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Paper 43
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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 IPR2014-00325
Patent 8,475,832 B2

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

YANG, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition 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."). On July 29, 2014, the Board instituted trial to review patentability of the challenged claims. Paper 17 ("Dec."). Thereafter, RB Pharmaceuticals Limited ("Patent Owner") filed a Corrected Response (Paper 25 ("PO Resp.")), and Petitioner filed a Reply (Paper 31). Petitioner also filed a Motion to Exclude Exhibit 2043. Paper 35. Patent Owner filed an Opposition to the Motion (Paper 37), and Petitioner filed a Reply in support of the Motion (Paper 38).

In support of their respective positions, Petitioner relies on the Declarations of Drs. Maureen Reitman (Ex. 1004), Philip T. Lavin (Ex. 1005), David W. Feigal (Ex. 1029), and Christine S. Meyer (Ex. 1031), and the deposition testimony of Dr. Thomas P. Johnston (Ex. 1028); Patent Owner relies on the Declaration of Dr. Johnston (Ex. 2003).

Oral hearing was held on March 20, 2015. *See* Paper 42 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c) and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner has established by a preponderance of the evidence that claims 15–19 of the '832 patent are unpatentable. In rendering this Decision, we do not rely on Exhibit 2043, the subject of Petitioner's Motion to Exclude. Thus, we dismiss the Motion as moot.

The '832 Patent

The '832 patent relates to compositions and methods for treating narcotic dependence using an orally dissolvable film comprising

buprenorphine and naloxone, wherein the film provides a bioequivalent effect to Suboxone®. Ex. 1001, 4:53–58. 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.

At the time of the '832 patent invention, Suboxone®, an orally dissolvable tablet of buprenorphine and naloxone, was on the market for treating opioid dependency. *Id.* at 4:51–55. Buprenorphine, an opioid agonist, 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, an opioid antagonist, reduces the effect of buprenorphine, 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. According to the '832 patent,

> There [was] a need for an orally dissolvable film dosage form that provides the desired absorption levels of the agonist and antagonist, while providing an adhesive effect in the mouth, rendering it difficult to remove once placed in the mouth, thereby making abuse of the agonist difficult.

Id. at 1:65–2:2.

The '832 patent relates to film dosage compositions comprising buprenorphine and naloxone. *Id.* at 2:6–3:2. Such compositions are particularly useful for treating narcotic dependence. *Id.* at 1:13–14.

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.

Reviewed Grounds of Unpatentability

The Board instituted trial on the following grounds of unpatentability:

Claims Challenged	Basis	Reference(s)
15–19	§ 102(b)	Labtec[1]
15–19	§ 103	Labtec, Birch,[2] and Yang[3]

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1280–81 (Fed. Cir. 2015). Under that standard, absent any special definitions, we assign claim terms

[1] Leichs et al., Int'l Pub. No. WO 2008/040534 A2, published on April 10, 2008 (Ex. 1017, "Labtec").
[2] Birch et al., U.S. Patent Publication No. 2005/0085440 A1, published on April 21, 2005 (Ex. 1019, "Birch").
[3] Yang et al., U.S. Patent No. 7,357,891 B2, issued on April 15, 2008 (Ex. 1016, "Yang").

their ordinary and customary meaning, as understood by a person of ordinary skill in the art, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Decision to Institute, we concluded that "film formulation" encompasses film dosage, film composition, or film, but not a formulation that is not in the form of a film. Dec. 11. We also determined that the term "provides an in vivo plasma profile" needs no construction beyond its ordinary meaning. *Id.* at 12. During trial, the parties did not dispute these constructions. Having considered the complete record developed at trial, we see no reason to change our interpretation of those terms.

In its Response, however, Patent Owner presents arguments with respect to two additional terms. PO Resp. 18–26. First, Patent Owner challenges Petitioner's position that the wherein clause of claim 15 is not entitled to patentable weight. *Id.* at 18–20. Second, Patent Owner contends that "the challenged claims should be construed as requiring a film formulation that provides, and as reciting pharmacokinetic ranges resulting from, oral transmucosal absorption." *Id.* at 20–26. We address each issue in turn.

The "Wherein" Clause

Claim 15 recites an orally dissolving film formation, "wherein said formulation provides" specific pharmacokinetic profiles. Ex. 1001, 24:56–61. Petitioner argues that the wherein clause merely recites a desired result, and is not entitled to patentable weight. Pet. 23–26. Patent Owner counters that the pharmacokinetic ranges recited in the wherein clause "give crucial meaning to, and provide defining characteristics provided by the film formulation at issue." PO Resp. 19–20. We agree with Patent Owner.

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