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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMPLEX INNOVATIONS, LLC,
Petitioner,

v.

AMGEN INC.,
Patent Owner.

Case IPR2016-00085
Patent 7,829,595 B2

Before LORA M. GREEN, JONI Y. CHANG, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

HARLOW, *Administrative Patent Judge.*

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

I. INTRODUCTION

Petitioner, Complex Innovations, LLC ("CI"), filed a Petition requesting an *inter partes* review of claims 1–25 of U.S. Patent No. 7,829,595 B2 (Ex. 1001, "the '595 patent"). Paper 2 ("Pet."). Patent Owner, Amgen, Inc. ("Amgen"), filed a Preliminary Response on February 2, 2016. Paper 7 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

For the reasons set forth below, we deny the Petition.

A. Related Matters

No related proceedings concerning the'595 patent have been identified. Pet. 4; Paper 5, 2.

B. The '595 Patent

The '595 patent, titled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound," issued November 9, 2010, from U.S. Patent Application No. 10/937,870 (Ex. 1002), filed September 10, 2004. Ex. 1001, [54], [45], [21], [22]. The '595 patent claims priority to U.S. Provisional Patent Application No. 60/502,219, filed September 12, 2003. *Id*. at [60].

The ’595 patent describes a “pharmaceutical composition comprising a therapeutically effective amount of a calcium receptor-active compound and at least one pharmaceutically acceptable excipient, wherein the composition has a controlled dissolution profile.” *Id*. at Abstract. The ’595 patent also describes methods for treating diseases, including hyperparathyroidism, using the disclosed pharmaceutical composition. *Id*. at 4:17–22.

The ’595 patent explains that although calcium receptor-active compounds, such as cinacalcet, are known in the art, the low solubility of these compounds in water limits pharmaceutical formulation and delivery options, and can result in low bioavailability for these compounds. *Id*. at 1:7–20. To address these limitations, the ’595 patent discloses a pharmaceutical composition including cinacalcet and six excipients: microcrystalline cellulose, povidone, starch, crospovidone, colloidal silicon dioxide, and magnesium stearate. *Id*. at 11:14–14:14. The ’595 patent also discloses a method for treating hyperparathyroidism, hyperphosphonia, hypercalcemia, or elevated calcium phosphorus product, through the administration of this composition. *Id*. at 4:17–22, 16:14–20.

C. Illustrative Claim

Of the challenged claims, claims 1 alone is independent. Claim 1, reproduced below, is illustrative of the claimed subject matter.

> 1. A pharmaceutical composition comprising
>
> (a) from about 10% to about 40% by weight of cinacalcet HCl;
>
> (b) from about 40% to about 75% by weight of microcrystalline cellulose;
>
> (c) from about 1% to about 5% by weight of povidone;
>
> (d) from about 5% to about 35% by weight of starch;
>
> (e) from about 1% to about 10% by weight of crospovidone;
>
> (f) from about 0.05% to about 1.5% by weight of colloidal silicon dioxide; and
>
> (g) from about 0.05% to about 1.5% by weight of magnesium stearate;
>
> wherein the percentage by weight is relative to the total weight of the composition.

Ex. 1001, 14:16–19:31.

D. Prior Art Relied Upon

CI relies upon the following prior art references (Pet. 4–6):

Van Wagenen et al., US 6,211,244 B1, issued Apr. 3, 2001 ("Van Wagenen") (Ex. 1003); and

Handbook of Pharmaceutical Excipients (Arthur H. Kibbe, ed., 3rd ed. 2000) ("HPE") (Exs. 1012; Ex. 2005 (includes portions of reference not contained in Ex. 1012)).

E. Asserted Grounds of Unpatentability

CI asserts the following grounds of unpatentability (Pet. 7):

Claims	Basis	Reference(s)
1–25	§ 103(a)	Van Wagenen, HPE, and general knowledge of a person of ordinary skill in the art.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also 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 (mem.) (2016). Under this standard, we may take into account definitions or other explanations provided in the written description of the specification. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Neither party proposes any claim term for construction. Furthermore, we determine that, for purposes of this decision, it is unnecessary to interpret any claim term recited in the challenged claims of the '595 patent.

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