

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2019-00977
Patent 8,603,044 B2

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 IPR2018-01675 (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 IPR2018-01675. 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 IPR2019-00978. 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 reference as prior art in the asserted
ground of unpatentability:

U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013,
“Burroughs”).

In support of its challenge, 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 Ground

Petitioner asserts that Burroughs would have rendered the subject matter of claims 11, 14, 15, 18, and 19 obvious, under 35 U.S.C. § 103, to one of ordinary skill in the art at the time of the invention. Pet. 5, 21–49.

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 (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 28.

Accordingly, we institute *inter partes* review of claims 11, 14, 15, 18, and 19 of the ’044 patent based on the asserted ground 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 asserts the same grounds as in the Mylan IPR, presents nearly identical arguments, and relies on substantially the same evidence. Paper 3, 5–6. Petitioner also contends that the Board will be determining the same issues

and joinder would be the most efficient and economical manner in which to proceed. *Id.*

Regarding what impact, if any, joinder would have on the trial schedule for the existing review, Petitioner argues 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 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 responds that it “does not oppose Pfizer’s Motion for Joinder” and “agrees that judicial economy will be served by joining Pfizer to the Mylan . . . IPR[.]” Paper 8, 2–5. Although Patent Owner proposed an extension of the trial schedule in its Response to Petitioner’s Motion (*id.* at 4–5), Petitioner subsequently explains in reply that the parties agreed that if joinder is granted, Petitioner would withdraw the declaration of Mr. Clemens and rely on the declaration and testimony of Mr. Leinsing such that an extension of the trial schedule would 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.*

In view of Petitioner’s representations and the parties’ agreement, Petitioner has persuaded us that joinder is appropriate. We, therefore, *grant* Petitioner’s Motion for Joinder.

V. CLAIM INTERPRETATION

The Petition in the Mylan IPR was filed on September 10, 2018. *See Mylan IPR*, Paper 8. 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). Accordingly, the broadest reasonable construction standard applies to the Mylan IPR.

The Petition in this case was filed on May 2, 2019. Paper 4. The claim construction standard applied in an *inter partes* review when a petition is 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). Accordingly, absent joinder, the federal court claim construction standard used in a civil action under 35 U.S.C. § 282(b) applies to this proceeding.

During a conference on July 25, 2019, with all involved parties, Petitioner and Patent Owner each indicated that, if the Motion for Joinder is granted, there would be no issues or objections to continuing with the broadest reasonable interpretation standard of claim construction in the joined proceeding. Paper 11, 2; *see also Mylan IPR*, Ex. 1043, 5:19–6:14 (asking if there were any issues with continuing with the broadest reasonable interpretation standard in the joined proceeding and Petitioner and Patent Owner each indicating no objections or issues with continuing with that

standard). Thus, we will construe any claim term that requires construction according to the broadest reasonable interpretation standard. If, however, any party contends that a claim term should be given a different interpretation from the broadest reasonable interpretation under the federal court claim construction standard used in a civil action under 35 U.S.C. § 282(b), that party may request authorization to file an additional brief in support of its contentions.

VI. CONCLUSION

We institute *inter partes* review of claims 11, 14, 15, 18, and 19 of the '044 patent based on the asserted ground of unpatentability set forth in the Petition. We *grant* Petitioner's Motion for Joinder and join Petitioner to IPR2018-01675. 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 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 is instituted with respect to the sole ground 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 IPR2018-01675;

FURTHER ORDERED that, in view of the joinder, this proceeding, IPR2019-00977, is *terminated* under 37 C.F.R. § 42.72, and that all further filings shall be made only in IPR2018-01675;

FURTHER ORDERED that the asserted ground of unpatentability on which the Board instituted *inter partes* review in IPR2018-01675 is unchanged and remains the only instituted ground;

FURTHER ORDERED that the claim construction standard of IPR2018-01675 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 IPR2018-01676;

FURTHER ORDERED that the Scheduling Order in IPR2018-01675, and any modifications thereto, shall govern the schedule of the joined proceeding;

FURTHER ORDERED that in IPR2018-01675, 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;

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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 IPR2018-01675 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 IPR2018-01675.

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Example Case Caption for Joined Proceeding

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MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
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v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

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Patent 8,603,044 B2

¹ Pfizer Inc., who filed a petition in IPR2019-00977, has been joined as petitioner in this proceeding.