

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LABORATOIRE FRANCAIS DU FRANCTIONNEMENT ET DES
BIOTECHNOLOGIES S.A.,
Petitioner,

v.

NOVO NORDISK HEALTHCARE AG,
Patent Owner.

IPR2017-00028
Patent 9,102,762 B2

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

ORDER

Denying Petitioner's Motion to Terminate, Dismiss, and Vacate
37 C.F.R. §§ 42.71 and 42.72

Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (“Petitioner”) moves to terminate and dismiss this *inter partes* review because a final written decision has not been entered as to all grounds in the Petition. Petitioner’s Motion to Terminate, Dismiss, and Vacate (Paper 98, “Mot.”) 1, 12. Petitioner also moves to vacate the Final Written Decision that we issued on April 5, 2018, which disposed of a subset of grounds in the Petition upon which an *inter partes* review was originally instituted, and all interlocutory decisions in this proceeding. *Id.* at 12. According to Petitioner, “any final determination issued now would be outside the Board’s statutory limits and in excess of its jurisdiction” and “the Board can no longer issue a final determination addressing all grounds raised in the petition as required by *SAS*.” *Id.* (citing *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2140–42 (2016)).

Novo Nordisk Healthcare AG (“Patent Owner”) responds that [Petitioner] LFB seeks to have its petition dismissed as if it never filed it in the first place and escape the effect of its loss on the originally instituted grounds, a clearly prejudicial result to Patent Owner Novo Nordisk. Setting aside the the equities of [Petitioner] LFB’s motion (which clearly favor Novo Nordisk), the motion has no basis in the law and should be denied in its entirety.

Patent Owner’s Opposition to Petitioner LFB’s Motion to Terminate, Dismiss, and Vacate (Paper 100, “Opp.”) 1–2.

As explained below, we have jurisdiction here and will proceed to a final written decision on the remaining grounds now before us.

Background

A review of the procedural posture of this proceeding provides context for determining the relative merits of the parties’ positions. On

April 11, 2017, we instituted an *inter partes* review for challenged claims of U.S. Patent No. 9,102,762 B2 (“the ’762 patent”), based upon only a subset of the grounds presented in the Petition. Paper 7, 5 (all grounds), 23 (instituted grounds). The *inter partes* review did not include certain grounds based on Eibl ’023,¹ for which we determined Petitioner had not demonstrated a reasonable likelihood of prevailing. *Id.* at 20–22. We also determined that Petitioner had not demonstrated a reasonable likelihood of prevailing with respect to its anticipation challenge based on Tolo.² *Id.* at 18. A trial was conducted on the grounds on which we instituted trial. This institution and trial on only a subset of the grounds set forth in the Petition was consistent with Board practice at the time. In our Final Written Decision, issued on April 5, 2018, we concluded that Petitioner had not shown by a preponderance of the evidence that claims 1–15 of the ’762 patent were unpatentable under 35 U.S.C. § 103 on the grounds upon which we instituted the *inter partes* review. Paper 53, 41.

After our Final Written Decision was entered, but during the time in which Petitioner could still file a Request for Rehearing, the United States Supreme Court issued its opinion in *SAS Institute, Inc. v. Iancu* requiring that all claims challenged in a petition must be included in any trial. *See SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1354–60 (2018) (“*SAS*”) (holding that 35 U.S.C. § 318(a) requires a final written decision addressing all of the claims challenged in a petition). Shortly thereafter, the Office issued guidance stating that “[i]f the PTAB institutes a trial, the PTAB will

¹ Eibl, WO 2004/011023 A1; Feb. 5, 2004 (Ex. 1008, “Eibl ’023”); Ex. 1009 (English Translation).

² Tolo et al., WO 99/64441; Dec. 16, 1999 (Ex. 1006, “Tolo”).

institute on all challenges raised in the petition.” *Guidance on the Impact of SAS on AIA Trial Proceedings* (April 26, 2018) (“Office Guidance”) (available at <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial>).

At the request of Petitioner, we held a conference call with the parties and granted Petitioner a three-week extension and more pages for its Request for Rehearing “to address all issues, including matters discussed in the Final Written Decision, *SAS*, and the previously non-instituted grounds.” Paper 54, 4. In deciding the Request for Rehearing, we stated “we find no reason to modify our analysis or conclusions in the FWD with respect to the Tolo Grounds.” Paper 60, 8. However, in view of *SAS* and the Office Guidance, we also stated that “it is appropriate to grant rehearing to now institute on the previously non-instituted grounds.” *Id.* at 9. Therefore, on August 7, 2018, we instituted a supplemental trial focusing on the Tolo anticipation ground and the Eibl ’023 grounds that we did not consider in our prior Final Written Decision. *Id.* at 11. The parties filed supplemental briefs, and we held a supplemental oral hearing addressing these grounds on February 6, 2019. *See* Paper 67 (Patent Owner’s Supplemental Rehearing Response); Paper 81 (Petitioner’s Supplemental Reply); Paper 101 (Transcript for Supplemental Oral Hearing).

Analysis

Petitioner asserts that we have no jurisdiction to render a final written decision on the remaining grounds for which we instituted trial on August 7, 2018 because 35 U.S.C. § 316(a)(11) requires that a final determination be entered in an *inter partes* review no later than one year after institution unless extended by not more than six months for good cause. Mot. 4–5;

see 35 U.S.C. § 316(a)(11) (requiring regulations setting forth the prescribed time limits for issuing a final written decision). Petitioner asserts that issuing a final written decision now would be *ultra vires* because “[t]he 12–18 month limit is not a mere legislative suggestion nor mere housekeeping; rather, exceeding the time limit contravenes the statute’s purpose and goal, and deprives the Board of the authority to further adjudicate the merits.” *Id.* at 4, 7. Petitioner concludes:

In sum, the statutory scheme and legislative history establish that the Board was never intended to have unfettered ability to ignore the 12–18 month deadline and issue final determinations whenever it wants. The intertwined provisions regarding the deadline and the application of estoppel, as well as Congress’s clear desire to avoid the open-ended timelines of prior PTO proceedings and to stay parallel litigation, unambiguously show the deadline imposed by § 316(a)(11) is jurisdictional and bars post-deadline final determinations by the Board.

The Board issued its rehearing decision on Aug. 7, 2018, granting in-part [Petitioner’s] request and instituting review on the previously non-instituted grounds. Paper 60, 9. This was an institution decision. Accordingly, pursuant to 35 U.S.C. § 316(a)(11) and 37 C.F.R. § 42.100(c), the Board had 12 months (Aug. 7, 2019)—or 18 months with good cause (Feb. 7, 2020)—to issue a final determination. We are now well past those deadlines, without a final resolution.

Mot. 11–12.

The Final Written Decision on the originally instituted challenges, Petitioner asserts, cannot be considered a final written decision because it “did not address all grounds raised by petitioner” as required by *SAS*. *Id.* at 12. Petitioner asserts that the issued Final Written Decision should be vacated and this proceeding terminated “since the Board can no longer issue

a final determination addressing all grounds raised in the petition as required by *SAS*.” *Id.* at 12.

Patent Owner responds that Petitioner’s argument “relies on the flawed assumption that rehearings are subject to the same statutory deadlines of 35 U.S.C. § 316(a)(11) as typical proceedings. . . . In this proceeding, the Board satisfied [the one-year] requirement by issuing the April 2018 FWD before April 11, 2018 – the one-year deadline for a determination following institution.” *Opp.* 6–7.

Patent Owner’s position that our Final Written Decision entered in April 2018 satisfied the one-year statutory deadline for this *inter partes* proceeding is correct.³ Our decision on rehearing to address the previously non-instituted grounds in light of the intervening *SAS* decision did not trigger another one-year statutory deadline. We have consistently held that once a final written decision is entered within one year of institution (or up to an additional six months for good cause shown) the requirement of 35 U.S.C. § 316(a)(11) has been met.

For instance, in *Shaw Industries Group, Inc., v. Automated Creel Systems, Inc.*, we decided whether a stay should remain in place on a case that was remanded from the United States Court of Appeals for the Federal

³ Petitioner acknowledges that the Trial Practice Guide states that no statutory time limit exists for completion of a re-opened proceeding following remand. *See* Mot. 13–14 (citing Trial Practice Guide Update 47 (July 2019); *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide 89 (Nov. 2019) (“Although no statutory time limit exists for completion of a re-opened proceeding following remand, the Board recognizes that delays caused by re-opening the record after remand may be inconsistent with the Board’s stated goal of issuing a remand decision within six months from the mandate.”)).

Circuit (“Federal Circuit”) pending a determination on a Supreme Court certiorari petition. *See Shaw*, IPR2013-00584, Paper 60, 2 (PTAB Oct. 14, 2016). In *Shaw*, we maintained the stay stating “[w]e have authority to do so under 37 C.F.R. § 42.5(a), and doing so will not violate the statutory period for *inter partes* reviews under 35 U.S.C. § 316(a)(11) because our Final Written Decision was issued within one year of institution.” *Id.* at 3 (citing *Microsoft Corp. v. Proxyconn, Inc.*, Case IPR2013-00109, Paper 20, 6 (PTAB Dec. 9, 2015)).

In *Microsoft*, the Board stated that the Federal Circuit had determined that the Board had erred in the construction of certain terms and remanded the case to the Board for proceedings consistent with its opinion. *Id.* at 2–3. On remand, the patent owner in that case asserted that “the Board is ‘without authority to take further action’ because the 18-month time period for the Board to make a final determination has expired.” *Id.* at 4–5 (citing 35 U.S.C. § 316(a)(11); 37 C.F.R. § 42.100(c)). The Board rejected that argument, stating:

[I]f the 18-month deadline were applicable, the Board’s Final Written Decision was entered within 18 months of the institution of trial, whether that date is measured from the institution of trial in IPR2012-00026 or the joined proceeding in IPR2013-00109. The Federal Circuit’s partial vacatur does not negate the Board’s prior compliance with the deadline. If it did, that would essentially foreclose any further proceedings consistent with the Federal Circuit’s mandate in this case.

Id. at 6.

Here, we issued a Final Written Decision on April 5, 2018, which was within the one-year statutory period disposing of all issues presented during the trial. *See* Paper 54. At that point in time, no issue remained requiring resolution by the Board. As in *Shaw* and *Microsoft*, the deadline for

rendering a final written decision had been met. The supplemental institution of the remaining grounds from the Petition in our rehearing decision in view of *SAS* and the Office Guidance was not subject to any statutory deadline.⁴ Therefore, we determine that we have the authority at this point to issue a supplemental decision on the remaining Tolo anticipation ground and the Eibl '023 grounds.

Petitioner also asserts that even if we have jurisdiction to render a decision on the remaining grounds, we “should terminate and dismiss this IPR and vacate the April 2018 non-final decision and both institution decisions,” because the Board has not provided a speedy resolution, which violates due process, is an abuse of discretion, is inconsistent with Office policy, and prejudices Petitioner. Mot. 12–15.

Patent Owner responds that Petitioner’s claims of prejudice and injustice ring hollow as it waited nearly one year to raise this jurisdictional issue for the first time in its correspondence to the Board requesting the August, 5, 2020 telephonic hearing. [Petitioner’s] own actions suggest it did not think a one-year deadline applied in August 2019 or it would have raised the argument then.

Opp. 10–11 (citation omitted). Patent Owner also asserts that Petitioner’s arguments are premised on the flawed assumption that a statutory deadline exists for rendering a decision on the remaining grounds, and Petitioner is not prejudiced as it “requested and received two complete trials on all

⁴ Patent Owner also points out that Petitioner’s actions with respect to its appeal to the Federal Circuit of the Final Written Decision appears inconsistent with the view that a one-year statutory deadline applied to resolution of the Tolo anticipation ground and the Eibl '023 grounds. *See* Opp. 3–5 (discussing Petitioner’s request for a stay of the rehearing pending its appeal to the Federal Circuit of the Final Written Decision). We agree.

petitioned claims and grounds.” *See id.* at 11. Patent Owner asserts, however, that it would be prejudiced if this *inter partes* review were terminated and the April 2018 Final Written Decision vacated. *Id.* at 12. Patent Owner states: “All the time and resources [Patent Owner] has spent defending its intellectual property against these [Petitioner]-initiated proceedings would be for naught and [Petitioner] would likely challenge its ’762 patent again.” *Id.*

We do not agree with Petitioner that this case should be terminated and all of our decisions vacated. As we have stated, after our Final Written Decision was entered in April 2018, the statutory deadline was met. No such deadline attaches to the second decision that we will issue on the remaining grounds on which we instituted trial in light of *SAS* and Office guidance. We agree with Patent Owner that it would face significant prejudice if we were now to undo the previous work performed during this *inter partes* review by vacating previous orders and decisions that have resolved disputes between the parties concerning the patentability of the challenged claims. Having considered and decided this matter, we will proceed to a final determination on the merits for the remaining challenges in this *inter partes* review.

Accordingly, it is hereby:

ORDERED that Petitioner’s Motion to Terminate, Dismiss, and Vacate is *denied*; and

FURTHER ORDERED that we will proceed to a determination on the merits for the Tolo anticipation ground and the Eibl ’023 grounds.

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