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Paper 17
Entered: July 29, 2014

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 IPR2014-00325
Patent 8,475,832 B2

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

YANG, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

## 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 8 ("Pet."). RB Pharmaceuticals Limited ("Patent Owner") timely filed a Preliminary Response. Paper 15 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine that Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a) and established a reasonable likelihood that it would prevail in showing the unpatentability of the challenged claims. Therefore, we institute an *inter partes* review of claims 15-19 of the '832 patent.

### *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 the 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.

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 . . . ." Ex. 1001, 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)[1] |
|---|---|
| § 102(b) | Suboxone Tablet Label |
| § 103 | Suboxone Tablet Label |
| § 103 | Suboxone Tablet Label and Yang |
| § 103 | Suboxone Tablet Label, Yang, and Birch |
| § 102(b) | Labtec |
| § 103 | Labtec |
| § 103 | Labtec and Birch |
| § 103 | Labtec, Birch, and Yang |
| § 102(b) | Euro-Celtique |
| § 103 | Euro-Celtique |
| § 103 | Euro-Celtique and Birch |
| § 103 | Euro-Celtique, Birch, and Yang |

[1] Suboxone Tablet Label, Revised September 2006 (Ex. 1013); Yang et al., U.S. Patent No. 7,357,891 B2 (Ex. 1016) ("Yang"); Leichs et al., Int'l Pub. No. WO 2008/040534 A2 (Ex. 1017) ("Labtec"); Oksche et al., Int'l Pub. No. WO 2008/025791 A1 (Ex. 1018) ("Euro-Celtique"); Birch et al., U.S. Patent Publication No. 2005/0085440 A1 (Ex. 1019) ("Birch").

## ANALYSIS

### *Preliminary Matters*

Reitman Declaration

In support of the Petition, Petitioner submits a declaration by Dr. Maureen Reitman, who testifies that the pH of Suboxone® tablets "was measured to be 3.5." Ex. 1004 ¶ 5. Patent Owner asks us to disregard the Reitman Declaration because (1) Suboxone® tablets do not constitute prior art for an *inter partes* review; and (2) the Reitman Declaration fails to provide sufficient and reliable evidence. Prelim. Resp. 20-22.

Patent Owner's argument is moot because we do not need to rely on Reitman Declaration at this stage of the proceeding. Petitioner, in discussing several asserted grounds, refers to pH 3-3.5 allegedly emphasized in the '832 patent. *See, e.g.*, Pet. 36 (asserting that "[t]o the extent the pH range of about 3 to about 3.5 is read into the challenged claims, the use of that pH range was already described and obvious in view of *Birch*"). As Patent Owner points out, however, "pH is not recited in the challenged claims." Prelim. Resp. 5. Thus, for purposes of this Decision, we do not address Petitioner's argument or the Reitman Declaration discussing the pH of Suboxone® tablets.

Lack of expert testimony on claim construction

Patent Owner faults Petitioner for presenting no expert testimony on how one of ordinary skill in the art would understand the term "film formulation." Prelim. Resp. 12. As explained below, in this case, disclosures in the Specification provide sufficient guidance for claim

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