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Paper No. 9
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS XI LLC,
Petitioner,

v.

INSYS PHARMA, INC.,
Patent Owner.

Case IPR2015-01799
Patent 8,835,460 B2

Before DEBORAH KATZ, GRACE KARAFFA OBERMANN, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 1–5 of U.S. Patent 8,835,460 B2 ("the '460 patent"). Paper 1 ("Pet."). Patent Owner filed a Preliminary Response. Paper 8 ("Prelim. Resp."). We have statutory authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless the Petition demonstrates "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Taking account of the information presented in the Preliminary Response, we conclude that the Petition fails to make that showing. On this record, we deny the Petition and decline to institute review.

A. Related Proceedings

Petitioner identifies no related district court proceedings. Pet. 2–3. With this decision, we issue decisions denying *inter partes* review in IPR2016-01797 and IPR2016-01800, which involve the same parties and related patents.

B. The '460 Patent

The '460 patent relates to a sublingual formulation of fentanyl, an opioid receptor agonist with analgesic potency up to 100 times that of morphine. Ex. 1001, 1:13–14. Sublingual delivery is achieved through the mucosal membranes lining the floor of the mouth. *Id*. at 8:27–28. The '460 patent describes a sublingual formulation of fentanyl useful for relieving "breakthrough pain" in cancer patients almost immediately after administration. *Id*. at 6:29–42.

The '460 patent distinguishes sublingual (floor of the mouth) administration from other routes of delivery, for example, buccal (lining of the cheeks) administration. *Id*. at 7:49–8:33. The '460 patent discloses a fentanyl formulation delivered "to the sublingual mucosa via spray," which "results in a rapid onset of therapeutic effect of" the active agent. *Id*. at 9:46–49. The formulations are

"delivered as liquid droplets having a mean diameter of at least about 10 microns," with a preferred distribution "from about 30 microns to about 70 microns." *Id.* at 9:36–45.

C. The Challenged Claims

Petitioner challenges claims 1–5 of the '460 patent. Critical to our analysis, each challenged claim relates to a sublingual fentanyl formulation in the form of liquid "droplets having a mean diameter" that falls within specified ranges. Claim 1 is illustrative and reads as follows (emphasis added):

> 1. A sublingual formulation comprising discrete liquid droplets of an effective amount of fentanyl or a fentanyl derivative selected from the group consisting of sufentanil, carfentanil, lofentanil and alfatenil,[1] a free base or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable liquid carrier, *said droplets having a mean diameter of from about 30 to about 70 microns*.

Claims 2 and 3 require a non-propellant sublingual fentanyl formulation comprising discrete liquid "droplets having a mean diameter of at least about 10 microns." Claim 4 requires liquid "droplets having a mean diameter of from about 30 to about 70 microns." Claim 5 depends from claim 1 and, thus, inherits the limitation that requires discrete liquid "droplets having a mean diameter of from about 30 to about 70 microns."

D. The Asserted Prior Art

The Petition asserts the following references in the grounds of unpatentability:

1. UK Patent Pub. No. GB 2399286 A, pub. Sept. 15, 2004. (Ex. 1003) ("Ross GB").

[1] The '460 patent specification discloses that the fentanyl derivative intended is alfentanil. Ex. 1001, 6:26–28; 18:29, 40.

2. US Patent Pub. No. 2002/0055496 A1, pub. May 9, 2002 (Ex. 1005) ("McCoy").

3. US Patent No. 5,370,862, issued Dec. 6, 1994 (Ex. 1004) ("Klokkers-Bethke").

4. US Patent No. 6,946,150 B2, issued Sept. 20, 2005 (Ex. 1007) ("Whittle").

D. Asserted Grounds of Unpatentability

The Petition asserts the following grounds of unpatentability:

References	Basis	Claim(s) Challenged
Ross GB and McCoy	§ 103	1, 4, 5
Ross GB, Klokkers-Bethke, and McCoy	§ 103	2, 3
Ross GB and Whittle	§ 103	1, 4, 5
Ross GB, Klokkers-Bethke, and Whittle	§ 103	2, 3
McCoy	§ 102(b)	1, 4, 5

In addition to the asserted prior art references, the Petition advances declaration testimony of Dr. Kinam Park. Ex. 1002.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe claim terms of an unexpired patent according to their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b). Under that standard, we assign terms their ordinary and customary meaning as understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d

1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We construe only those terms necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The broadest reasonable interpretation of "discrete liquid droplets" requires express construction. That term is not defined, but is closely associated with the term "spray," in the '460 patent specification. Ex. 1001, 3:17–20 (invention is directed to "a liquid spray formulation in the form of discrete liquid droplets"). Based on the information presented, we accept Petitioner's view that the broadest reasonable interpretation of "discrete liquid droplets" is "water or other liquid broken up into minute droplets and blown, ejected into, or falling through the air." Pet. 14 (quoting Ex. 1008) (dictionary definition of "spray"). That interpretation is reasonable in view of the claim wording, the specification, and the dictionary definition of "spray" advanced by Petitioner. No other claim term requires express construction for the purposes of this decision.

B. Grounds Based on Obviousness

The Petition states four grounds of obviousness based on various combinations of asserted prior art references. Pet. 5–6. We focus on a single dispositive issue; namely, whether the information presented shows sufficiently that the asserted prior art references would have recommended, to one of ordinary skill in the art, modifying Ross GB's "spray" formulation to provide "droplets having a mean diameter" within the specified ranges of the challenged claims.

We first address whether Ross GB's reference to a "spray" formulation constitutes disclosure of "discrete liquid droplets." *Id*. at 19. We then turn to whether Petitioner shows sufficiently that an ordinary artisan would have been led

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