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Paper No. 13
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

J. KYLE BASS and ERICH SPANGENBERG,
Petitioners,

v.

ALPEX PHARMA SA,
Patent Owner.

Case IPR2016-00245
Patent 8,440,170 B2

Before TONI R. SCHEINER, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Messrs. J. Kyle Bass and Erich Spangenberg ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 8,440,170 B2 (Ex. 1001, "the '170 patent"). Paper 5 ("Pet."). Alpex Pharma SA ("Patent Owner") filed a Corrected Preliminary Response to the Petition. Paper 12 ("Prelim. Resp.").

We have jurisdiction 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." Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–3, 5, 6, 8, and 9. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Neither Petitioner nor Patent Owner identifies any related matters. *See, e.g.*, Pet. 2 ("Petitioner is unaware of any other matter related to the '170 patent").

B. The '170 Patent (Ex. 1001)

The '170 patent issued on May 14, 2013, with Federico Stroppolo and Shahbaz Ardalan as the listed co-inventors. Ex. 1001. As set forth in the '170 patent, "the invention relates to orally disintegrating tablets with speckled appearance for easy identification by physicians, nurses and patents." *Id.* at 1:13–16. According to the '170 patent:

> Orally Disintegrating Tablets (ODT) dissolve in the oral cavity by contact with saliva, do not require water for ingestion and could permit a buccal absorption of the active ingredient.

> The advantageous properties of ODT over conventional tablets are making them always more and more popular for drug administrations.

Id. at 1:38–43.

The '170 patent teaches that the use of solid or semisolid forms having a speckled appearance is common in cosmetic and laundry products, such as toothpastes and soaps, with the speckled appearance being achieved by incorporating a colored bead comprised of a different material into the composition. *Id.* at 2:4–8. For ODT, the '170 patent teaches that the

> colored beads must be soluble and dissolve as fast as the tablets to avoid an unpleasant grinding sensation when the tablet disintegrates in the oral cavity. Moreover, the colored beads must be stable, i.e. they must not release the color during storage, and should give minimal coloration of the oral cavity after disintegration of the tablet.

Id. at 2:9–14.

The '170 patent teaches that the speckled appearance is achieved by using colored granules of a water-soluble sugar, such as sucrose or sorbitol, which are mixed with a pharmaceutically acceptable carrier in the preparation of the ODT. *Id.* at 2:20–39. The colored granules "have a particle size from about 10 µm to about 1200 µm, preferably from about 200 µm to about 800 µm, most preferably from about 300 µm to about 500 µm." *Id.* at 2:55–58. According to the '170 patent, the "particle size of the colored granules is critical," as "[c]olored granules with too small particle size are not visible," and will not provide a speckled appearance, whereas "the use of colored granules with too large particle size results in a tablet which appears uniformly colored." *Id.* at 2:49–54.

C. Illustrative Claim

Petitioner challenges claims 1–9 of the '268 patent. Claim 1 is the only independent claim, is illustrative of the challenged claims, and is reproduced below:

> 1. An orally disintegrating tablets with speckled appearance comprising (a) speckles comprising colored granules of a water-soluble sugar, and (b) a pharmaceutically acceptable carrier.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–9 of the '268 patent on the following grounds (Pet. 11):

References	Basis	Claims Challenged
Prevacid Label®[1] and Stawski[2]	§ 103(a)	1–9
Prevacid Label and Serpelloni[3]	§ 103(a)	1–3, 5, 6, 8, and 9

Petitioner relies also on the Declaration of Kinam Park, Ph.D. Ex. 1002.

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[1] *PREVACID® (lansoprazole) Delayed-Release Capsules; PREVACID® (lansoprazole) For Delayed-Release Oral Suspension; PREVACID® SoluTab™ (lansoprazole) Delayed-Release Orally Disintegrating Tablets*, Medicine Online (June 2007), http://www.medicineonline.com/drugs/p/3694/PREVACID-lansoprazole-Delayed-Release-CapsulesPREVACID-lansoprazole-For-Delayed-Release-Oral-SuspensionPREVACID-SoluTab-lansoprazole-Delayed-Release-Orally-Disintegrating-Tablets.html (Ex. 1004) ("Prevacid® Label").

[2] Stawski et al., Pub. No. US 2006/0193909 A1, published Aug. 31, 2006 (Ex. 1005) ("Stawski").

[3] Serpelloni, U.S. Patent No. 4,744,991, issued May 17, 1988 (Ex. 1006) ("Serpelloni").

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable constructions in light of the Specification of the patent in which they appear. *See* 37 C.F.R. §42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA," and "the standard was properly adopted by PTO regulation."), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (2016) (mem.) (No. 15-446). Under the broadest reasonable construction standard, claim terms are presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

i. "Orally Disintegrating Tablets"

Patent Owner contends that "orally disintegrating tablets" should be construed as "one that dissolves in the mouth (without requiring water for ingestion) such that absorption of the active ingredient can occur there." Prelim. Resp. 7. Specifically, Patent Owner points to the following teaching of the '170 patent:

> Orally Disintegrating Tablets (ODT) dissolve in the oral cavity by contact with saliva, do not require water for ingestion and could permit a buccal absorption of the active ingredient.

Id. (quoting Ex. 1001, 1:38–41).

Based on the above quoted language and citing *In re Suitco Surface*, 603 F.3d 1255 (Fed. Cir. 2010), and *In re Buszard*, 504 F.3d 1364 (Fed. Cir. 2007), Patent Owner argues that "orally disintegrating tablets" "must mean

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