delivery", Chapter 1, In: *Oral Mucosal Drug Delivery and Therapy*.

13. I am familiar with how pharmaceutical film dosage forms are prepared/manufactured, administered, and subsequently evaluated both *in vitro* and *in vivo*, including the interpretation of pharmacokinetic data arising from said testing. I am also familiar with drug absorption by the sublingual and/or buccal mucosa in the oral cavity, which includes the effects of pH modifiers, routes of drug

transport, potential depot effects, relevant anatomy and physiology of the oral cavity, mucoadhesion of dosage forms intended for oral transmucosal drug delivery, and the relevant pharmacokinetics after the drug has been absorbed and enters the bloodstream so as to produce a plasma concentration-time profile. I am also familiar with the pharmacokinetics associated with drug input by other routes of drug administration. I have evaluated numerous dosage forms for drug delivery through the mucosa in the oral cavity, including various types of tablets, solutions, hydrogels and films.

II. MATERIALS CONSIDERED

14. In reaching the conclusions set forth below, I have relied on my close to three decades of experience in pharmaceutical studies and have specifically considered the '832 patent, its file history, relevant portions of BioDelivery Sciences International, Inc.'s ("BDSI") 1/15/2014 Petition for IPR (Paper 8; the "Petition"), the Board's 7/29/2014 Institution Decision (Paper 17), and the other materials cited below.

III. UNDERSTANDNG OF THIS PROCEEDING

15. I understand that this is an *inter partes* review ("IPR") proceeding conducted before the Patent Trial and Appeal Board ("Board") of the U.S. Patent and Trademark Office ("PTO") to determine if claims 15-19 of the '832 patent (the challenged claims) should be cancelled as unpatentable. I understand that BDSI

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