

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PFIZER INC.,  
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case IPR2019-01023  
Patent 9,526,844 B2

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Before HYUN J. JUNG, BART A. GERSTENBLITH, and  
JAMES A. TARTAL, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

DECISION  
Instituting *Inter Partes* Review  
and  
Granting Motion for Joinder  
*35 U.S.C. §§ 314, 315(c)*

## I. INTRODUCTION

Pfizer Inc. (“Petitioner”) concurrently filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 21–30 of U.S. Patent No. 9,526,844 B2 (Ex. 1004, “the ’844 patent”) and a Motion for Joinder (Paper 3) with *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01682 (the “Mylan IPR”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Response to Petitioner’s Motion for Joinder (Paper 8) and a Waiver of Patent Owner’s Preliminary Response (Paper 9). Thereafter, Petitioner filed a Reply in Support of Petitioner’s Motion for Joinder Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22, 42.122(b). Paper 10. We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . and any response . . . 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.” 35 U.S.C. § 314(a).

Applying that standard, and upon consideration of the Petition and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we authorize an *inter partes* review to be instituted as to all challenged claims of the ’844 patent on all grounds raised in the Petition. We also *grant* Petitioner’s Motion for Joinder and, because we join Petitioner to the Mylan IPR, we terminate this proceeding.

## II. BACKGROUND

### A. *The '844 Patent*

The '844 patent, titled “Pen-Type Injector,” issued December 27, 2016, from an application filed May 17, 2016. Ex. 1004, [54], [45], [22]. The application that matured into the '844 patent claims priority to a foreign application filed March 3, 2003. *Id.* at [30]. The '844 patent “relates to pen-type injectors . . . where a user may set the dose.” *Id.* at 1:25–29.

### B. *Related Proceedings*

*Inter partes* review of claims 21–30 of the '844 patent was instituted on April 3, 2019, on petitions filed by Mylan Pharmaceuticals Inc. (“Mylan”) in both the Mylan IPR (i.e., IPR2019-01682) and in *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01680. Pet. 1. Additionally, *inter partes* review of claims 21–30 of the '844 patent was denied in *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01696. *Id.*

The parties indicate that patents related to the '844 patent are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01684, IPR2019-00122, IPR2019-00977, IPR2019-00978, IPR2019-00979, IPR2019-00980, IPR2019-00981, IPR2019-00982, IPR2019-00987, IPR2019-01022. Pet. 2; Paper 6, 2–4. The parties also identify related patent applications and patents. Pet. 2–4; Paper 6, 4–6.

The parties further indicate that the '844 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC, et al.*

*v. Mylan GmbH, et al.*, No. 1:17-cv-00181 (N.D.W.Va.). Pet. 1; Paper 6, 3.

The parties also indicate that patents related to the '844 patent have been asserted in *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, Nos. 1:14-cv-00113-RGA-MPT and 1:14-cv-00884 (D. Del.). Pet. 1–2, Paper 6, 3.

### C. *Real Parties in Interest*

Petitioner identifies itself and Hospira, Inc. as real parties in interest. Pet. 1. Patent Owner identifies itself, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 6, 1.

### D. *The Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 21–30 of the '844 patent on the following grounds:

Reference(s)	Basis	Claim(s) Challenged
Steenfeldt-Jensen <sup>1</sup>	§ 103	21–29
Steenfeldt-Jensen and Klitgaard <sup>2</sup>	§ 103	30

Pet. 5. Petitioner supports its challenge with a declaration by Charles E. Clemens, dated May 1, 2019. Ex. 1011. According to Petitioner, “[t]he opinions set forth in Mr. Clemens’s declaration are nearly identical to the opinions set forth in the declaration of Mr. Karl R. Leinsing filed in the Mylan IPR (Mylan IPR Ex. 1011).” Paper 3, 3.

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<sup>1</sup> U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, “Steenfeldt-Jensen”).

<sup>2</sup> U.S. Patent No. 6,582,404 B1, issued June 24, 2003 (Ex. 1017, “Klitgaard”).

### III. ANALYSIS

#### A. *Principles of Law*

A claim is unpatentable for obviousness under 35 U.S.C. § 103 if the differences between the claimed subject matter and the prior art are “such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which such subject matter pertains.” 35 U.S.C. § 103(a). The question of obviousness under 35 U.S.C. § 103 is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

#### B. *Claim Construction*

The Petition was filed on May 2, 2019. Paper 2. The claim construction standard applied in an *inter partes* review in which the petition was filed on, or after, November 13, 2018, is the federal court claim construction standard used in a civil action under 35 U.S.C. § 282(b). *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340, 51,344 (Oct. 11, 2018). Petitioner proposes the same construction of claim terms in the Petition as asserted by Mylan in the Mylan IPR. *Compare* Pet. 19–23 *with Mylan*, Case IPR2018-01682 (PTAB Sept. 10, 2018) (Paper 2, 18–22).

The petition in the Mylan IPR was filed prior to November 13, 2018. *See Mylan*, Case IPR2018-01682 (PTAB Sept. 10, 2018) (Paper 2). In an

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