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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

INDIVIOR UK LIMITED,
Patent Owner.

Case IPR2019-00328
Patent No. 9,687,454 B2

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and RICHARD J. SMITH, *Administrative Patent Judges.*

SMITH, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. ("Petitioners") filed a Petition to institute an *inter partes* review of claims 1–3 and 5–14 ("the challenged claims") of U.S. Patent No. 9,687,454 B2 (the "'454 patent"). Paper 1 ("Pet."). Indivior UK Limited ("Patent Owner") filed a Preliminary Response to the Petition. Paper 12 ("Prelim. Resp.").

In its Preliminary Response, Patent Owner argued that the Petition should not be granted because the same or substantially the same prior art or arguments presented in the Petition were previously considered and rejected by the Office. Prelim. Resp. 1–29; *see* 35 U.S.C. § 325(d). Petitioners thereafter requested, via e-mail, a telephone conference with the Board to seek authorization to file a reply to the Preliminary Response to address the § 325(d) issue and other issues raised in the Preliminary Response.

A conference call was held between counsel for the parties and Judges Zhenyu Yang and Richard J. Smith on April 16, 2019, to discuss Petitioners' request. During the conference call, Petitioners were authorized to file a reply addressing the issues discussed during the conference call, and Patent Owner was authorized to file a sur-reply to Petitioner's reply. Paper 17. Petitioners filed their reply (Paper 19, "Reply") and Patent Owner filed its sur-reply (Paper 20, "Sur-reply").

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the arguments and evidence, we determine that it is appropriate to exercise our discretion to deny institution under 35 U.S.C. § 325(d). Accordingly, we

decline to institute *inter partes* review of the challenged claims of the '454 patent.

A. Related Proceedings

Petitioners and Patent Owner indicate that the '454 patent is involved in litigation in the District of New Jersey in three separate actions: *Indivior Inc. v. Dr. Reddy's Laboratories S.A.*, No. 2:17-cv-07111 (D.N.J.) (Consolidated); *Indivior Inc. v. Alvogen Pine Brook, Inc.*, No. 2:17-cv-07106 (D.N.J.) (Consolidated); and *Indivior Inc. v. Teva Pharmaceuticals USA, Inc.*, 2:17-cv-07115 (D.N.J.) (Consolidated). Paper 3, 2; Paper 4, 1. According to the parties, the '454 patent is also involved in litigation in the District of Delaware in *Indivior Inc. v. Actavis Laboratories UT, Inc.*, No. 1:18-cv-00499 (D. Del.). *Id.*

Petitioners state that the '454 patent is commonly owned with, shares the same specification as, and is a direct descendant of, U.S. Patent No. 8,475,832 ("the '832 patent"). Paper 3, 2. According to Petitioners, claims of the '832 patent were previously found invalid by the District of Delaware in *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Labs., Inc.*, No. CV 13-1674-RGA, 2016 WL 3186659, at *1 (D. Del. June 3, 2016) (Ex. 1006, "the Delaware Opinion"). *Id.* at 2–3. Petitioners state that aspects of that decision that do not involve the '832 patent are currently on appeal in: *Indivior Inc. v. Dr. Reddy's Laboratories, S.A.*, No. 17-2587 (Fed. Cir.); *Indivior Inc. v. Actavis Laboratories UT, Inc.*, No. 18-1405 (Fed. Cir.); and *Indivior Inc. v. Alvogen Pine Brook LLC*, No. 18-1949 (Fed. Cir.). *Id.* at 3.

Patent Owner states that the '454 patent descends from the '832 patent, and that claims 15–19 of the '832 patent were canceled on June 30, 2015, in Case No. IPR2014-00325. *BioDelivery Sciences Int'l Inc. v. RB Pharm. Ltd*, IPR2014-00325, slip op. 47 (Paper 43) (PTAB June 30, 2015).

Paper 4, 1. According to Patent Owner, that decision was affirmed by the Federal Circuit. *RB Pharm. Ltd. v. BioDelivery Sciences Int'l, Inc.*, 667 Fed. Appx. 997 (Fed. Cir. 2016). *Id.* Patent Owner also states that the Delaware district court separately found that certain asserted claims of the '832 patent, including claims 15–19, were invalid, citing the Delaware Opinion. *Id.* at 1–2; Ex. 1006.

The parties also identify U.S. Patent Application Serial No. 15/483,769, filed on April 10, 2017, that claims the benefit of the '454 patent, and Petitioners' filing of a second petition for *inter partes* review of the '454 patent in Case No. IPR2019-00329. Paper 3, 3; Paper 4, 1.

B. The '454 Patent (Ex. 1001)

The '454 patent "relat[es] to films containing therapeutic actives . . . [and] more particularly relates to self-supporting film dosage forms which provide a therapeutically effective dosage, essentially matching that of currently-marketed tablets containing the same active." Ex. 1001, 1:20–25. The '454 patent states that "[s]uch compositions are particularly useful for treating narcotic dependence while providing sufficient buccal adhesion of the dosage form." *Id.* at 1:25–27.

The '454 patent further states that "the invention relates to the treatment of opioid dependence in an individual, while using a formulation and delivery that hinders misuse of the narcotic." *Id.* at 4:64–67. The '454 patent explains that "[c]urrently, treatment of opioid dependence is aided by administration of Suboxone®, which is an orally dissolvable tablet. This tablet [] provides a combination of buprenorphine (an opioid agonist) and naloxone (an opioid antagonist)." *Id.* at 4:67–5:4. The '454 patent further explains that "the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides

a bioequivalent effect to Suboxone®. The film dosage preferably provides buccal adhesion while it is in the user's mouth, rendering it difficult to remove after placement." *Id.* at 5:4–10.

The '454 patent further states that "[t]he film dosage composition preferably includes a polymer carrier matrix. Any desired polymeric carrier matrix may be used, provided that it is orally dissolvable." *Id.* at 5:11–13. According to the '454 patent, "[t]he film may contain any desired level of self-supporting film forming polymer, such that a self-supporting film composition is provided." *Id.* at 13:1–3.

The '454 patent describes film compositions that "desirably contain[] a buffer so as to control the local pH of the film composition." *Id.* at 13:26–27. The '454 patent also describes several examples and states that "[t]he data indicates that not only is the local pH of significant importance, but the amount of buffer present in the formula is also important." *Id.* at 23:54–56.

C. Illustrative Claim

Claims 1 recites:

> 1. An oral, self-supporting, A mucoadhesive film comprising:
> (a) about 40 wt % to about 60 wt % of a water-soluble polymeric matrix;
> (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;
> (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and
> (d) an acidic buffer;
> wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;
> wherein the weight ratio of (b):(c) is about 4:1;
> wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and
> wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption

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