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Paper 18
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,
Petitioners,

v.

INDIVIOR UK LIMITED,
Patent Owner.

Case IPR2016-01113
Patent 8,475,832 B2

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

BONILLA, *Vice Chief Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Petitioner"), filed a Request for Rehearing under 37 C.F.R. § 42.71(d) of our Decision (Paper 16, "Decision" or "Dec.") denying *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 17 ("Req. Reh'g"). In our Decision, we denied institution as to all of the grounds set forth in the Petition (Paper 1, "Pet."). Dec. 2–4, 10–19. Petitioner's Request for Rehearing seeks reconsideration of our denial to institute each of the grounds. Req. Reh'g 1.

Under 37 C.F.R. § 42.71(c), "[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion." An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus., Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988). The request for rehearing "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." 37 C.F.R. § 42.71(d). A party who requests rehearing bears the burden of showing that a decision should be modified. *Id.*

II. ANALYSIS

Petitioner argues that we "erred in applying a legally improper, overly restrictive obviousness analysis and ignoring the ample evidence provided by Petitioner and its expert." Req. Reh'g 3. Specifically, Petitioner takes issue with our statement in the Decision that Petitioner did "not point to

where the SBOA,[1] the Suboxone® 2002 Label,[2] and/or LabTec[3] suggest that anyone actually measured a local pH for the Suboxone tablets in an oral cavity, much less determined that local pH should be from about 3 to about 3.5." *Id.* at 4, 10 (quoting Dec. 13). Petitioner states that we "applied an overly restrictive standard in requiring the SBOA, the Suboxone® 2002 Label, and/or LabTec to 'actually measure a local pH for the Suboxone tablets in an oral cavity' or to '[determine] that a local pH should be from about 3 to about 3.5,'" and that we "ignored the teachings in these references of the importance of pH, including specifically teaching that a pH range exists, for dissolution and transmucosal absorption." *Id.* at 10 (alteration in original) (quoting Dec. 13).

Petitioner alleges that our Decision took a teaching from LabTec out of context, namely that "[f]or a basic active ingredient," one would lower the pH for the purpose of "retarding absorption of the active ingredient through the oral mucosa." *Id.* at 9 (alteration in original) (emphasis omitted) (quoting Dec. 17). Petitioner also repeats its argument that given the teachings of the applied references, including "knowledge of the pH dependence of the transmucosal absorption of buprenorphine and naloxone," it only would have required routine experimentation to obtain an optimal pH range, and to arrive at the claimed pH range of about 3 to about 3.5. *Id.* at 13.

Petitioner further argues that it did not rely solely on the SBOA,

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

[2] Suboxone® 2002 Label (Ex. 1008).

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

Suboxone® 2000 Label, and LabTec. *Id.* at 4. Specifically, the Request for Rehearing summarizes the Petition's description of LabTec, Oksche,[4] Yang,[5] the Suboxone® 2002 Label, the SBOA, Dr. Çelik's testimony (Ex. 1003), Birch,[6] and the '055 publication,[7] and argues that as supported by Dr. Çelik's testimony, LabTec and Oksche provided a motivation to develop the film version of Suboxone® tablets, and Yang established a reasonable likelihood of success in manufacturing a film product bioequivalent to Suboxone® tablets. Req. Reh'g 4–8.

The Request for Rehearing also asserts that Birch taught administration of buprenorphine-containing formulations to the nasal mucosa at a pH of about 3.5, which successfully resulted in transmucosal absorption of buprenorphine and the desired bioequivalence, such that as a result, there was a motivation to use a pH of 3.4 for a film dosage form of buprenorphine and naloxone with a reasonable likelihood of success of achieving bioequivalence to the tablet form. *Id.* at 6, 11–12. Petitioner relies on Dr. Çelik's testimony in support of this assertion. *Id.* at 11–12. Furthermore, Petitioner alleges that we erred in discounting Dr. Çelik's testimony regarding similar anatomy of the oral and nasal mucosa as conclusory. *Id.*

We disagree with Petitioner that we applied an overly restrictive

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[4] WO 2008/025791 A1, published Mar. 6, 2008 ("Oksche") (Ex. 1005).

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

[6] Birch et al., U.S. Patent Application Publication No. 2005/0085440 A1, published Apr. 21, 2005 ("Birch") (Ex. 1004).

[7] Yang et al., U.S. Patent Application Publication No. 2005/0037055 A1, published Feb. 17, 2005 ("the '055 publication") (Ex. 1010).

obviousness analysis. In stating that Petitioner did "not point to where the SBOA, the Suboxone® 2002 Label, and/or LabTec suggest that anyone actually measured a local pH for the Suboxone tablets in an oral cavity, much less determined that local pH should be from about 3 to about 3.5, as recited in the challenged claims," we addressed Petitioner's reliance on those three references as collectively teaching or suggesting the claim limitations "[a] buffer in an amount to provide a local pH" of "about 3 to about 3.5." Dec. 13 (citing Pet. 27–32). We concluded that those three references did not provide sufficient evidence to establish those claim limitations as known prior art elements. *See id.* at 13–14.

Petitioner is incorrect that we ignored teachings in those three references concerning pH. Rather, we considered the Suboxone® Label's disclosure of a buffering system consisting of citric acid and sodium citrate and Petitioner's contention, relying on Dr. Çelik's testimony, that a citric acid and sodium citrate buffer operates within the range of 3.0 to 6.2. *Id.* at 12–13 (citing Pet. 31–32). We also considered the SBOA's disclosure of *in vitro* dissolution studies identifying redacted pH values, and Petitioner's conclusion based on the SBOA, "that in order for buprenorphine to dissolve, the local pH of the saliva had to be below a certain value, and for naloxone to dissolve, the pH had to be above a certain value because the solubility profiles of these drugs are dependent on pH." *Id.* at 11 (quoting Pet. 29); *id.* at 13 (citing Pet. 29–32). And we further considered LabTec's disclosure of the relationship between pH and absorption. *Id.* at 11 (citing Pet. 27–28); *id.* at 17. We found, however, insufficient evidence to support a conclusion that a local pH value for Suboxone® in the oral cavity or a local pH range of about 3 to about 3.5 were known or obvious. *Id.* at 11–14.

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