

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 IPR2016-00348
Patent 7,297,761 B2

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

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying 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, 3–6, 10–20, 22, 24–26, 30–33, 35, and 37–40 of US 7,297,761 B2 (Ex. 1001; “the ’761 patent”). AstraZeneca Pharmaceuticals LP and Amylin Pharmaceuticals, LLC (collectively, “Patent Owner”) filed a Patent Owner Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Based on the record before us, we are not persuaded that the information presented in the Petition demonstrates a reasonable likelihood that Petitioner will prevail in proving that at least one challenged claim would have been obvious under 35 U.S.C. § 103(a) based on the cited references. Accordingly, we deny the Petition and do not institute an *inter partes* review.

A. Related Proceedings

The parties identify the following co-pending cases involving the ’761 patent: 1) *Sanofi-Aventis U.S. LLC, et al. v. AstraZeneca Pharmaceuticals LP, et al.*, Civil Action No. 15-cv-00662-GMS (D. Del.); 2) *AstraZeneca Pharmaceuticals LP, et al. v. Teva Pharmaceuticals USA Inc., et al.*, No. 14-cv-1478-GMS (D. Del.); and 3) *Teva Pharmaceuticals USA Inc. v. AstraZeneca Pharmaceuticals LP, et al.*, No. 15-cv-50-GMS (D. Del.). Pet. 57–58; Paper 6.

Case No. 15-cv-50-GMS has been consolidated with *AstraZeneca Pharmaceuticals LP, et al. v. Teva Pharmaceuticals USA Inc., et al.*, No. 14-

cv-1478-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. 7,691,963 (Case IPR2016-00353); U.S. Patent No. 8,445,647 (Case IPR2016-00354); and U.S. Patent No. 8,951,962 (Case IPR2016-00355).

B. The '761 patent (Ex. 1001)

The '761 patent discloses pharmaceutical compositions comprising exendin-3 and an exendin-4, which are peptides found in the venom of the Gila-monster. Ex. 1001, 1:48–54, 3:63–4:60.

C. Challenged claims

Independent claims 1, 18, and 22 are illustrative of the challenged claims of the '761 patent and are reproduced below:

1. A pharmaceutical composition comprising an exendin-4 and an acetate buffer.

18. A pharmaceutical composition comprising exendin-4, mannitol, and an acetate buffer, wherein said composition has a pH from about 3.5 to about 5.0.

22. A pharmaceutical composition comprising a buffer and an exendin selected from at least one of the group consisting of an exendin-3, and an exendin-4, wherein said composition has a pH from about 3.5 to about 5.

Ex. 1001, 202:62–63, 203:43–45, 58–61.

Claims 3–6 and 10–17 depend, directly or indirectly, from claim

1. Claims 19–20 depend directly from claim 18. Claims 24–26, 30–33, 35, and 37–40 depend, directly or indirectly, from claim 22.

D. Asserted Grounds of Unpatentability

Petitioner contends that claims 1, 3–6, 10–20, 22, 24–26, 30–33, 35,

and 37–40 of the '761 patent are unpatentable as obvious under 35 U.S.C. § 103. Pet. 12. Petitioner does not set forth a specific ground of obviousness under 35 U.S.C. § 103. Rather, Petitioner contends that “[t]he claims of the '761 patent are obvious over [Eng¹] and secondary references that together would have pointed toward the claimed formulation in multiple different ways.” *Id.* at 20. Such secondary references include the following:

Elie G. Shami et al., Preformulation (Chapter 1), in *The Theory and Practice of Industrial Pharmacy* (Leon Lachman et al. eds., 2d ed. 1976). Ex. 1026 (“Shami”).

Kenneth E. Avis, Sterile Products (Chapter 21), in *The Theory and Practice of Industrial Pharmacy* (Leon Lachman et al. eds., 2d ed. 1976). Ex. 1027 (“Avis”).

Sol Motola & Shreeram Agharkar, Preformulation Research of Parenteral Medications (Chapter 4), in *Pharmaceutical Dosage Forms: Parenteral Medications Vol. 1* (Kenneth E. Avis et al. eds, 1984). Ex. 1028 (“Motola”).

Neelima P. Bhatt et al., Chemical Pathways of Peptide Degradation. I. Deamidation of Adrenocorticotrophic Hormone, 7 *Pharm. Res.* 593 (June 1990). Ex. 1030 (“ACTH”).

Kamlesh Patel & Ronald T. Borchardt, Chemical Pathways of Peptide Degradation. II. Kinetics of Deamidation of an Asparaginyl Residue in a Model Hexapeptide, 7 *Pharm. Res.* 703 (July 1990). Ex. 1031 (“Patel”).

Kamlesh Patel & Ronald T. Borchardt, Chemical Pathways of Peptide Degradation. III. Effect of Primary Sequence on the Pathways of

¹ U.S. Patent No. 5,424,286 to John Eng, issued on June 13, 1995. Ex. 1003 (“Eng”).

Deamidation of Asparaginyl Residues in Hexapeptide, 7 Pharm. Res. 787 (August 1990). Ex. 1032 (“Patel II”).

Cecilia Oliyai & Ronald T. Borchardt, Chemical Pathways of Peptide Degradation. IV. Pathways, Kinetics, and Mechanism of Degradation of an Aspartyl Residue in a Model Hexapeptide, 10 Pharm. Res. 95 (January 1993). Ex. 1033 (“Oliyai”).

Medical Economics Data Production Company, Physicians’ Desk Reference (49th ed. 1995). Ex. 1034 (“PDR”).

The United States Pharmacopeia (21st rev. 1985). Ex. 1036 (“Pharmacopeia”).

Petitioner relies also on the Declaration of Dr. Ralph Tarantino (Ex. 1002).

II. ANALYSIS

Section 312 requires that a petition for *inter partes* review “identif[y], . . . with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. § 312 (a)(3). Furthermore, our rules require a petition for *inter partes* review to (i) identify “[t]he specific statutory grounds under 35 U.S.C. [§] 102 or 103 on which the challenge to the claim is based and the patents or printed publications relied upon for each ground”; (ii) identify “[h]ow [each] construed claim is unpatentable under the statutory grounds identified”; (iii) “specify where each element of the claim is found in the prior art patents or printed publications relied upon”; and (iv) identify “the relevance of the evidence to the challenge raised, including identifying specific portions of the evidence that support

the challenge.” 37 C.F.R. § 42.104(b)(2), (4)–(5). Here, the Petition fails to explain sufficiently the specific combination of references it relies upon to satisfy these requirements.

We are persuaded by Patent Owner’s assessment of the Petition and agree that

Nowhere does the Petition actually state what particular combination or combinations of prior art references are being relied upon. Instead, the Petition obscures the particulars of the challenge, repeatedly stating that it is based on Eng and some unspecified combination of numerous secondary references that purportedly can be combined in what it generically terms “multiple different ways[.]”

Prelim. Resp. 21–22. As a result, the Petition fails to explain any specific combination of teachings, which creates an ambiguity as to which reference(s) Petitioner proposes would have been relied upon by a person of ordinary skill in the art to modify Eng to achieve the subject matter of the challenged claims. The Petition adds further ambiguity by setting forth multiple combinations and/or theories of obviousness without explaining with sufficient clarity how one of ordinary skill in the art would have combined the alleged disclosures to satisfy each limitation of the challenged claims. For example, Petitioner appears to argue that a group of references disclosing preformulation pH studies and another group of references suggesting the susceptibility of the exendins to deamidation “would have led to the same result,” thus suggesting that the Petitioner is advancing multiple combinations of references in its Petition to demonstrate obviousness. Pet. 41–42. Thus, we are left to speculate on the exact combination of references

relied upon to teach or suggest multiple limitations recited in the claims at issue, which we decline to do.

We will not attempt to fit evidence together into a coherent explanation that supports an argument demonstrating a reasonable likelihood that Petitioner would prevail. *See Hopkins Mfg. Corp. v. Cequent Performance Prods., Inc.*, IPR2015-00609, slip op. at 12 (Paper 9) (PTAB Aug. 14, 2015):

While it might be possible for us to arrive at an articulable ground by sifting through [p]etitioners' identifications of grounds, the claim charts, the references, and the numerous cited paragraphs of the expert declaration . . . we decline to do so or to require [p]atent [o]wner to engage in a similar exercise.

It is Petitioner's burden to demonstrate how the prior art would have made obvious the claimed subject matter as a whole, and Petitioner has not done this. Petitioner's presentation is incomplete in this respect and, therefore, insufficient to demonstrate a reasonable likelihood of prevailing on its obviousness challenge(s).

III. ORDER

For the reasons given, it is

ORDERED that the Petition is *denied* as to all challenged claims of the '761 patent and *inter partes* review is not instituted.

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IPR2016-00348
Patent 7,297,761 B2

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