From: Torczon, Richard (External)
Sent: Monday, September 30, 2019 8:24 PM
To: Precedential_Opinion_Panel_Request
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Subject: Request for Precedential Opinion Panel review, IPR2019-00451
Attachments: 010 - NEURELIS rehearing request.pdf; 008 - DECISION instituting.pdf; 014 - DECISION denying rehearing.pdf

Your Honors:

In IPR2019-00451, a panel of the Board granted institution on the basis of an unbriefed application of 37 CFR §1.57. Paper 8 (attached). Because neither party raised the issue before institution, Patent Owner Neurelis did not have an opportunity to advise the Board that the rule is not applicable, and that it would not have been applied in examination as the panel does at institution. The Board's application of the rule is contrary to both binding case law and Office authorities. Neurelis filed a timely request for rehearing (Paper 10, attached) pointing out these errors. In response, the panel again shifted its rationale, quoting the rehearing request but replacing the key point with ellipses, then requiring Neurelis to meet a burden of production when Petitioner Aquestive never met its initial burden. Paper 14 (attached). The new theory is as contrary to law as the old one and highlights the recurring issue of the Board providing its own theory of the case (without advance notice and opportunity to respond), shifting rationales, and improperly shifting burdens (such as here, where Aquestive indisputably failed to address the entire disclosure in asserting a lack of written description).

Neurelis requests review by a Precedential Opinion Panel, pursuant to the Board's Standard Operating Procedure 2.

Based on my professional judgment, I believe the institution decision is contrary to the following decisions of the Supreme Court of the United States, the United States Court of Appeals for the Federal Circuit, and the Board:

- *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)
- *Aristocrat Techs. v. Int'l Game Tech.*, 543 F.3d 657 (Fed. Cir. 2008)
- *Exela Pharma Sciences, LLC v. Lee*, 781 F.3d 1349 (Fed. Cir. 2015)
- *Exxon Corp. v. Phillips Petroleum Co.*, 265 F.3d 1249 (Fed. Cir. 2001)
- *Harari v. Hollmer*, 602 F.3d 1348 (Fed. Cir. 2010)
- *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956 (Fed. Cir. 1997)
- *Ex parte Maziere*, 27 USPQ2d 1705 (BPAI 1993)
- *McDonnell v. United States*, 579 U.S. _, 136 S.Ct. 2355 (2016)
- *SAS Inst. v. Iancu*, 584 U.S. _, 138 S.Ct. 1348 (2018)
- *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991)

Additionally, the decision on rehearing is contrary to:

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- *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375 (Fed. Cir. 2015)

Based on my professional judgment, I believe the Board panel decision is contrary to the following constitutional provision, statutes, and regulations:

- U.S. Constitution, Amendment V
- 5 U.S.C. 557
- 35 U.S.C. 111
- 35 U.S.C. 112, first paragraph
- 35 U.S.C. 119
- 35 U.S.C. 120
- 35 U.S.C. 132
- 35 U.S.C. 312
- 35 U.S.C. 314
- 35 U.S.C. 318
- 37 CFR §1.57
- Manual of Patent Examining Procedure §608.01(p), I.B

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

1. May the Board enforce a rule (here, 37 CFR §1.57) at variance to the plain language of the rule and contrary to specifically relevant patent operations guidance and consistent Board appellate decisions holding the rule inapplicable in the circumstances of this case, thus creating a conflict between Office practice generally and Board trial practice, when the Board's new application is also inconsistent with binding case law?

2. May the Board shift the burden of production to the patent owner when there is no dispute that the Petitioner has failed to address the most pertinent disclosure when asserting a lack of written description in a priority document, contrary to the authority the panel cites (*Dynamic Drinkware*), which affirms a Board decision that the *Petitioner* failed to address priority in a reference, and confirms that the burden of production shifts to the Patent Owner *only after* the Petitioner has made out a prima facie case (800 F.3d at 1378-79)?

3. Also, may a panel provide its own, unbriefed theory for institution, plus continue to shift theories for institution, without giving a party advance notice of the unbriefed theory and a chance to respond, contrary to express requirements in the Administrative Procedure Act regarding preliminary decisions, as well as general principles of due process and fair play?

The panel's sua sponte application of an inapplicable rule without notice is improper by statute, even at a preliminary stage. The panel's sua sponte application of an inapplicable rule shows the wisdom of this statutory bar against such surprise rulings. The panel's silence on rehearing about the rule error and its shift to requiring the patent owner to meet a burden of production when there is no possible dispute that the petitioner failed to even address the most pertinent

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disclosure, thus failing to make out a facial case sufficient to shift any burden to the patent owner, simply compounds the error.

For the reasons provided above, and those provided in greater detail in the request for rehearing, Patent Owner Neurelis respectfully requests review by a Precedential Opinion Panel to address both the due process issues and the conflict in Office authority created by the institution decision, and to deny institution. Neurelis can provide additional briefing on any of these questions if the Board wishes.

Respectfully submitted,

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