

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANOFI-AVENTIS U.S. LLC and
SANOFI-AVENTIS DEUTSCHLAND GMBH,
Petitioners,

v.

ASTRAZENECA PHARMACEUTICALS LP and
AMYLIN PHARMACEUTICALS, LLC,
Patent Owners.

Case IPR2016-00354
Patent 8,445,647 B2

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and
TINA E. HULSE, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GMBH (“Petitioner”) filed a Petition (Paper 3; “Pet.”) to institute an *inter partes* review of claims 1–6 of US 8,445,647 B2 (Ex. 1001; “the ’647 patent”). AstraZeneca Pharmaceuticals LP and Amylin Pharmaceuticals, LLC (“Patent Owner”) did not file a Patent Owner Preliminary Response. We apply the threshold for review under 35 U.S.C. § 314.

Upon consideration of the above-mentioned Petition, we conclude that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. We institute an *inter partes* review as to claims 1–6 of the ’647 patent.

A. *Related Proceedings*

Patent Owner identifies the following co-pending case involving the ’647 patent: *Sanofi-Aventis U.S. LLC, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, Civil Action No. 15-cv-00662-GMS (D. Del.). Paper 6.

Concurrent with the present *inter partes* review, Petitioner also requested review of claims in related patents, including: U.S. Patent No. 7,297,761 (Case IPR2016-00348); U.S. Patent No. 7,691,963 (Case IPR2016-00353); and U.S. Patent No. 8,951,962 (Case IPR2016-00355).

B. *The ’647 patent (Ex. 1001)*

The ’647 patent discloses “modified exendins and exendin agonists having an exendin or exendin agonist linked to one or more molecular weight increasing compounds, of which polyethylene glycol polymers (or other molecular weight increasing agents), and related products and methods.” Ex. 1001, 3:64–4:2. The ’647 patent discloses exendin-4 as a

peptide that has the sequence set forth in SEQ ID NO: 2. *Id.* at 1:38–48, 31:33–39, Figure 2. The “molecular weight increasing compounds” are described as follows:

A “molecular weight increasing compound” is one that can be conjugated to an exendin or exendin agonist and thereby increase the molecular weight of the resulting conjugate. Representative examples of molecular weight increasing compounds, in addition to PEG, are polyamino acids (e.g., poly-lysine, poly-glutamic acid, and poly-aspartic acid; see Gombotz, et al. (1995), *Bioconjugate Chem.*, vol. 6: 332-351; Hudecz, et al. (1992), *Bioconjugate Chem.*, vol. 3, 49-57; Tsukada, et al. (1984), *J. Natl. Cancer Inst.*, vol 73: 721-729; Pratesi, et al. (1985), *Br. J. Cancer*, vol. 52: 841-848), particularly those of the L conformation, pharmacologically inactive proteins (e.g., albumin; see Gombotz, et al. (1995) and the references cited therein), gelatin (see Gombotz, et al. (1995) and the references cited therein), succinyl-gelatin (see Gombotz, et al. (1995) and the references cited therein), (hydroxypropyl)-methacrylamide (see Gombotz, et al. (1995) and the references cited therein), a fatty acid, a polysaccharide, a lipid amino acid, and dextran.

Id. at 4:36–57.

The '647 patent discloses that “[t]he polyethylene glycol polymers (or other molecular weight increasing agents) are preferably linked to an amino, carboxyl, or thio group, and may be linked by N or C termini of side chains of lysine, aspartic acid, glutamic acid, or cysteine, or alternatively, the polyethylene glycol polymers or other molecular weight increasing agents may be linked with diamine and dicarboxylic groups.” *Id.* at 5:20–39.

C. Challenged claims

Claim 1 is the only independent claim of the '647 patent. Claim 1 is illustrative of the challenged claims and is reproduced below:

1. A compound comprising exendin-4, or agonist analog of exendin-4, linked to a polyamino acid through the C-terminal amino acid of the exendin-4 or agonist analog of exendin-4 and wherein the polyamino acid is selected from the group consisting of poly(L-lysine), poly-glutamic acid, and poly-aspartic acid.

Challenged claims 2–6 depend from claim 1, either directly or indirectly.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–6 of the '647 patent on the following grounds. Pet. 31–56.

Ground	Reference[s]	Basis	Claim[s] Challenged
1	Larsen PCT ¹	§ 102(e)	1–4
2	Larsen '107 ²	§ 102(e)	1–4
3	Larsen '486 ³	§ 102(e)	1, 2, 5, 6
4	RE '313 ⁴	§ 102(e)	1, 2, 5, 6
5	Larsen PCT	§ 103(a)	1–4

¹ International Application No. PCT/DK99/00118 to Bjarne Due Larsen, filed March 9, 1999, published in English as International Publication No. WO 99/46283 on September 16, 1999. Ex. 1009 (“Larsen PCT”).

² U.S. Patent No. 7,414,107 to Bjarne Due Larsen, issued August 19, 2008. Ex. 1010 (“Larsen '107”). Larsen '107 Patent is a continuation of Larsen '118 PCT.

³ U.S. Patent No. 6,528,486 to Bjarne Due Larsen et al., issued March 4, 2003. Ex. 1011 (“Larsen '486”).

⁴ U.S. Patent No. RE45,313 to Bjarne Due Larsen et al., issued December 30, 2014. Ex. 1012 (“RE '313”). RE '313 Patent is a reissue of Larsen '486 Patent.

Ground	Reference[s]	Basis	Claim[s] Challenged
6	Larsen '107	§ 103(a)	1–4

Petitioner relies also on the Declaration of Dr. S. Russ Lehrman (Ex. 1002).

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, No. 15-446, 2016 WL 3369425 (U.S. June 20, 2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only terms that are in controversy need to be construed, however, and then 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).

We interpret the following terms of the challenged claims as part of our analysis. Based upon the facts presented, we determine that the explicit construction of any other specific claim term is unnecessary to reach our decision that Petitioner has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir.

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