Trials@uspto.gov
Tel: 571-272-7822

Paper 7
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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 IPR2016-00355
Patent 8,951,962 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 (collectively, "Petitioner") filed a Petition (Paper 3; "Pet.") to institute an *inter partes* review of claims 1–3 and 7–9 of US 8,951,962 B2 (Ex. 1001; "the '962 patent"). AstraZeneca Pharmaceuticals LP and Amylin Pharmaceuticals, LLC (collectively, "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 1–3 and 7–9 of the '962 patent.

A. Related Proceedings

Patent Owner identifies the following co-pending case involving the '962 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. 8,445,647 (Case IPR2016-00354).

B. The '962 patent (Ex. 1001)

The '962 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, 4:9–15. The '962 patent discloses exendin-4 as a peptide that has the sequence set forth in SEQ ID NO: 2. *Id.* at 1:57–58, 31:1–21, 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 polysaccaride, a lipid amino acid, and dextran.

Id. at 4:52–5:3.

The '962 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 5:42–48.

C. Challenged claims

Challenges claims 1–3 and 7–9 of the '962 patent are 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, wherein the agonist analog of exendin-4 comprises one or more naturally occurring amino acids deleted or replaced with another amino acid or amino acids and said polyamino acid is selected from the group consisting of poly(L-lysine), poly-glutamic acid, and poly-aspartic acid.

2. The compound according to claim 1, wherein the polyamino acid is poly(L-lysine).

3. A pharmaceutical composition comprising the exendin-4, or agonist analog of exendin-4 according to claim 1 and a pharmaceutically acceptable carrier wherein the exendin-4, or the agonist analog of exendin-4 has a kidney clearance that is less than 50% of the kidney clearance of the exendin-4, or the agonist analog of exendin-4 without the C-terminal linked polyamino acid.

7. A method for treating diabetes, postprandial hyperglycemia, or impaired glucose tolerance comprising administering to a human in need of treatment for diabetes, postprandial hyperglycemia, or impaired glucose tolerance a therapeutically effective amount of a composition according to claim 3.

8. The method for treating diabetes according to claim 7.

9. The method according to claim 8, wherein the diabetes is type II diabetes.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1–3 and 7–9 of the '962 patent on the following grounds. Pet. 32–59.

Ground	Reference[s]	Basis	Claim[s] Challenged
1	Larsen PCT[1]	§ 102(e)	1–3
2	Larsen '107[2]	§ 102(e)	1–3
3	Larsen '486[3]	§ 102(e)	1–3, 7–9
4	RE '313[4]	§ 102(e)	1–3, 7–9
5	Larsen PCT	§ 103(a)	1–2
6	Larsen '107	§ 103(a)	1–2

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

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[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 is a continuation of Larsen 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 is a reissue of Larsen '486.

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