UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC., Petitioner,

v.

RB PHARMACEUTICALS LIMITED, Patent Owner.

> Case IPR 2014-00325 Patent 8,475,832

DECLARATION OF CHRISTINE SIEGWARTH MEYER, PH. D. IN SUPPORT OF PETITIONER'S REPLY

Date: January 30, 2015

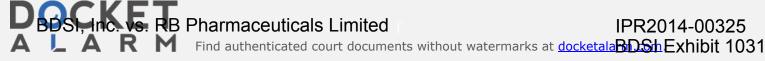


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NFRA Economic Consulting



I. INTRODUCTION

A. Professional Qualifications and Expertise

1. I am an economist and Senior Vice President at National Economic Research Associates, Inc. ("NERA"). NERA is a firm of consulting economists that was founded in 1961 and that provides research and analysis in economics, including analysis in the areas of competition, regulation, and finance. I joined the firm in 2000 and have worked since then mainly in the areas of the economics of intellectual property, antitrust analysis, and the evaluation of commercial damages. I have testified in U.S. District Court, the Federal Court of Canada, the Supreme Court of the State of New York, and the High Court of Justice in England as an expert witness.

2. Since joining NERA, I have analyzed economic issues in a wide variety of cases including analyses of commercial success, irreparable harm and damages in patent cases. I have been retained to analyze commercial success on behalf of brand and generic pharmaceutical companies in both District Court and Patent Trial and Appeals Board ("PTAB") proceedings.

3. I received my bachelor's degree with a concentration in economics from the United States Military Academy at West Point and my Ph.D. in economics from the Massachusetts Institute of Technology. I taught economics and statistics at Bentley College and Colgate University. A complete list of my prior testimony and publications can be found in my curriculum vitae, Exhibit 1032.

B. Retention and Assignment

4. I have been retained by the counsel for BioDelivery Sciences International, Inc. ("BDSI" or "Petitioner"), McCarter & English, LLP, to provide an economic opinion regarding whether Suboxone® film is a commercial success, and whether RB Pharmaceuticals Limited ("RB") has proven a nexus between any such commercial success and the subject matter claimed in claims 15-19 of U.S. Patent No. 8,475,832 (the "challenged claims").

5. Specifically, I have been asked by counsel for BDSI to assess the claims made by RB in its "Patent Owner's Corrected Response" submitted to this Board on November 7, 2014 concerning Suboxone® film's alleged commercial success and whether there is a nexus between such alleged success and the subject matter claimed in the challenged claims. This report summarizes my opinions.

C. Compensation

6. NERA is being compensated for the time I spend on this assignment at my customary hourly rate of \$595. Professional staff members employed by NERA and working under my direction on this matter have hourly billing rates that range from \$295 to \$495. No part of my or NERA's compensation is dependent upon the outcome of this review or the nature of the opinions that I express.

D. Sources Relied Upon

7. In preparing this declaration, I (or economists working under my direction) have reviewed pleadings, documents, exhibits and data submitted to the Board by the parties in this *Inter Partes* Review, as well as information and data from publicly available sources. A complete list of the information that has been relied on in preparing this declaration can be found in Exhibit 1032.

E. Summary of Opinions

8. Based on the information available to me and my analysis to date, it is my opinion that:

- RB has not demonstrated the commercial success of Suboxone® film, and
- RB has failed to show a nexus between any alleged commercial success of Suboxone® film and the subject matter claimed in the challenged claims.

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