Trials@uspto.gov
571-272-7822

Paper 49
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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.

IPR2019-00329
Patent 9,687,454 B2

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

SMITH, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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 1–5 and 7–14 ("the challenged claims") of U.S. Patent No. 9,687,454 B2 (the "'454 patent"). Paper 1 ("Pet.").

On June 3, 2019, we entered our Decision on Institution (Paper 21, "Inst. Dec." or "Institution Decision") instituting *inter partes* review of all challenged claims under the only asserted ground. Inst. Dec. 28. Patent Owner filed a Response (Paper 33, "PO Resp."), Petitioner filed a Reply (Paper 42, "Reply"), and Patent Owner filed a Sur-reply (Paper 45, "Sur-reply").[1]

Petitioners and Patent Owner requested an oral hearing. Papers 43, 44. An oral hearing was held on March 3, 2020, and a transcript of that hearing has been entered into the record. Paper 48 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioners have demonstrated by a preponderance of the evidence that claims 1–5, 7, and 9–14 of the '454 patent are unpatentable, but have not demonstrated by a preponderance of the evidence that claim 8 of the '454 patent is unpatentable.

[1] Petitioners and Patent Owner filed objections to the other party's evidence, but did not file motions to exclude to preserve any objection. Papers 23, 24, 35; 37 C.F.R. § 42.64(c).

A. Real Parties-in-Interest

Petitioners identify the real parties-in-interest as Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. Pet. 42.

Patent Owner identifies Indivior UK Limited and Indivior Inc. as the real parties-in-interest. Paper 4, 1.

B. Related Matters

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.). Paper 3, 2; Paper 4, 1.

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. at 47 (Paper 43) (PTAB June 30, 2015). Paper 4, 1. Patent Owner indicates 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. *Id.* at 1–2 (citing the Delaware Opinion); 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. IPR2019-00328.[2] Paper 3, 3; Paper 4, 1.

C. The '454 Patent

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.

[2] Institution of a trial based on that second petition was denied on June 3, 2019. *See Dr. Reddy's Labs. S.A. v. Indivior UK Ltd.*, IPR2019-00328, Paper 21 at 21 (PTAB June 3, 2019).

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. However, the ’454 patent states that tablet forms have the potential for abuse and, in some instances, “the patient who has been provided the drug may store the tablet in his mouth without swallowing the tablet, then later extract the agonist from tablet and inject the drug into an individual’s body.” *Id.* at 2:1–5.

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 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

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