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The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22313-1450

Mail Stop Patent Board
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Michael Tierney, Vice Chief Administrative Patent Judge

Via email: PTABNPRM2020@uspto.gov

Re: Comments of Thermo Fisher Scientific Inc. on Notice of Proposed Rulemaking Regarding “PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence” 85 Fed. Reg. No. 102 (May 27, 2020) [Docket No. PTO–P–2019–0024]

Dear Director Iancu and Judge Tierney:

Thermo Fisher Scientific Inc. (“Thermo Fisher”) appreciates the opportunity to provide comments on the United States Patent and Trademark Office (“USPTO”) Notice of Proposed Rulemaking regarding PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence, published in the Federal Register dated May 27, 2020, 85 Fed. Reg. No. 102. Thermo Fisher provides its comments specifically on the proposed rule that would, in part, eliminate the

presumption at institution favoring petitioner as to testimonial evidence (37 CFR § 42.108(c), § 42.208(c)) for IPR, PGR, and CBM proceedings (collectively, “post-grant proceedings”).¹

Thermo Fisher is a company based in the United States whose mission is to enable its customers in the life sciences industries to make the world healthier, cleaner and safer. Its products help its customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics, deliver medicines to market and increase laboratory productivity. Thermo Fisher invests significantly in research & development and heavily relies on a strong U.S. patent system to protect its innovations.² Thermo Fisher also depends on post-grant proceedings to defend itself when faced with dubious allegations of patent infringement – many of which are premised on patents of questionable validity.

Thermo Fisher commends the USPTO’s continued interest in improving post-grant proceedings. However, Thermo Fisher disagrees with the proposed elimination of the presumption at institution favoring petitioner as to testimonial evidence. If the USPTO nevertheless adopts this change, Thermo Fisher recommends an additional reform to enable petitioners to reply to testimonial evidence submitted with patent owners’ preliminary responses.

The Presumption Should Remain Undisturbed

Eliminating the presumption would unfairly prejudice petitioners because the Board could deny institution based on unchallenged evidence presented by a patent owner that has not been subject to cross-examination. Under the pre-institution procedural framework, a petitioner has no opportunity to challenge testimonial evidence provided with patent owner’s preliminary response. The USPTO recognized this inequity in 2016 as a basis for *adopting* the presumption:

“Because the time frame for the preliminary phase of an AIA proceeding does not allow generally for cross-examination of a declarant before institution as of right, nor for the petitioner to file a reply brief as of right, the Office is amending the rules to provide that any factual dispute created by testimonial evidence that is material to the institution decision will be resolved in favor of the petitioner solely for purposes of determining whether to institute a trial.”

81 FR 18755 (April 1, 2016). Also, the risk of prejudice is acute at the institution stage because of the lack of any judicial review of such decisions. *Thryv, Inc v. Click-To-Call Techs., LP*, 140 S. Ct.

¹ 37 CFR § 42.108(c) currently states, *inter alia*, “The Board’s decision will take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence, **but a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an inter partes review.**” (emphasis added). 37 CFR § 42.208(c) states same for post-grant reviews.

² Thermo Fisher and its affiliates own ~4,200 U.S. patents, and in 2019, filed ~600 applications for U.S. patents.

1367, 1372–73 (2020); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016). Indeed, the USPTO recognized this when it further justified adoption of the pre-institution presumption in 2016 on the ground that petitioners cannot appeal from petition denial. 81 FR 18756 (April 1, 2016) (“A presumption in favor of petitioner for disputed facts ... is appropriate given the effect of denial of a petition.”). The existing rules of practice, therefore, promote fairness by resolving material factual disputes at trial, not as part of the decision to institute. Importantly, the justifications for the 2016 amendment establishing the presumption remain unchanged.

The USPTO now identifies two grounds apparently necessitating elimination of the presumption. The USPTO states the absence of the presumption will: (1) resolve “some confusion” that the presumption in favor of the petitioner extends to “whether a document is a printed publication”; and (2) eliminate a perception by just “some patent owners” that testimonial evidence filed with preliminary responses “will not be given any weight at the time of institution.” (85 FR 31729-30)

Neither concern outweighs the aforementioned justifications the USPTO stated in 2016 for adopting the presumption, nor requires abrogating the presumption. Both concerns can be adequately – indeed, better – addressed by alternate approaches, such as providing guidance in the Office Patent Trial Practice Guide. With respect to the first concern, disputes concerning whether a document qualifies as a printed publication are more properly resolved after institution, and there are ample opportunities for patent owners to raise factual challenges, including through motions to exclude evidence. With respect to the second concern, there is no basis for the perception that a patent owner’s testimonial evidence is disregarded at the institution stage in view of the PTAB’s precedential decision in *Hulu*. As the USPTO observes, “[i]n determining whether the information presented in the petition meets the standard for institution, the PTAB considers the totality of the evidence currently in the record.” 85 FR 31750, citing *Hulu, LLC v. Sound View Innovations LLC*, Case IPR2018-01039, Paper 29 at 3, 19 (PTAB Dec. 20, 2019).

The presumption should remain undisturbed.

If the Presumption is Eliminated, Additional Reform is Required to Put Petitioner and Patent Owner on Even, Pre-Institution Footing

The proposed elimination of the presumption is not coupled with further reform that would provide petitioners with an opportunity as a matter of right to file a reply and/or cross-examine testimonial evidence provided with patent owner’s preliminary response.³ The prejudice to petitioners is manifest in the absence of these safeguards, which represent important checks on the credibility of declaratory evidence. Indeed, in 2016, the USPTO acknowledged the procedural inequity created by petitioner’s inability to cross-examine patent owner’s declarant:

³ *E.g.*, 37 CFR § 42.108(c) bars petitioner from filing a reply to the preliminary response, unless permitted by the PTAB on good cause shown.

“[B]ecause a denial of institution is a final, non-appealable decision, deciding disputed factual issues in favor of the patent owner when a petitioner has not had the opportunity to cross-examine patent owner's declarant is inappropriate and contrary to the statutory framework for AIA review.”

81 FR 18756 (April 1, 2016).

If the presumption is eliminated, the USPTO should, at minimum, further amend 37 CFR § 42.108(c) and § 42.108(c) to permit a petitioner to file a reply to patent owner's preliminary response and cross-examine testimonial evidence provided with it.⁴ Otherwise, patent owners will have the unrebutted “last word,” and that will inevitably lead to a reduction in institution grants and erosion of post-grant proceedings as a faster and cheaper alternative to district court litigation^{5, 6} to weed out weak patents.⁷ Moreover, the absence of an opportunity to cross-examine and respond to evidence introduced by the patent owner raises serious concerns under the Administrative Procedure Act as well as due process concerns.

Sincerely,

/s/ Gillian Thackray

Gillian Thackray
Vice President and Chief IP Counsel
Thermo Fisher Scientific Inc.

⁴ This approach is well-founded in motion briefing practice in federal court. *See, e.g.*, E.D. Va. L.R. 7 (F)(1).

⁵ *E.g.*, 77 F. Reg. 48680-01 (Aug. 14, 2012) (stating IPRs are intended “to create a timely, cost-effective alternative to litigation”).

⁶ Per the Report by the Committee on the Judiciary on the America Invents Act, AIA reviews were designed to provide “a more efficient system for challenging patents that should not have issued” and “limit unnecessary and counterproductive litigation costs.” H.R. Rep. No. 112-98 at 39-40 (2011), available at https://www.uspto.gov/sites/default/files/aia_implementation/crpt-112hrpt98-pt1.pdf (last visited June 26, 2020).

⁷ *E.g., Thryv, Inc v. Click-To-Call Technologies, LP*, 140 S.Ct. 1367, 1374 (2020) (“By providing for inter partes review, Congress ... sought to weed out bad patent claims efficiently.”).