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Paper No. 12
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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 IPR2014-00998
Patent 8,475,832 B2

Before TONI R. SCHEINER, JACQUELINE WRIGHT BONILLA, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
and Dismissing Motion for Joinder
37 C.F.R. §§ 42.108, 42.122

INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") petitioned for an *inter partes* review of claims 15–19 of U.S. Patent No. 8,475,832 B2 (Ex. 1001, "the '832 patent"). Paper 2 ("Pet."). Petitioner also sought to join this proceeding with IPR2014-00325, an *inter partes* review of the same challenged claims currently pending before the Board. Paper 6. RB Pharmaceuticals Limited ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). In addition, Patent Owner filed an Opposition to Petitioner's Motion for Joinder. Paper 10. We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we exercise our discretion and deny the Petition under 35 U.S.C. § 325(d). Because we do not institute an *inter partes* review, we dismiss as moot the Motion for Joinder under 35 U.S.C. § 315(c).

Related Proceedings

Parties state that Patent Owner previously asserted the '832 patent against Petitioner in *Reckitt Benckiser Pharmaceuticals, Inc., v. BioDelivery Sciences International, Inc.*, No. 5:13-cv-760 (E.D.N.C.). *See* Pet. 3; Paper 5, 3. The case was later dismissed without prejudice as premature on procedural grounds. *See* Pet. 3; Paper 5, 3.

According to Patent Owner, Petitioner filed *BioDelivery Sciences International, Inc. v. Reckitt Benckiser Pharmaceuticals, Inc.*, No. 14-cv-529

(E.D.N.C.), seeking a declaratory judgment of invalidity of the '832 patent claims.[1] Prelim. Resp. 1–2.

Petitioner previously petitioned for review of, and the Board instituted trial on, the same challenged claims of the '832 patent in IPR2014-00325 ("the '325 IPR"), currently pending before the Board.

The '832 Patent

The '832 patent relates to compositions and methods for treating narcotic dependence using an orally dissolvable film comprising buprenorphine and naloxone, where the film provides a bioequivalent effect to Suboxone®. Ex. 1001, 4:55–58.

Suboxone® is an orally dissolvable tablet of buprenorphine and naloxone. *Id.* at 4:51–55. Buprenorphine provides an effect of satisfying the body's urge for narcotics, but not the "high" associated with misuse. *Id.* at 1:36–40. Naloxone reduces the effect and, thus, decreases the likelihood of diversion and abuse of buprenorphine. *Id.* at 1:46–52. The tablet form, however, still has the potential for abuse because it can be removed easily from the mouth for later extraction and injection of buprenorphine. *Id.* at 1:55–62. The film of the '832 patent "provides buccal adhesion while it is in the user's mouth, rendering it difficult to remove after placement." *Id.* at 4:58–60.

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[1] Patent Owner does not specify when Petitioner filed the declaratory judgment action in the district court. We observe that, despite pointing to the district court case, Patent Owner does not challenge Petitioner's standing in this proceeding as barred under 35 U.S.C. § 315(a)(1).

The ’832 patent teaches controlling the local pH to maximize the absorption of the buprenorphine while simultaneously minimizing the absorption of the naloxone. *Id.* at 11:28–30. According to the ’832 patent, “it has been surprisingly discovered” that, at a local pH level from about 2 to about 4, and most desirably from 3 to 4, the film composition of the invention achieves bioequivalence to the Suboxone® tablet. *Id.* at 11:50–61.

The ’832 patent defines bioequivalent as “obtaining 80% to 125% of the Cmax and AUC values for a given active in a different product.” *Id.* at 3:48–50. According to the ’832 patent, “Cmax refers to the mean maximum plasma concentration after administration of the composition to a human subject;” and “AUC refers to the mean area under the plasma concentration-time curve value after administration of the compositions .” *Id.* at 3:9–14. The ’832 patent discloses:

> [T]o be considered bioequivalent to the Suboxone® tablet, the Cmax of buprenorphine is between about 0.624 and 5.638, and the AUC of buprenorphine is between about 5.431 to about 56.238. Similarly, to be considered bioequivalent to the Suboxone® tablet, the Cmax of naloxone is between about 41.04 to about 323.75, and the AUC of naloxone is between about 102.88 to about 812.00.

Id. at 17:41–47.

Illustrative Claim

Among the challenged claims, claim 15 is the sole independent claim. It reads:

> 15. An orally dissolving film formulation comprising buprenorphine and naloxone, wherein said formulation provides an in vivo plasma profile having a Cmax of between about

> 0.624 ng/ml and about 5.638 ng/ml for buprenorphine and an in vivo plasma profile having a Cmax of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 15–19:

Basis	Reference(s)
§ 103	Euro-Celtique[2]
§ 103	Euro-Celtique and EMEA Study Report[3]
§ 103	Euro-Celtique, EMEA Study Report, and the '883 Application[4]
§ 103	Euro-Celtique, EMEA Study Report, and Yang[5]

ANALYSIS

Under 35 U.S.C. § 325(d),

> In determining whether to institute or order a proceeding under . . . chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

Patent Owner asks us to exercise our discretion under 35 U.S.C. § 325(d) and deny this Petition. Prelim. Resp. 20–33. Patent Owner argues

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[2] Oksche et al., Int'l Pub. No. WO 2008/025791 A1, published on March 6, 2008 (Ex. 1018) ("Euro-Celtique").
[3] European Medicines Agency (EMEA) Study Report on Suboxone® Tablets, 2006 (Ex. 1015) ("EMEA Study Report").
[4] Fuisz et. al., Int'l Pub. No. WO 03/030883 A1, published on April 17, 2003 (Ex. 1031) ("the '883 Application").
[5] Yang et al., U.S. Patent No. 7,357,891 B2, issued on April 15, 2008 (Ex. 1016) ("Yang").

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