Paper No._____

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BIODELIVERY SCIENCES INTERNATIONAL, INC.
Petitioner

v.

RB PHARMACEUTICALS LIMITED
Patent Owner

Case No. IPR2014-00325
Patent 8,475,832

DECLARATION BY DAVID W. FEIGAL, MD MPH
IN SUPPORT OF PETITIONER'S REPLY

I. QUALIFICATIONS

1. I am a physician, am board certified in Internal Medicine, and have a Master's Degree in Public Health (M.P.H.) in the fields of epidemiology and biostatistics. I graduated from Stanford University Medical School in 1976; completed my internship and residency at the University of California, Davis in 1979; and earned an M.P.H from the University of California, Berkeley in 1983.

2. From 1982-1989, I held several positions at the University of California, San Francisco, including Associate Director of the Clinical Epidemiology program and Assistant Professor of Medicine with joint appointments in Epidemiology and Biostatistics, and was a member of the Clinical Pharmacology faculty. I was also Director of the Data Center at the AIDS Clinical Research Center. From 1989 to 1991, I was a Clinical Associate Professor of Clinical Medicine at the University of California, San Diego.

3. During my career, I have practiced medicine as a general internist in faculty practices at the University of California, as well as taught medical students, interns, residents and fellows, and cared for patients on the in-patient services at several university hospitals. As an internist-epidemiologist, I designed and conducted clinical trials. My responsibilities for clinical trials included monitoring and reporting adverse drug reactions to FDA and to the trials' data safety and monitoring boards, as well as to Institutional Review Boards (IRBs). Clinical trials

that I designed and conducted led to the approval of new drugs and devices. I presented to and served on FDA Advisory Committees, as well as National Institutes of Health and Public Health Service Consensus Task Forces on disease prevention and treatment that included evaluation of the quality of evidence from epidemiology and clinical trials.

4. From 1992 to 2004, I held a number of senior positions at FDA. From 1992-1997, I held positions in FDA's Center for Drug Evaluation and Research (CDER). This Center has the responsibility for the review and approval of all new drugs, and the ongoing assessment of the quality, safety and effectiveness of marketed drugs. It has the authority to take actions through its compliance programs to assure that drugs meet standards defined in law. At CDER, I held the positions of Director of the Division of Anti-Viral Drug Products and Acting Director of the Anti-Infective Drug Products, and in addition from 1994 to 1997, I was Director of the Office of Drug Evaluation IV.

5. I had the direct authority to approve investigational studies of new drugs for various indications, including the clinical pharmacology studies, to halt such studies for safety reasons, to approve the protocols for studies that would be the evidence to demonstrate effectiveness, to approve new indications and new formulations for approved drugs in these areas, and to approve the manufacturing methods and take compliance actions through the CDER Office of Compliance and

FDA field staff. My responsibilities included the supervisions of the review disciplines, including the pharmaceutical chemists, pharmacologists, toxicologists, statisticians and medical reviewers. Based on my review of the reports of the review disciplines and my own assessments, I had the decision-making authority for the approval of new drug indications, new formulations, and product labeling. Approval of generic drugs that required clinical trials were also among my responsibilities. As an Office Director, I supervised the directors of the Divisions of Antiviral Drug Products, Anti-Infective Drug Products, and Special Pathogens and was one of five people at FDA with the authority for the initial approval of new drugs. I also shared responsibility for policy development including drafting FDA Guidance documents, many on the FDA requirements for drug approval.

6. From 1997-1999, I served as the Medical Deputy Director of the Center for Biologics Evaluation and Research (CBER). I directly supervised the Biostatistics and Epidemiology Division, among others, as well as the Advisory Committee Staff and served as the Center Ombudsman.

7. From 1999-2004, I served as Director of the Center for Devices and Radiological Health (CDRH). Many medical devices are used as drug delivery devices, including the combination products designed for novel delivery methods. Whether approved as drugs or medical devices, these products involved CDRH and CDER or CBER.

8. My career has included extensive experience in the evaluation of safety and effectiveness of pharmaceutical drugs and biologics, as well as medical devices. At FDA, I was responsible for the evaluation of safety and efficacy of new drugs within my Divisions, including the initial approval process and continuing oversight of the safety and effectiveness of those drugs after approval, and as new dosage forms were developed and approved. This involved extensive interactions with sponsors about their study design and product development programs, evaluating the results of those programs, and analyzing the adequacy and completeness of product labeling.

9. As a CDER Division Director and Office Director, I had direct responsibility for evaluating the adequacy of the preclinical, the pharmacology and the clinical outcome studies that were the basis for investigational studies of new drugs (INDs) and New Drug Applications (NDAs), and I had direct sign-off authority, known as "signatory authority," for their approval. In addition to direct review of applications, I participated in policy and guidance efforts at FDA and participated in many meetings of several different FDA Advisory Committees. I presented safety evaluations to Committees of the Institute of Medicine, in congressional testimony, and published invited commentaries on product safety. I understand fully the process and criteria utilized by FDA in assessing safety and

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