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

_____

PETITIONER'S REPLY

Table of Contents

Page

Table of Contents

I. INTRODUCTION

RB does not dispute that every *recited* element of the challenged claims, as arranged in the claims, is disclosed in Labtec. Instead, RB asks the Board to read in a new limitation—oral transmucosal absorption ("OTA")—not by interpretation of any specific claim language, but because the '832 patent "solely concerns" OTA. RB then asks the Board to *ignore* the disclosure of OTA in Labtec.

But RB's reasons for reading in OTA from the specification, and ignoring its disclosure in Labtec—based on a theory that Labtec and the '832 patent have mutually exclusive disclosures—did not bear up to cross-examination.

RB's non-enablement arguments fail because even RB cannot tell us *what* is not enabled. RB similarly cannot tell us *why* its claims are not obvious. And while RB *argues* commercial success, it provides no evidence of it.

II. RB DOES NOT DENY THAT EACH AND EVERY LIMITATION RECITED IN THE CHALLENGED CLAIMS IS DISCLOSED IN LABTEC.

RB does not refute that Labtec (Ex. 1017) discloses the *recited* elements of the challenged claims, as arranged in the claims. For example, when asked, RB's expert could not identify any recited element of claim 15 that was not disclosed in Labtec. Ex. 1028, 108:24-109:20, 126:19-127:19.

III. INSTEAD OF CONSTRUING A SPECIFIC CLAIM TERM, RB ARGUES THE CLAIMS SHOULD BE READ "AS RECITING…ORAL TRANSMUCOSAL ABSORPTION"

In the Institution Decision, the Board declined to read mucosal absorption

into the claims. Decision, 15 ("In, addition, [RB] does not propose that we construe 'film formulation'[1] to require … mucosal absorption of buprenorphine, and we decline to read those unrecited features into the challenged claims."). RB now asks the Board to read OTA into the claims from the specification, contrary to the broadest reasonable interpretation standard applied in *inter partes* review proceedings. Patent Owner Corrected Response ("POCR"), 20.

A. Under the broadest reasonable interpretation, limitations that have no express basis in the claim are not read in.

In asking the Board to read a limitation into the claims from the specification, RB cites a Federal Circuit case not based on the broadest reasonable interpretation. POCR, 20. When reviewing Board decisions under the broadest reasonable interpretation standard, the Federal Circuit has found that, because the applicant has the opportunity to amend the claims during prosecution, giving a claim its broadest reasonable interpretation reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Yamamoto,* 740 F.2d 1569, 1571 (Fed. Cir. 1984); *In re Prater,* 415 F.2d 1393, 1404-05 (CCPA 1969). Because RB had the opportunity to amend the claims, the policy

[1] BDSI's proposed construction of "film formulation" does *not* read out the word "film"—it explicitly requires that it be "capable of being used to prepare a single film." Petition, 22.

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