

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.

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Case IPR2014-00998  
Patent 8,475,832

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**PATENT OWNER'S OPPOSITION TO  
PETITIONER'S MOTION FOR JOINDER**

Patent Owner RB Pharmaceuticals Limited opposes Petitioner Biodelivery Sciences International, Inc.'s motion for joinder seeking to join the present proceeding with IPR2014-00325 ("the '325 IPR"). This opposition is timely pursuant to the Board's Order on September 2, 2014. Paper 7, 3.

As shown in the concurrently filed Patent Owner's Preliminary Response, trial should not be instituted in the present proceeding because Petitioner's redundant second Petition asserting substantially the same arguments and art against the same claims of the same patent should be denied in its entirety as to all challenged claims under 35 U.S.C. §§ 314(a) and 325(d). This motion for joinder will then be moot.

However, although the primary reference, Euro-Celtique, that Petitioner relies on in each of the four Grounds asserted in this proceeding, was asserted in the Petition in the '325 IPR, the Board did not institute on any Ground based on that reference in the '325 IPR. Therefore, in the event that the Board does not find that the present Euro-Celtique-based Grounds are redundant of those presented in the '325 IPR and decides to institute trial on any of the presently asserted Grounds, joinder with the '325 IPR (and under the schedule now set in that IPR) would be inappropriate for numerous reasons: (1) this proceeding, if instituted, would present separate Grounds of unpatentability relying on separate art (specifically, a separate primary reference) than the Grounds instituted on the '325 IPR (again,

Euro-Celtique was asserted but not instituted on in the '325 IPR), and (2) the current trial schedule in the '325 IPR would not accommodate the additional briefing and discovery required by institution of one or more Grounds in this proceeding due to the 5 month delay between Petitioner's filing of the two proceedings.

**I. Statement of Material Facts<sup>1</sup>**

1. On January 15, 2014, Petitioner filed a petition for *inter partes* review of Claims 15-19 of U.S. Patent No. 8,475,832 (“the '832 patent”) (“first Petition”).

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<sup>1</sup> Petitioner submitted a statement of material facts in its motion for joinder. Paper 6, 1-7. Because it believes Petitioner's statement to be incomplete of the facts material to whether joinder is appropriate in this proceeding, Patent Owner submits the following statement of material facts. Additionally, Patent Owner notes that Petitioner spends nearly half of its statement of material facts discussing events relating to U.S. Application No. 13/964,975. Paper 6, 4-7. Patent Owner submits those purported “facts” are wholly irrelevant, i.e., not material, to whether joinder should be granted in the instant proceeding. Indeed, the immateriality of that discussion is evidenced by the fact that Petitioner doesn't rely on a single “fact” relating to that proceeding to support the merits of its motion. *See generally* Paper 6, 7-15.

*Biodelivery Sciences Int'l, Inc. v. RB Pharmaceuticals Ltd.*, IPR2014-00325 (“the ’325 IPR”), Paper 5. The first Petition requested trial be instituted for Claims 15-19 on the following Grounds:

- Ground 1 – Anticipated by the Suboxone Tablet Label
- Ground 2 – Obvious in view of the Suboxone Tablet Label
- Ground 3 – Obvious in view of the Suboxone Tablet Label and Yang
- Ground 4 – Obvious in view of the Suboxone Tablet Label, Yang, and Birch
- Ground 5 – Anticipated by Labtec
- Ground 6 – Obvious in view of Labtec
- Ground 7 – Obvious in view of Labtec and Birch
- Ground 8 – Obvious in view of Labtec, Birch, and Yang
- Ground 9 – Anticipated by Euro-Celtique
- Ground 10 – Obvious in view of Euro-Celtique
- Ground 11 – Obvious in view of Euro-Celtique and Birch
- Ground 12 – Obvious in view of Euro-Celtique, Birch, and Yang

2. In support of the first Petition, Petitioner presented declarations of Dr. Reitman (Ex. 1004 in this proceeding and the ’325 IPR) and Dr. Lavin (Ex. 1005 in this proceeding and the ’325 IPR).

3. On April 30, 2014, Patent Owner filed its Preliminary Response in the ’325 IPR, which challenged the sufficiency of each Ground proposed by Petitioner and argued Petitioner failed to present evidence in the form of expert testimony supporting its obviousness Grounds. IPR2014-00325, Paper 15.

4. On June 20, 2014, more than five months after the first Petition and almost two months after Patent Owner’s Preliminary Response in the ’325 IPR, Petitioner filed another petition for *inter partes* review of Claims 15-19 of the ’832

patent (“second Petition”). Paper 2. The second Petition requested trial be instituted for Claims 15-19 on the following Grounds:

- Ground 1 – Obvious in view of Euro-Celtique
- Ground 2 – Obvious in view of Euro-Celtique and the EMEA Study Report
- Ground 3 – Obvious in view of Euro-Celtique, the EMEA Study Report, and the ’883 Application
- Ground 4 – Obvious in view of Euro-Celtique, the EMEA Study Report, and Yang

5. In support of the second Petition, Petitioner presented declarations of Dr. Reitman (Ex. 1004 in this proceeding and the ’325 IPR), Dr. Lavin (Ex. 1005 in this proceeding and the ’325 IPR), and Dr. Celik (Ex. 1033). Dr. Celik did not provide a declaration in the ’325 IPR. The second Petition does not cite to the declarations of Dr. Reitman or Dr. Lavin in discussion of any of its proposed rejections. *See generally* Paper 2, 34-54. Rather, Petitioner only relies on the declaration of Dr. Celik in its proposed Grounds 1-4 in the second Petition.

6. On July 29, 2014, the Board issued a Decision instituting trial in the ’325 IPR only with regard to Ground 5 (anticipation by Labtec) and Ground 8 (obviousness over Labtec, Birch, and Yang). IPR2014-00325, Paper 17. The Board also issued a Scheduling Order that specified October 17, 2014 as the Due Date for Patent Owner’s Response to the Petition (Due Date 1) and March 20, 2015 as the Due Date for Oral Argument (Due Date 7). IPR2014-00325, Paper 18.

7. On August 26, 2014, the Board held an initial conference call with the parties during which Petitioner’s proposed motion for joinder was discussed and

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