Paper No. __
Filed: November 7, 2014

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

PATENT OWNER'S RESPONSE

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I. INTRODUCTION

Patent Owner RB Pharmaceuticals Limited respectfully submits this Response to BDSI's Petition (Paper 8) seeking *inter partes* review ("IPR") of Claims 15-19 ("the challenged claims") of U.S. Patent No. 8,475,832 ("the '832 patent") (Ex. 1001).[1]

The only issue presently before the Board is whether Petitioner has carried its burden of proving that the challenged claims are invalid as i) anticipated by Labtec or ii) obvious over the combination of Labtec, Yang and Birch.[2] Paper 17, 21. As shown below, the complete record demonstrates that these claims are valid, and that Petitioner has failed to carry its burden of proving otherwise.

Patent Owner's Preliminary Response did not have the benefit of expert testimony. Now, in support of this Response, Patent Owner submits the accompanying declaration of Dr. Thomas Johnston, an expert in the pharmaceutical sciences, that makes clear that the challenged claims are neither anticipated nor rendered obvious by the Grounds in issue. In particular, Dr. Johnston provides critical information about the pharmacokinetics of the relevant active ingredients, buprenorphine and naloxone, information that fully rebuts

[1] This Response is timely because it is filed on revised Due Date 1 set forth in the Joint Notice of Stipulated Revised Due Dates (Paper 22).

[2] Terms defined in the Board's Institution Decision are used herein as so defined.

Petitioner's invalidity theories of anticipation and obviousness.

A. Lack Of Anticipation Overview

Dr. Johnston explains why the knowledge a skilled person would have of the pharmacokinetic profile of buprenorphine in combination with a proper understanding of both Labtec and the '832 patent refute Petitioner's anticipation arguments. In particular, Dr. Johnston explains that it ***has long been known that, due to extensive first-pass metabolism effects, buprenorphine has very poor bioavailability if administered perorally***, i.e., swallowed such that it is absorbed in the gut, as opposed to in the mouth. Thus, ***it has also long been known that it is not therapeutically effective or acceptable to administer buprenorphine perorally*** due to buprenorphine's poor bioavailabilty and the expectation that peroral administration would likely increase inter- and intra-patient variability, make effective dosing less predictable and increase the risk of incurring side effects from buprenorphine, which is a potent opioid. Additionally, given the poor bioavailability resulting from peroral administration, peroral dosing would require significantly higher dosing as compared, for example, to sublingual administration, thus providing more of the agonist to be potentially abused or diverted, as well as increasing the amounts needed, and thus increasing manufacturing costs. Peroral administration, therefore, would be regarded by those skilled in the art as disfavored and therapeutically inappropriate, particularly given that it has long

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