

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2019-01023
Patent 9,526,844 B2

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 ¹	§ 103	21–29
Steenfeldt-Jensen and Klitgaard ²	§ 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.

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

² 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

inter partes review based on a petition filed prior to November 13, 2018, “[a] claim in an unexpired patent . . . shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (upholding the use of the broadest reasonable interpretation standard). During a conference call held on July 25, 2019, with Petitioner, Patent Owner, and the petitioner in the Mylan IPR, each indicated that if the Motion for Joinder is granted in this proceeding, there are no issues or objections to continuing with the broadest reasonable interpretation standard of claim construction in the joined proceeding. Paper 11, 2. For purposes of this Decision, we determine that no claim term requires an express construction.

C. Showing of a Reasonable Likelihood of Prevailing

The Petition is substantively identical to the petition in the Mylan IPR. *Compare* Pet. with Mylan, Case IPR2018-01682 (PTAB Sept. 10, 2018) (Paper 2); *see also* Paper 3, 3 (contending that “the same claims of the ’844 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 21–30 of the ’844 patent”). Based on the information presented in the Petition, and for substantially the same reasons discussed in the decision instituting *inter partes* review in the Mylan IPR, we find Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least

one of the challenged claims of the '844 patent. *See Mylan*, Case IPR2018-01682 (PTAB Apr. 3, 2019) (Paper 19).

Accordingly, we institute *inter partes* review of claims 21–30 of the '844 patent based on all of the asserted grounds of unpatentability set forth in the Petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) (providing that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition). This is not a final decision as to patentability of claims for which *inter partes* review is instituted or as to any underlying factual or legal issue. Any final decision will be based on the record, as fully developed during trial.

IV. MOTION FOR JOINDER

Petitioner seeks to join this case with the Mylan IPR. Paper 3, 1. Petitioner's Motion for Joinder is timely, because it was filed on May 2, 2019, within one month of institution of *inter partes* review in the Mylan IPR on April 3, 2019. *See* 37 C.F.R. § 42.122(b) (“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.”).

Patent Owner does not oppose joinder in light of the resolution by the parties of certain concerns Patent Owner previously raised. Paper 8, 5 (Patent Owner states that “[p]ursuant to the representations noted above . . . [Patent Owner] does not oppose [Petitioner's] Motion for Joinder and agrees that judicial economy will be served.”); Paper 11, 2 (noting that “Petitioner, Patent Owner, and Mylan each confirmed that agreement had

been reached regarding joinder so that Patent Owner would not oppose joinder under certain conditions”).

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).

Petitioner has persuasively shown reasons why joinder is appropriate. Petitioner explains that the same grounds are asserted in the Petition as in the Mylan IPR, that no new grounds of unpatentability are asserted, and that the Petition presents nearly identical arguments and relies on substantially the same evidence as the Mylan IPR. Paper 3, 5. Petitioner also asserts that the Board will be determining the same issues and that joinder would be the most efficient and economical manner in which to proceed. *Id.*

Petitioner has also shown that joinder would not affect the schedule in the Mylan IPR because joinder “will not add any procedural complications or delay the progress of resolving the substantive issues already pending in

the Mylan IPR,” Petitioner “will coordinate with the Mylan IPR petitioner,” and Petitioner “agrees to take an understudy role . . . if joinder is granted.” *Id.* at 5–6. Lastly, with respect to how briefing and discovery may be simplified, Petitioner argues that joinder would avoid the filing of “largely duplicative briefs and other papers” and that “Petitioner will maintain a secondary role in the proceeding, if joined.” *Id.* at 6–7.

Patent Owner initially proposed an extension of the trial schedule in its Response to Petitioner’s Motion. Paper 8, 5. Petitioner subsequently explains in reply that the parties agreed that if joinder is granted, Petitioner will rely only on the declaration and testimony of Mr. Leinsing in the joined proceeding, and not on the declaration of Mr. Clemens, such that an extension of the trial schedule will not be required. Paper 10, 1–2. Petitioner also represents that the petitioner in the Mylan IPR does not oppose joinder if there is no change to the trial schedule. *Id.*

For the foregoing reasons, we are persuaded that joinder is appropriate and, therefore, *grant* Petitioner’s Motion for Joinder.

VI. CONCLUSION

We institute *inter partes* review of claims 21–30 of the ’844 patent based on the asserted grounds of unpatentability set forth in the Petition. We *grant* Petitioner’s Motion for Joinder and join Petitioner to IPR2018-01682. In view of this joinder, we terminate the present proceeding in accordance with 37 C.F.R. § 42.72.

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 21–30 of U.S. Patent No. 9,526,844 B2 is instituted with respect to all grounds set forth in the Petition;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(a), Petitioner’s Motion for Joinder is *granted*, and that Petitioner is joined as a petitioner in IPR2018-01682;

FURTHER ORDERED that, in view of the joinder, this proceeding, IPR2019-01023, is *terminated* under 37 C.F.R. § 42.72, and that all further filings shall be made only in IPR2018-01682;

FURTHER ORDERED that the asserted grounds of unpatentability on which the Board instituted *inter partes* review in IPR2018-01682 are unchanged and remain the only instituted grounds;

FURTHER ORDERED that the claim construction standard of IPR2018-01682 is applied to the joined proceedings;

FURTHER ORDERED that, as agreed to by all the parties, Petitioner will no longer rely upon the declaration of Mr. Clemens and will, instead, rely on the declaration and testimony of Mr. Leinsing in IPR2018-01682;

FURTHER ORDERED that the Scheduling Order in IPR2018-01682, and any modifications thereto, shall govern the schedule of the joined proceeding;

FURTHER ORDERED that in IPR2018-01682, Petitioner will file each paper, except for any paper that does not involve the other party, as a single, consolidated filing with Mylan, subject to the page limits set forth in 37 C.F.R. § 42.24, and shall identify such filing as a consolidated filing;

FURTHER ORDERED that for any consolidated filing, if Petitioner wishes to file an additional paper to address points of disagreement with Mylan, Petitioner must request authorization from the Board to file a motion for an additional paper or pages;

FURTHER ORDERED that Petitioner shall collectively designate attorneys with Mylan to conduct the cross-examination of any witness produced by Patent Owner and the redirect of any witness produced by Mylan and Petitioner, within the timeframes set forth in 37 C.F.R. § 42.53(c) or agreed to by the parties;

FURTHER ORDERED that Petitioner shall collectively designate attorneys with Mylan to present at the oral hearing, if requested and scheduled, in a consolidated argument;

FURTHER ORDERED that the case caption in IPR2018-01682 shall be changed to reflect joinder of Petitioner in accordance with the attached example; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2018-01682.

IPR2019-01023
Patent 9,526,844 B2

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IPR2019-01023
Patent 9,526,844 B2

Example Case Caption for Joined Proceeding

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01682³
Patent 9,526,844 B2

³ Pfizer Inc., who filed a petition in IPR2019-01023, has been joined as Petitioner in this proceeding.