

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

CHUGAI SEIYAKU KABUSHIKI KAISA,
GENENTECH, INC., and HOFFMANN LA ROCHE INC.,
Patent Owner.

IPR2022-00578
Patent 8,580,264 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and TINA E. HULSE,
Administrative Patent Judges.

HULSE, *Administrative Patent Judge.*

ORDER
Granting Petitioner's Motion to Submit Supplemental Information
37 C.F.R. § 42.123(a)

I. INTRODUCTION

With our authorization (Paper 12), Petitioner filed a Motion to Submit Supplemental Information Pursuant to 37 C.F.R. § 42.123(a). Paper 13 (“Mot.”). Specifically, Petitioner seeks to submit the Second Declaration of Professor Maarten Boers, M.D., M.SC., Ph.D. in Support of Celltrion’s Petition for Inter Partes Review of U.S. Patent No. 8,580,264. Ex. 1119¹ (“Second Boers Declaration” or “Declaration”). Patent Owner opposes Petitioner’s motion. Paper 14 (“Opp’n”).

Having considered the parties’ respective arguments, we grant Petitioner’s motion based on the facts and circumstances of this case.

II. ANALYSIS

After trial has been instituted, a party may file a motion to submit supplemental information, provided that: (1) the request for authorization to file the motion is made within one month of the date the trial is instituted; and (2) the supplemental information is relevant to a claim for which trial has been instituted. 37 C.F.R. § 42.123(a). Satisfying the two provisions of Rule 123(a), however, does not require granting the motion. Rather, the Federal Circuit has instructed us that the “guiding principle” in making any determination, including whether to grant a motion to submit supplemental information, is to “ensure efficient administration of the Office and the ability of the Office to complete [*inter partes* review] proceedings in a timely manner.” *Redline Detection LLC v. Star Envirotech, Inc.*, 811 F.3d

¹ We note Petitioner filed the Second Boers Declaration as an exhibit despite our Order, which instructed Petitioner to submit the declaration as an appendix to the motion. Paper 12 at 3 n.2. Because we grant Petitioner’s motion, we find Petitioner’s error to be harmless. But we advise the parties to read and adhere to our Orders more carefully in the future.

435, 445 (Fed. Cir. 2015). Moreover, the Federal Circuit recognized that “the PTAB has discretion to grant or deny motions as it sees fit.” *Id.* at 446–47 (citing 37 C.F.R. § 42.5(a), (b)).

Petitioner asserts that its request for authorization to file its motion was made on September 16, 2022, within one month of our Decision on Institution. Mot. 2. Petitioner further asserts that the Second Boers Declaration is relevant because it “explains how the [person of ordinary skill in the art] would have understood the *Kremer 2009* reference[, which] is unquestionably relevant to at least the patentability of claim 12 of the ’264 Patent.” *Id.* at 2–3. Patent Owner does not dispute either of these assertions. *See generally* Opp’n. We, therefore, find that Petitioner’s request satisfies the requirements of 37 C.F.R. § 42.123(a).

Under *Redline Detection*, however, our analysis does not end there. We must further determine whether granting Petitioner’s motion comports with our guiding principles of efficiency. *See Redline Detection*, 811 F.3d at 445. Under the facts and circumstances of this case, we determine that it does.

Petitioner argues that the submission of the Second Boers Declaration will not delay the proceedings, as he has yet to be deposed and Patent Owner’s Response is not due for two months. Mot. 2. Patent Owner does not appear to dispute this argument. *See generally* Opp’n. Instead, Patent Owner’s sole argument is that admitting the Second Boers Declaration would violate the Board’s prohibition against bolstering the deficiencies of the Petition that were highlighted by our Decision on Institution. *Id.* at 1.

In our Decision on Institution, we determined Petitioner had not shown a reasonable likelihood of prevailing on its assertion that claim 12

would have been obvious over Kremer² and other cited art. *See, e.g.*, Paper 10, 20–21. Specifically, we found “Kremer appears to be silent as to whether the patients’ joints were examined at week 24 or 48, as required by the claims, and what those results were.” *Id.* at 21. We, therefore, found that Petitioner did not show sufficiently that Kremer teaches or suggests the limitation of “wherein structural joint damage at week 24 or week 48 is found to be inhibited.” *Id.*

According to Petitioner, the Second Boers Declaration addresses why our interpretation of Kremer was incorrect and how a person of ordinary skill in the art would have understood that the data of Kremer cited in the Petition teaches the inhibition of joint damage at weeks 24 and 48. Mot. 3. Petitioner states the Declaration also explains that a person of ordinary skill in the art would not have understood claim 12 to require actual joint examination at week 24 or 48. *Id.* And even if actual examination were required, the Declaration explains that doing so would have been obvious after reading the results in Kremer. *Id.* at 4.

As our colleagues have thoughtfully illustrated, the Board has allowed supplemental information that did not change the grounds of patentability or the evidence relied upon in the petition, and has rejected supplemental information that was used to bolster the petition based on information in the preliminary response or institution decision. *See Am. Well Corp. v. Teladoc*

² J. Kremer et al., *LITHE: Tocilizumab Inhibits Radiographic Progression and Improves Physical Function in Rheumatoid Arthritis (RA) Patients (Pts) at 2 Yrs with Increasing Clinical Efficacy Over Time*, AM. COLLEGE OF RHEUMATOLOGY ABSTR. SUPPL. (2009). Ex. 1029 (“Kremer”).

Health, Inc., IPR2021-00748, Paper 23 at 5–7 (PTAB Feb. 28, 2022)
(collecting cases).

After considering the Second Boers Declaration, we find this case to be a close one. On the one hand, we agree with Petitioner that the Declaration is useful in that it clarifies the Kremer data cited in the Petition. We also agree that in doing so, the Declaration is not adding to or changing the grounds of unpatentability or evidence on which the Petition is based. In this respect, we find the Second Boers Declaration to be akin to the second expert declaration admitted in *Med-El Elektromedizinische Gerate GES.M.B.H. v. Advanced Bionics AG*, IPR2020-00190, Paper 24 (PTAB Aug. 10, 2020). There, the panel granted Petitioner’s motion to submit a second expert declaration that “explains and clarifies an argument made in the Petition (Paper 1) regarding [a reference] that Petitioner perceives was misunderstood by the Board in the Institution Decision.” *Id.* at 3–4.

On the other hand, we agree with Patent Owner that the claim construction argument and the additional obviousness argument in the Declaration go beyond simply clarifying the data in Kremer and were not arguments made in the Petition.

That said, we find, on balance, that admitting the Declaration as supplemental information is appropriate in this case. The Declaration does not change the grounds of unpatentability—Petitioner continues to rely on Kremer as teaching the limitation of claim 12 and maintains the same positions it asserted in the Petition. To the extent our Decision on Institution raised an unforeseen claim construction dispute regarding whether the structural joint damage must actually be measured at week 24 or week 48, we find it to be more efficient to address that dispute as early as possible to

allow the parties an opportunity to fully brief that issue and any related issues that may arise. Thus, we find that admitting the Declaration as supplemental information at this stage of the proceeding rather than with the Reply would further our goals of efficiency and our mandate to “secure the just, speedy, and inexpensive resolution” of this proceeding. *See* 37 C.F.R. § 42.1(b); *see also The Boeing Co. v. Seymour Levine*, IPR2015-01341, Paper 30 at 4–5 (PTAB Apr. 15, 2016) (granting motion to submit supplemental declaration as “inclusion of the evidence at this stage in the proceeding will provide Patent Owner with a greater opportunity to respond to the supplemental information and will further the Board’s mandate to ‘secure the just, speedy, and inexpensive resolution’ of the proceeding”).

Accordingly, because Petitioner’s motion satisfies the requirements of 37 C.F.R. § 123(a) and because admitting the supplemental information at this stage of the proceeding would further our guiding principles in this proceeding, we grant Petitioner’s motion.

III. CONCLUSION

Having considered the parties’ respective arguments, Petitioner’s motion to submit the Second Boers Declaration as supplemental information is granted.

IV. ORDER

Accordingly, it is
ORDERED that Petitioner’s motion to submit supplemental information is *granted*.

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