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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").

that the Petition is redundant "because it substantially repeats the *same arguments* and relies substantially on the *same prior art* that the *same Petitioner* relied upon in its earlier ['325 IPR] Petition regarding the *same claims* of the *same patent*." *Id.* at 1. We agree.

In the '325 IPR, Petitioner challenged claims 15–19 of the '832 patent on numerous grounds, including, among others, (1) grounds based on Labtec[6] as the primary reference (for example, anticipation by Labtec, and obviousness over the combination of Labtec, Birch,[7] and Yang); and (2) grounds based on Euro-Celtique as the primary reference (including anticipation by Euro-Celtique, and obviousness over Euro-Celtique, either alone or in combination with Birch, or with Birch and Yang). *See* the '325 IPR, Paper 8 ("the '325 IPR Pet."). We instituted a trial to review whether the challenged claims are anticipated by Labtec and/or rendered obvious over the combination of Labtec, Birch, and Yang. *See* the '325 IPR, Paper 17.

In the '325 IPR, Petitioner did not explain any meaningful advantage of the Euro-Celtique-based grounds over the Labtec-based grounds. To the contrary, according to Petitioner, the Labtec-based grounds are not cumulative to the Euro-Celtique-based grounds "at least because [Labtec] explicitly 'identifies and understands the criticality of pH' to modify absorption"—a teaching that, according to Petitioner, Patent Owner "stated

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[6] Leichs et al., Int'l Pub. No. WO 2008/040534 A2, published on April 10, 2008 (Ex. 1017) ("Labtec").
[7] Birch et al., U.S. Patent Pub. No. 2005/0085440 A1, published on April 21, 2005 (Ex. 1019) ("Birch").

was lacking in Euro-Celtique" during the prosecution of the '832 patent. The '325 IPR Pet., 39. As a result, we exercised our discretion and declined to institute an *inter partes* review on all Euro-Celtique-based grounds. *See* the '325 IPR, Paper 17, 20.

Nearly two months after Patent Owner filed its Preliminary Response in the '325 IPR, Petitioner filed this second Petition, challenging claims 15–19 of the '832 patent based on four grounds: obviousness over (1) Euro-Celtique alone, (2) the combination of Euro-Celtique and the EMEA Study Report, (3) the combination of Euro-Celtique, the EMEA Study Report, and the '883 Application, or (4) the combination of Euro-Celtique, the EMEA Study Report, and Yang. Pet. 34–54. Petitioner acknowledges:

> This petition is directed to the same five claims of the same patent as the IPR2014-00325 proceedings. This petition involves the same parties as the IPR2014-00325 proceedings. The grounds in this petition are substantially based on a subset of the references cited in the IPR2014-00325 proceedings. While grounds in this petition cite two references that were not cited in IPR2014-00325, these two references are related to a reference cited in IPR2014-00325.

Id. at 2–3.

The two references allegedly not cited in the '325 IPR are the EMEA Study Report and the '883 Application. Petitioner, however, did present the EMEA Study Report in the '325 IPR Petition. *See* the '325 IPR Pet., iii (showing the EMEA Study Report as Ex. 1015 in the Exhibit list). In addition, Petitioner specifically cited the EMEA Study Report for disclosing the Cmax and AUC values of naloxone. *Id.* at 28, *see also id.* at 40–41 (citing the EMEA Study Report in claim chart for unpatentability grounds

based on Labtec), 49 (citing the EMEA Study Report in claim chart for unpatentability grounds based on Euro-Celtique). Noting Petitioner's argument, we cited the EMEA Study Report in our decision to institute the '325 IPR. *See* the '325 IPR, Paper 17, 14 (acknowledging Petitioner's reliance on page 12 of the EMEA Study Report). In the present case, Petitioner cites the same page of the EMEA Study Report (page 12) for the same disclosure, i.e., for disclosing "mean Cmax and AUC values for buprenorphine and naloxone following administration of Suboxone tablets that fall within the ranges recited in claims 15-17." Pet. 45.

Petitioner did not cite the '883 Application in the '325 IPR petition. But, according to Petitioner, Euro-Celtique, "a primary reference in both this petition and the IPR2014-00325 petition . . . repeatedly cites" the '883 Application. *Id.* at 3; *see also id.* at 49 (stating that Euro-Celtique identifies the '883 Application as "describing 'standard technology' for preparing films"). Petitioner explains that the '883 Application is part of a family of patent applications that resulted in Yang, a U.S. patent that Petitioner relied on in the '325 IPR. *Id.* at 49. In its Motion for Joinder, Petitioner further states that the '883 Application "is cited for the same relevant disclosure as a related family member cited in the ['325 IPR] Petition (*i.e.*, *Yang*)." Paper 6, 9.

Having considered the papers filed in this proceeding, as well as the papers filed in the '325 IPR, we agree with Patent Owner that Petitioner has recycled previous art and arguments. *See* Prelim. Resp. 24–32. Petitioner does not provide any persuasive reasoning as to why we should institute

another *inter partes* review of the same challenged claims over "the same or substantially the same prior art or arguments" that were presented in the '325 IPR.[8] Based on the totality of the facts before us, we exercise our discretion and deny the Petition under 35 U.S.C. § 325(d). We dismiss as moot Petitioner's Motion for Joinder with the '325 IPR.

ORDER

Accordingly, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 15–19 of the '832 patent is *denied*; and

FURTHER ORDERED that the Motion for Joinder with Case IPR2013-00325 is *dismissed*.

[8] Petitioner contends that "[i]n addition to the recited limitations, Euro-Celtique discloses features that are disclosed in the '832 patent but not required by the claims 15-19," such as a mucoadhesive film and a film that delivers active through the mucosa. Pet. 41. This argument was not presented in the '325 IPR. Petitioner does not, however, explain why these features matter to our patentability analysis, if they are not required by the challenged claims.

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