Attorney Docket No. 117744-00048

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 LTD.,

Patent Owner.

_____

IPR2014-00998

Patent 8,475,832 B2

PETITIONER'S MOTION FOR JOINDER UNDER 37 C.F.R. § 42.122(B)

Table of Contents **Page**

I. INTRODUCTION AND REQUESTED RELIEF

Petitioner, BioDelivery Sciences International, Inc. ("BDSI"), requests joinder of IPR2014-00998 with IPR2014-00325. Both proceedings involve the same patent, the same claims, the same parties, and overlapping prior art. Joinder will not unduly delay the resolution of either proceeding. Joinder of at least Ground 3 will significantly simplify the instituted proceeding by eliminating at least three lines of argument already advanced by Patent Owner in its Preliminary Response. Joinder will also avoid unnecessary duplication by resolving numerous issues in common between the two proceedings.

BDSI is willing to file a motion limiting its petition in IPR2014-00998 to Ground 3 if the Board so advises to render joinder more feasible. *See ABB Inc. v. Roy-G-Biv Corp*., IPR2013-00286, Paper 14, Aug. 9, 2013, at 2-3. As instructed by the Board on August 26, BDSI will work with Patent Owner to develop an agreed-upon proposed schedule for the joined proceeding, and will agree to all reasonable requests.

II. STATEMENT OF MATERIAL FACTS

A. The First Petition

On January 15, 2014, BDSI filed a first Petition for *Inter Partes* Review requesting review of claims 15-19 of the '832 patent ("First Petition"), designated

IPR2014-00325. The First Petition requested cancellation of claims 15-19 on the following grounds among others:

Ground 5	Anticipated by *Labtec*
Ground 6	Obvious over *Labtec*
Ground 7	Obvious over *Labtec* and *Birch*
Ground 8	Obvious over *Labtec*, *Birch,* and *Yang*
Ground 9	Anticipated by *Euro-Celtique*
Ground 10	Obvious over *Euro-Celtique*
Ground 11	Obvious over *Euro-Celtique* and *Birch*
Ground 12	Obvious over *Euro-Celtique*, *Birch,* and *Yang*

On July 29, 2014, the Board issued a decision in IPR2014-00325 instituting trial of claims 15-19 on Grounds 5 and 8 (*i.e.*, anticipation by *Labtec* and obviousness over *Labtec*, *Birch,* and *Yang*). *See* IPR2014-00325, Paper No. 17, at 17, 20. The Board found Grounds 6-7 and 9-12 to be redundant in light of its decision to institute review on Grounds 5 and 8. *See id*. at 17, 20.

B. The Second Petition

On June 20, 2014—more than one month before the Board issued its institution decision in IPR2014-00325—BDSI filed the instant Petition for *Inter Partes* Review ("Second Petition"), which initiated IPR2014-00998. In the Second Petition, BDSI requests cancellation of claims 15-19 of the '832 patent on each of the following grounds:

Ground 1	Obvious over *Euro-Celtique*
Ground 2	Obvious over *Euro-Celtique* and the *EMEA Study Report*
Ground 3	Obvious over *Euro-Celtique*, the *EMEA Study Report,* and WO 03/030883
Ground 4	Obvious over *Euro-Celtique*, the *EMEA Study Report,* and *Yang*

While the *EMEA Study Report* (Ex. 1015 in both petitions) was not applied as a secondary reference in the First Petition, it was applied to evidence the known pharmacokinetic parameters of naloxone resulting from administration of the prior art SUBOXONE® tablets. IPR2014-00325, Paper No. 8, at 49.

Patent Owner, if not already well aware of the *EMEA Study Report*—which is a study of Patent Owner's own SUBOXONE® tablets prepared by the European equivalent of the drug arm of the US FDA—was made aware of that reference in the First Petition over eight months ago. Indeed, the Board refers to the *EMEA Study Report* in its Institution Decision. *See* IPR2014-00325, Paper No. 17, at 14 (citing *EMEA Study Report* as "Suboxone Tablet Study Report").

Both petitions cite the *EMEA Study Report* for the same reason—as evidencing the known naloxone *in vivo* plasma profile produced by administration of the Patent Owner's SUBOXONE® tablets. *Compare, e.g.*, IPR2014-00325, Paper No. 8, at 49 (citing *EMEA Study Report* as "*Suboxone Tablet Study Report*") *with* IPR2014-00998, Paper No. 2, at 45-46.

In support of the Second Petition, BDSI filed the Declarations of Dr.

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