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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GRAY SQUARE PHARMACEUTICALS, LLC,
Petitioner,

v.

POZEN, INC.,
Patent Owner.

Case IPR2016-00191
Patent 7,332,183 B2

Before DONNA M. PRAISS, JO-ANNE M. KOKOSKI, and JEFFREY W. ABRAHAM, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

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

I. INTRODUCTION

Gray Square Pharmaceuticals, LLC[1] ("Petitioner"), filed a Petition seeking *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,332,183 B2 (Ex. 1001, "the '183 patent"). Paper 1 ("Pet."). Pozen, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). After considering the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood of prevailing with respect to any of the challenged claims of the '183 patent. *See* 35 U.S.C. § 314(a). Accordingly, we deny the Petition, and do not institute *inter partes* review.

II. BACKGROUND

A. Related Proceedings

Patent Owner states that there are currently no judicial or administrative matters that would affect, or be affected by a decision in this case. Paper 6, 3. Petitioner identifies several previously-filed district court and Federal Circuit matters involving the '183 patent. Pet. 3.

B. The '183 Patent

The '183 patent, titled "Multilayer Dosage Forms Containing NSAIDs and Triptans," is directed to the treatment of migraine and other pain relief. Ex. 1001, 1:1–15. The '183 patent discloses pharmaceutical tablets containing naproxen and a triptan, wherein substantially all of the triptan is

[1] As of the November 12, 2015 filing date of the Petition, Petitioner operated under the name Graybar Pharmaceuticals, LLC. Pet. 3. Petitioner changed its name to Gray Square Pharmaceuticals, LLC on January 6, 2016. Paper 7.

found in one layer, and substantially all of the naproxen is found in a second, separate layer. *Id.* at 1:66–2:6. The layers are in a "side-by-side arrangement such that the dissolution of the naproxen occurs independently of the dissolution of triptan." *Id.* at 2:7–9. According to the '183 patent, a bilayer tablet dosage form having separate layers of naproxen and triptan has "surprisingly better properties" than other tablet arrangements. *Id.* at 2:9–11, 1:60–65 (noting advantages in terms of release properties, stability, and pharmacokinetic profile that "could not have been predicted a priori").

C. Challenged Claims

Petitioner challenges claims 1 and 2 of the '183 Patent, which are reproduced below:

> 1. A multilayer pharmaceutical tablet comprising naproxen and a triptan and, wherein:
>
> a) substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer; and
>
> b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said naproxen occurs independently of said triptan.
>
> 2. The tablet of claim 1, wherein said naproxen is in the form of naproxen sodium at between 200 and 600 mg.

D. References

Petitioner relies on the following references:

> Plachetka, U.S. Patent No. 6,060,499, issued May 9, 2000 ("Plachetka," Ex. 1007).
>
> Desai, U.S. Patent No. 5,756,125, issued May 26, 1998 ("Desai," Ex. 1009).

Ouali et al., U.S. Patent No. 6,183,779 B1, issued Feb. 6, 2001 ("Ouali," Ex. 1011).

Elger et al., U.S. Patent No. 4,844,907, issued July 4, 1989 ("Elger," Ex. 1012).

Devane et al., U.S. Patent No. 6,730,325 B2, issued May 4, 2004 ("Devane," Ex. 1013).

E. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

References	Statutory Basis	Claims Challenged
Plachetka and Ouali	§103	1 and 2
Plachetka and Elger	§103	1 and 2
Devane and Elger	§103	1 and 2
Plachetka and Desai	§103	1 and 2

Petitioner also relies on the declaration of Dr. Arthur H. Kibbe, Ph.D. Ex. 1002 ("Kibbe Declaration").

III. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct.

890 (mem.) (2016) (No. 15-446). Claim terms generally should be given their ordinary and customary meaning, except "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Id.* (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)).

An extraneous limitation should not be read into the claims from the specification. *E.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). An extraneous limitation is one the presence of which in a claim is unnecessary for the purpose of making sense of the claim. *See, e.g., In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994); *Renishaw PLC, v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

Petitioner proposes constructions under a broadest reasonable interpretation for "side-by-side arrangement" and "naproxen." Pet. 26–28. We determine that no express claim construction of these terms is required for purposes of this decision.

Patent Owner proposes a construction under the broadest reasonable interpretation for "dissolution of said naproxen occurs independently of said triptan." Prelim. Resp. 21–24. Patent Owner contends that this phrase means "the naproxen and triptan are in an immediate release form in the first and second layer such that their dissolution occurs at approximately the same rate as if the drugs were given separately." *Id.* at 21–22. In support of

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