

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 IPR2019-00978  
Patent 8,603,044 B2

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

GERSTENBLITH, *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”) filed a Petition (Paper 2, “Pet.”) requesting institution of an *inter partes* review of claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 (Ex. 1002, “the ’044 patent”). Concurrently with its Petition, Petitioner filed a Motion for Joinder seeking to join *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01676 (the “Mylan IPR”). Paper 3, 1.

Sanofi-Aventis Deutschland GmbH (“Patent Owner”) waived its Preliminary Response. Paper 9, 1; *see also* Paper 8, 1 (stating “Sanofi has also concurrently filed a waiver of its Preliminary Response in the above Pfizer IPRs”). Patent Owner filed a Response to Petitioner’s Motions for Joinder. Paper 8. 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.

For the reasons below, we institute *inter partes* review of challenged claims 11, 14, 15, 18, and 19 of the ’044 patent. We also grant Petitioner’s Motion for Joinder and join Petitioner to IPR2018-01676. In view of the joinder, we terminate this proceeding.

## II. BACKGROUND

### A. *Related Proceedings*

The parties indicate that the ’044 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.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113 (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*,

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No. 1:14-cv-00884 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Mylan GmbH*,  
No. 1:17-cv-00181 (N.D. W.Va.). Pet. 1–2; Paper 6, 2.

The parties also indicate that the '044 patent is challenged in Cases  
IPR2018-01675, IPR2018-01676, and IPR2019-00977. Pet. 1–2; Paper 6, 2.

The parties additionally indicate that patents related to the '044 patent  
are challenged in Cases IPR2018-01670, IPR2018-01677, IPR2018-01678,  
IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684,  
IPR2018-01696, IPR2019-00122, IPR2019-00979, IPR2019-00980,  
IPR2019-00981, IPR2019-00982, IPR2019-00987, IPR2019-01022, and  
IPR2019-01023. Pet. 2; Paper 6, 2–4. The parties further identify related  
patent applications and patents. Pet. 2–4; Paper 6, 4–6.

*B. 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.

*C. Evidence Relied Upon*

Petitioner identifies the following references as prior art in the  
asserted ground of unpatentability:

U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014,  
“Steenfeldt-Jensen”); and

U.S. Patent Application Publication No. 2002/0052578 A1, issued  
May 2, 2002 (Ex. 1015, “Moller”).

In support of its challenges, Petitioner provides a Declaration of  
Mr. Charles E. Clemens (Ex. 1011). *See* Paper 3, 3 (the “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)").

*D. Asserted Grounds*

Petitioner asserts that the subject matter of claims 11, 14, 15, 18, and 19 would have been obvious, under 35 U.S.C. § 103, to one of ordinary skill in the art at the time of the invention based on (1) Steinfeldt-Jensen alone and (2) the combination of Moller and Steinfeldt-Jensen. Pet. 5, 23–89.

III. INSTITUTION OF *INTER PARTES* REVIEW

The Petition is substantively identical to the petition in the Mylan IPR. *Compare* Pet. with Mylan IPR (Paper 2); *see also* Paper 3, 3–4 (stating that “the same claims of the ’044 patent are obvious over the same grounds and for substantially the same reasons set forth in the Mylan IPR” and that “the Petition does not contain any additional arguments or evidence (except for reliance on a different expert, as noted above) in support of the unpatentability of claims 11, 14, 15, 18, and 19 of the ’044 patent”). For substantially the same reasons discussed in the Institution Decision in the Mylan IPR, which we incorporate expressly herein, Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims of the ’044 patent. *Mylan IPR*, Paper 20.

Accordingly, we institute *inter partes* review of claims 11, 14, 15, 18, and 19 of the ’044 patent based on the asserted grounds of unpatentability set forth in the Petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). At this stage of the proceeding, we have not made a final determination as to the unpatentability of any challenged claim or any underlying factual or legal issue.

#### IV. MOTION FOR JOINDER

Petitioner contends that its Motion for Joinder is timely “because it is submitted within one month of the date the Mylan IPR was instituted.”

Paper 3, 4.

“Any request for joinder must be filed . . . no later than one month after the institution date of any *inter partes* review for which joinder is requested.” 37 C.F.R. § 42.122(b). On May 2, 2019, Petitioner filed the Motion for Joinder requesting to join the Mylan IPR. The Board instituted an *inter partes* review in the Mylan IPR on April 2, 2019. Petitioner requested joinder no later than one month after the institution date of the Mylan IPR. Petitioner’s Motion for Joinder, therefore, is timely.

Acting under the designation of the Director, we have discretion to determine whether to join a party to an instituted *inter partes* review.

35 U.S.C. § 315(c); 37 C.F.R. § 42.122(a). We may

join as a party to [an instituted] *inter partes* review any person who properly files a petition under section 311 that . . . after receiving a preliminary response under section 313 or the expiration of the time for filing such a response . . . warrants the institution of an *inter partes* review under section 314.

35 U.S.C. § 315(c). We have explained that a motion for joinder should:

(1) set forth reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact, if any, joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified.

*Kyocera Corp. v. Softview LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

As for reasons why joinder is appropriate and identifying any new grounds of unpatentability asserted in the Petition, Petitioner contends that it

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