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To: Precedential_Opinion_Panel_Request
Cc: jabauer@mintz.com; KKim@mintz.com; Robbins, Jennifer L; PGR2019-00002
Subject: Precedential Opinion Panel Recommendation – PGR2019-00002

To the members of the Precedential Opinion Panel,

I write on behalf of The University of Chicago (“Patent Owner”) regarding the Post-Grant Review Petition for PGR2019-00002 concerning Patent 9,855,302. On April 15, 2019, a panel of the Board instituted review on the petition. Paper 8.

Patent Owner has submitted a request for rehearing of the Board’s decision to institute review (Paper 11), and respectfully recommends that the matter be heard by the Precedential Opinion Panel pursuant to Standard Operating Procedure 2, rev. 10.

Question Presented

Based on my professional judgment, I believe this case requires an answer to one or more precedent-setting questions of exceptional importance, including:

1. Whether denial of an entire petition for post-grant review under 35 U.S.C. § 324(a) is warranted to avoid compelling a patent owner to defend its patent claims against even one legally insufficient challenge in the petition.

The Board excused Petitioner from its burden to present evidence essential to one of its grounds of unpatentability.

The Board instituted post-grant review on all claims for non-enablement and for obviousness. As explained more fully in the request for rehearing, the Board instituted the non-enablement challenge despite the petitioner not having presented any evidence that the required experimentation, even if large in quantity, was “undue,” aside from its expert’s unsupported assertion that “[u]nquestionably, such testing is burdensome and undue.” That was error, because evidence of “undue” experimentation is essential to any challenge for non-enablement. This situation is analogous to that in *Cephalon*, in which the Federal Circuit held that a challenger failed “as a matter of law” to prove non-enablement where the only evidence of undue experimentation was an expert’s assertion that the testing would be “difficult” and “complicated.” *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1339 (Fed. Cir. 2013).

In instituting this review, the Board stated that the petitioner “more likely than not” will prevail in proving the claims unpatentable for non-enablement, despite the petitioner’s case being legally insufficient, just as in *Cephalon*. The Board thus has relieved the petitioner of its burden to prove non-enablement by a preponderance of the evidence. 35 U.S.C. § 326(e).

The Board’s decision to institute in the absence of essential evidence creates a de facto burden shift to Patent Owner.

By instituting review and determining that the petitioner is “more likely than not” to prove non-enablement despite legally insufficient evidence, the Board effectively has raised a presumption of non-enablement and expressed its belief that the petitioner need do nothing further to prevail. The Board has prejudiced Patent Owner by assigning it the burden of disproving this presumption of non-enablement. This burden shift violates principles established in, e.g., *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1377–78 (Fed. Cir. (2016) for the immutable burden of proof in *inter partes* reviews that are equally applicable, by identical statutory language, to post-grant reviews. 35 U.S.C. § 326(e).

Denial of the entire petition under 35 U.S.C. § 324(a) is warranted to avoid compelling Patent Owner to defend its claims against the petitioner’s legally insufficient enablement challenge.

The Office has expressed its intention to deny institution of *inter partes* review proceedings as a tool in the statutory charge to the Director to safeguard the “integrity of the patent system.” SAS Q&A’s, Part D, Effect of SAS on Future Challenges that Could Be Denied for Statutory Reasons (June 5, 2018, available at https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf) (“[T]he panel will evaluate the challenges and determine whether, in the interests of efficient administration of the Office and integrity of the patent system (see 35 USC § 316(b)), the entire petition should be denied under 35 USC § 314(a).” The Director is identically charged to consider the “integrity of the patent system” in administering post-grant review. 35 U.S.C. § 326(b).

Fairness and consistency dictate that Patent Owner not be compelled to defend the claims of the ’302 patent against the petitioner’s legally deficient enablement challenge. To do otherwise damages the integrity of the patent system by upending statutes and precedent concerning burden-shifting, as well as those concerning enablement. The Precedential Opinion Panel should take the opportunity this case presents to reaffirm the applicability of these lines of Federal Circuit precedent to the statutes establishing post-grant review, while post-grant review is still in its formative period.

For the reasons above and as described in more detail in the request for rehearing, Patent Owner respectfully requests that the Precedential Opinion Panel convene to rehear and assess the issues described in this recommendation.

Respectfully submitted,

/s/ Scott E. Kamholz

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Ex. 3001

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