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Paper 12
Entered: August 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2019-00980
Patent 8,992,486 B2

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

JUNG, *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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, “the ’486 patent”). Concurrently with its Petition, Petitioner filed a Motion for Joinder seeking to join the instituted *inter partes* review in *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, Case IPR2018-01678 (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 also 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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent. We also grant Petitioner’s Motion for Joinder and join Petitioner to IPR2018-01678. In view of the joinder, we terminate this proceeding.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the ’486 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 v. Eli Lilly*

and Co., No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1–2; Paper 3, 2–3; Paper 5, 2; Exs. 1029, 1030.

The parties also indicate that the '486 patent is challenged in Cases IPR2018-01677, IPR2018-01679, IPR2019-00122, IPR2019-00981, and IPR2019-00982. Pet. 1, 2; Paper 5, 3–4. Petitioner notes that IPR2018-01677 was terminated after granting an unopposed motion to dismiss. Pet. 1; Paper 3, 2.

The parties additionally indicate that related patents are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00977, IPR2019-00978, IPR2019-00979, IPR2019-00987, IPR2019-01022, and IPR2019-01023. Pet. 2; Paper 5, 2–4. The parties further identify related patent applications and patents. Pet. 2–4; Paper 5, 4–6.

B. Evidence Relied Upon

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

- (1) U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, “Steenfeldt-Jensen”); and
- (2) U.S. Patent Application Publication No. US 2002/0052578 A1, published May 2, 2002 (Ex. 1015, “Moller”).

In support of its challenges, Petitioner provides a Declaration of Charles Clemens (Ex. 1011). *See* Paper 3, 3 (stating that the “Petition is also supported by the expert declaration of Charles Clemens” and that 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)”).

C. Asserted Grounds

Petitioner challenges, under 35 U.S.C. § 103, claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 as unpatentable over (1) Steenfeldt-Jensen and (2) the combination of Moller and Steenfeldt-Jensen. Pet. 5, 23–98.

III. INSTITUTION OF *INTER PARTES* REVIEW

The Petition is substantively identical to the petition in the Mylan IPR. *Compare Pet. with Mylan*, Case IPR2018-01678 (PTAB Sept. 10, 2018) (Paper 2); *see also* Paper 3, 3 (stating that “the same claims of the ’486 patent are obvious over the same grounds and for substantially the same reasons set forth in the Mylan IPR”), 3–4 (stating 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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent”). For substantially the same reasons discussed in the Decision instituting *inter partes* review in the Mylan IPR, Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the challenged claims of the ’486 patent. *Mylan*, Case IPR2018-01678 (PTAB Apr. 3, 2019) (Paper 20).

Accordingly, we institute *inter partes* review of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the ’486 patent based on the asserted grounds of unpatentability set forth in the present 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 3, 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. 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 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 044, 486, 008, and 844 IPRs.” Paper 8, 2–5. Although Patent Owner 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 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*, Case IPR2018-01678 (PTAB Oct. 4, 2018) (Paper 6). 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 *inter partes* reviews in which petitions were 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 held 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* Ex. 1043 in IPR2018-01678, 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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of the '486 patent based on the asserted grounds of unpatentability set forth in the Petition. We grant Petitioner's Motion for Joinder and join Petitioner to IPR2018-01678. 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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 of U.S. Patent No. 8,992,486 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 IPR2018-01678;

FURTHER ORDERED that, in view of the joinder, this proceeding, IPR2019-00980, is *terminated* under 37 C.F.R. § 42.72, and that all further filings shall be made only in IPR2018-01678;

FURTHER ORDERED that the asserted grounds of unpatentability on which the Board instituted *inter partes* review in IPR2018-01678 are unchanged and remain the only instituted grounds;

FURTHER ORDERED that the claim construction standard of IPR2018-01678 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 IPR2018-01678;

FURTHER ORDERED that the Scheduling Order in IPR2018-01678, and any modifications thereto, shall govern the schedule of the joined proceeding;

FURTHER ORDERED that in IPR2018-01678, 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 IPR2018-01678 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 IPR2018-01678.

PETITIONER:

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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 IPR2018-01678¹
Patent 8,992,486 B2

¹ Pfizer Inc., who filed a petition in IPR2019-00980, has been joined as petitioner in this proceeding.