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Paper No. 23
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INDIVIOR INC.,
Petitioner,

v.

RHODES PHARMACEUTICALS L.P.,
Patent Owner.

Case IPR2018-00795
Patent 9,370,512 B2

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

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I. INTRODUCTION

Indivior Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–24 of U.S. Patent No. 9,370,512 B2 (Ex. 1001, "the '512 patent"). Paper 1 ("Pet."). Rhodes Pharmaceuticals L.P. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 17 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to the Preliminary Response (Paper 20), and Patent Owner filed a Surreply ("Surreply," Paper 22).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is 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 an *inter partes* review of the challenged claims of the '512 patent.

A. Related Proceedings

Patent Owner has asserted the '512 patent against Petitioner in a pending lawsuit, *Rhodes Pharmaceuticals L.P. v. Indivior Inc.*, Case No. 1-16-cv-01308 (D. Del.). Pet. 3; Paper 4, 2.

Patent Owner has also identified several patents and applications that are related by priority to the '512 patent, but "does not concede that any of the above-identified patents or applications would affect, or be affected by, a decision" in this proceeding. Paper 4, 1.

B. The '512 Patent

The '512 patent relates to oral pharmaceutical dosage forms comprising buprenorphine that release buprenorphine instantly upon oral application of the dosage form. Ex. 1001, 1:4–7. Buprenorphine

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preparations are administered in drug substitution programs to treat opioid addiction. *Id.* at 1:61–63. According to the specification, buprenorphine is administered in the form of a tablet for sublingual administration. *Id.* Drug addicts, however, sometimes attempt to divert the tablets by removing them from the mouth when the supervising healthcare professional is not looking. *Id.* at 2:4–7. The tablets may then be sold or the buprenorphine may be extracted to administer it parenterally. *Id.* at 2:7–9.

The '512 patent specification notes the drug Suboxone, which is approved in the United States, is also aimed at preventing the possibility of abuse. *Id.* at 2:10–12. Suboxone comprises buprenorphine and the opioid antagonist naloxone. *Id.* at 2:13–15. The naloxone is intended to prevent parenteral abuse of buprenorphine, as naloxone causes serious withdrawal symptoms when co-administered parenterally with buprenorphine. *Id.* at 2:15–18.

Accordingly, the specification states it is an object of the invention to provide an oral dosage form of buprenorphine "that is less prone to diversion and/or abuse in drug substitution therapy." *Id.* at 2:31–34. Thus, in one embodiment, the invention relates to a dosage form that releases buprenorphine instantly upon oral, preferably sublingual, application of the dosage form. *Id.* at 2:38–43.

C. Illustrative Claim

Petitioner challenges claims 1–24 of the '512 patent, of which claims 1 and 19 are the only independent claims. Claim 1 is representative and is reproduced below:

> 1. A method of opioid substitution therapy for treating opioid addiction, the method comprising contacting the sublingual mucosa of a patient in need

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thereof with a sublingual film dosage form comprising:

a) approximately 0.1 mg to approximately 16 mg buprenorphine, or an equivalent amount of a pharmaceutically acceptable salt thereof;

b) naloxone or a pharmaceutically acceptable salt thereof; and

c) at least one non-gelatin polymeric film-forming material in which the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof, are dissolved or homogeneously dispersed;

the buprenorphine or the equivalent amount of the pharmaceutically acceptable salt thereof and the naloxone or the pharmaceutically acceptable salt thereof being present in the sublingual film dosage form in a weight ratio of from 1:1 to 10:1;

such that within less than 5 minutes after contacting the sublingual mucosa of the patient with the sublingual film dosage form, the buprenorphine or the pharmaceutically acceptable salt thereof and approximately substantially all of the naloxone or the pharmaceutically acceptable salt thereof contact the sublingual mucosa, and wherein said contacting achieves:

(i) an average buprenorphine AUC_{0-48} from approximately 10 to approximately 15 (hrs*ng)/ml when the sublingual film dosage form includes 4 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof;

(ii) an average buprenorphine AUC_{0-48} from approximately 15 to approximately 25 (hrs*ng)/ml when the sublingual film dosage

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form includes 8 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof, or

(iii) an average buprenorphine AUC_{0-48} from approximately 25 to approximately 40 (hrs*ng)/ml when the sublingual film dosage form includes 16 mg buprenorphine or an equivalent amount of a pharmaceutically acceptable salt thereof.

Ex. 1001, 11:39–12:14.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–24 of the '512 patent on the following grounds:

References	Basis	Claim(s) challenged
Cremer[1] and Suboxone PDR[2] in view of Fuisz[3] and/or Rademacher[4]	§ 103	1–5 and 7–24
Cremer, Suboxone PDR, and McAleer[5] in view of Fuisz and/or Rademacher	§ 103	6

[1] Cremer et al., AU 741362, published July 15, 1998 ("Cremer," Ex. 1004).
[2] Entry for Suboxone in PHYSICIANS' DESK REFERENCE 2866–69 (58th ed., 2004) ("Suboxone PDR," Ex. 1005).
[3] Fuisz et al., WO 03/030883 A1, published Apr. 17, 2003 ("Fuisz," Ex. 1007).
[4] Rademacher et al., US 2005/0163830 A1, published July 28, 2005 ("Rademacher," Ex. 1009).
[5] McAleer et al., *Pharmacokinetics of High-Dose Buprenorphine Following Single Administration of Sublingual Tablet Formulations in Opioid Naïve Healthy Male Volunteers Under a Naltrexone Block*, 72 DRUG AND ALCOHOL DEPENDENCE 75–83 (2003) ("McAleer," Ex. 1013).

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