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Paper 23
Date: June 10, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

INDIVIOR UK LIMITED,
Patent Owner.

Case IPR2016-00280
Patent 8,475,832 B2

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

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

Teva Pharmaceuticals USA, Inc., ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–7 and 9–12 of U.S. Patent No. 8,475,832 B2 (Ex. 1001, "the '832 patent"). Paper 1 ("Pet."). Indivior UK Limited ("Patent Owner") filed a Preliminary Response. Paper 16 ("Prelim. Resp."). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless it is determined that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

We determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any claim challenged in the Petition. Accordingly, we decline to institute an *inter partes* review.

A. Related Proceedings

The parties identify multiple lawsuits where Patent Owner has filed suit against Petitioner and other defendants asserting infringement of the '832 patent in several U.S. district courts. Pet. 7–8; Paper 7, 3–4. In addition, the parties discuss IPR2014-00998, where a panel previously denied an *inter partes* review based on a petition filed by a different petitioner, challenging claims 15–19 of the same patent at issue here. Pet. 8–9; Paper 7, 2; *BioDelivery Scis. Int'l., Inc. v. RB Pharm. Ltd.*, Case No. IPR2014-00998 (PTAB Dec. 19, 2014) (Paper 12). The parties also refer to IPR2014-00325, where a panel determined in a Final Written Decision that the petitioner in IPR2014-00998 had established by a preponderance of the evidence that claims 15–19 of the '832 patent were unpatentable. Pet. 8–9; Paper 7, 2; *BioDelivery Scis. Int'l., Inc. v. RB Pharm. Ltd.*, Case No.

IPR2014-00325 (PTAB June 30, 2015) (Paper 43). Patent Owner indicates that the Final Written Decision "is currently on appeal to the Court of Appeals for the Federal Circuit, Docket No. 16-1044." Paper 7 at 2–3; Pet. 9.

B. Proposed Grounds of Unpatentability

Petitioner advances four grounds of unpatentability under 35 U.S.C. § 103(a) in relation to claims 1–7 and 9–12 of the '832 patent (Pet. 12–13):

References	Statutory Basis	Challenged Claims
LabTec[1] in view of Yang,[2] the Suboxone® 2002 Label,[3] SBOA[4] and Birch[5]	§ 103(a)	1, 2, 4–7, 9, and 10
LabTec in view of Yang, the Suboxone® 2002 Label, SBOA, Birch, and the '055 publication[6]	§ 103(a)	3, 11, and 12

[1] WO 2008/040534 A2, published Apr. 10, 2008 ("LabTec") (Ex. 1007)

[2] Yang et al., U.S. Patent No. 7,357,891 B2, issued Apr. 15, 2008 ("Yang") (Ex. 1006).

[3] Suboxone® 2002 Label (Ex. 1008).

[4] Suboxone® Tablet Summary Basis of Approval ("SBOA") (Ex. 1009).

[5] Birch et al., U.S. Pat. Appl. Publ. No. 2005/0085440 A1, published Apr. 21, 2005 ("Birch") (Ex. 1004).

[6] Yang et al., U.S. Pat. Appl. Publ. No. 2005/0037055 A1, published Feb. 17, 2005 ("the '055 publication") (Ex. 1010).

References	Statutory Basis	Challenged Claims
Oksche[7] in view of Yang, the Suboxone® 2002 Label, SBOA, and Birch	§ 103(a)	1, 2, 4–7, 9, and 10
Oksche in view of Yang, the Suboxone® 2002 Label, SBOA, Birch, and the '055 publication	§ 103(a)	3, 11, and 12

In addition, Petitioner supports its challenges in the Petition with a Declaration by Nandita Das, Ph.D. ("Das Decl.") (Ex. 1003). Pet. 13.

C. 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 release profile and drug absorption as compared to that of a Suboxone® tablet. Ex. 1001, 4:53–58, 2:55–62, 3:19–21. 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

[7] WO 2008/025791, published March 6, 2008 ("Oksche") (Ex. 1005).

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.

In relation to a "self-supporting film composition," the '832 patent describes that "local pH of the dosage is preferably controlled to provide the desired release and/or absorption" of the drugs. *Id.* at 11:8–10, 44–46, 11:62–12:3. As described in the patent:

> Buprenorphine is known to have a pKa of about 8.42, while naloxone has a pKa of about 7.94. According to pH partition theory, one would expect that saliva (which has a pH of about 6.5) would maximize the absorption of both actives. However, it has been surprisingly discovered by the Applicants that by buffering the dosage to a particular pH level, the optimum levels of absorption of the agonist and antagonist may be achieved. Desirably, the local pH of a composition including an agonist and an antagonist is between about 2 to about 4, and most desirably is from 3 to 4. At this local pH level, the optimum absorption of the agonist and the antagonist is achieved.

Id. at 11:46–57. Thus, the inventors achieved optimum absorption of both buprenorphine (agonist) and naloxone (antagonist) at a "local pH" of "about

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