

**From:** [wg\\_tech](#) on behalf of [Webmaster](#)  
**To:** [Precedential Opinion Panel Request](#)  
**Subject:** Precedential Opinion Panel (POP) Amicus Request Form  
**Date:** Tuesday, August 16, 2022 6:17:48 PM

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Name = Alex H Moss

Affiliation = Public Interest Patent Law Association

Client represented = Public Interest Patent Law Association

Case number = PGR2021-00030

Case name = Daiichi Sankyo, Inc. et a

Paper number = Paper 31

Type of amicus = Supporting POP Review

Brief description = We express the strongest possible support for POP review of the PTAB's de-institution decision in PGR2021-00030.

The decision contradicts the Director's recent Fintiv memo, undermines the purpose of PGR proceedings, and ignores the difference between district court and agency proceedings.

The Director's memo is clear: the "PTAB should not discretionarily deny institution" a petition presenting a "compelling unpatentability challenge." Memo at 4–5. The PTAB concluded the petition's evidence of unpatentability was "'strong.'" Paper 31 (July 15, 2022) at 6. Under the Director's memo, that determination alone should preclude discretionary denial.

Instead, the PTAB reversed its institution decision on the ground that a jury verdict which did not find non-enablement precluded the petition from raising a compelling challenge. That contravenes the Director's memo as well as the purpose of PGR proceedings: "improving patent quality and providing a more efficient system for challenging patents that should not have issued." H.R. REP. 112-98, 39-40 (2011).

The notion that a court's invalidity decision precludes a compelling challenge at the PTAB ignores their different burdens of proof: "In [post-grant] review, the challenger ... must establish unpatentability 'by a preponderance of the evidence'; in district court, a challenger must prove invalidity by 'clear and convincing evidence.'" *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016).

PGRs have a lower burden of proof because Congress intended to make it easier to challenge questionable patents. See H.R. REP. 112-98 ("questionable patents are too easily obtained and are too difficult to challenge"). If anything, the conflict between the jury verdict and PTAB decision further supports institution.

Denying institution deviates from the USPTO's reexamination practice. It often found patents invalid after contrary court decisions—and the Federal Circuit approved. See *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1364 (Fed. Cir. 2012) ("[T]he PTO in reexamination proceedings and the court system in patent infringement actions 'take different approaches in determining validity and on the same evidence could quite correctly come to different conclusions.'").

A jury verdict cannot substitute for a PTAB decision. While "a court's decision upholding a patent's validity is not ordinarily binding on another challenge to the patent's validity . . . in either courts or the PTO," *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 n.3 (Fed. Cir. 1988), a PTAB decision denying a patent's validity leads to its cancellation, "extinguish[ing] the underlying basis for suits based on the patent" against anyone. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1344 (Fed. Cir. 2013).

PGR2021-00030  
Ex. 3011

The public has a strong interest in ensuring the challenged patent is cancelled if not properly enabled to protect space for innovation and access to cancer medication. Given the petition's strong merits, PGR should proceed immediately.

Relationship to a party to the proceeding = none

I certify that I am submitting this amicus form within seven business days of entry of the Notification of POP request into the case docket or patent application file = Yes

Signature = /Alex H Moss/

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