From: Dorothy Whelan
To: Precedential_Opinion_Panel_Request
Cc: IPR46094-0002IP1; lweinstein@windelsmarx.com; ppollard@windelsmarx.com; Michael Kane; Chad Shear
Subject: IPR2020-01053
Date: Thursday, January 6, 2022 1:05:57 PM
Attachments: IPR2020-01053 Request for rehearing.pdf

Dear Precedential Opinion Panel:

I write on behalf of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") to request Precedential Opinion Panel review of the Board's December 7, 2021 final written decision in IPR 2020-01053 finding challenged claims 1-75 unpatentable as obvious (Ground 3) and declining to rule on Grounds 1 and 2, which challenged priority. See Paper 29. Sumitomo is concurrently filing a request for rehearing, a copy of which is attached.

QUESTIONS PRESENTED:

1. Whether the Board erred in instituting the IPR on the basis of Grounds 1 and 2 when it applied an incorrect legal standard to find that certain claims were entitled to a filing date "no earlier than the filing date" of the latest-filed application, and then, relying on this legally erroneous filing date, found that an intervening printed publication anticipated these claims.

2. Whether the Board erred in finding claims 1-75 unpatentable over Saji in view of Horisawa when the petition never raised this specific ground.

In my professional judgment, and as further explained below and in Sumitomo's request for rehearing, I believe the Board Panel Decision is contrary to the following decisions of the U.S. Supreme Court and the Court of Appeals for the Federal Circuit:

1. *ICU Medical Inc. v. Alaris Medical Sys., Inc.,* 558 F.3d 1368 (Fed. Cir. 2009);
2. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016);
3. *In re Magnum Oil Tools Int'l*, 829 F.3d 1364 (Fed. Cir. 2016);
4. *EmeraChem Holdings, LLC v. Volkswagen Group of America, Inc.,* 859 F.3d 1341(Fed. Cir. 2017);
5. *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

The odd procedural history of this case may have played a role in the Board's belated reliance on a new ground of unpatentability in the final written decision. Here, the petition presented three grounds. Grounds 1 and 2 related to a subset of the claims, and raised a priority issue. Ground 3 was based on obviousness and applied to all 75 claims. The bulk of the petition was directed towards the priority issue. The Board based its Institution Decision on Grounds 1 and 2. With respect to Ground 3, the Board summarily stated that it raised fact issues. The Board never found that Ground 3 raised a reasonable likelihood that one of the challenged claims was obvious. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141-42 (2016) (institution decisions involving "shenanigans" may be reviewable on appeal).

In its preliminary and patent owner response, Sumitomo argued that the Board lacked jurisdiction to consider Grounds 1 and 2 in an IPR. In particular, Sumitomo argued that where, as here, the specifications of the priority application and the last-filed application were the same, and allegedly new matter was added by amendment after filing, the challenged claims are not legally entitled to a priority date "no earlier than" the filing date of the last-filed application. Rather, the claims could only be unpatentable under § 112. See *ICU Medical Inc. v. Alaris Medical Sys., Inc.,* 558 F.3d 1368 (Fed. Cir. 2009) As such, neither Ground 1 nor Ground 2 was eligible for IPR, and that earlier Board decisions to the contrary were incorrectly decided.

The Board disagreed and, consistent with earlier Board decisions, assigned a filing date "no earlier than" the filing date of the last-filed application, and then analyzed intervening printed publications alleged to anticipate the claims under § 102. The Board found that the intervening art was reasonably likely to anticipate and "[t]hus, we institute an *inter partes* review as to all challenges raised in the petition." The Board erred by instituting review on "all challenges" based on an erroneous legal analysis of priority. This resulted in the petitioner arguing in its reply that "[b]ecause Patent Owner did not meet its priority burden the [intervening references] are prior art and the [] claims should be cancelled under Grounds 1 and 2."

Ground 3 alleged that claims 1-75 were obvious over Saji. The petition summarized Saji, as well as a number of other references, including Horisawa. The petition explicitly stated: "Ground 3 ***does not*** hinge on Horisawa being prior art." Likewise, petitioner's expert stated that his opinion was based on a POSA who did not know that "SM-13496" referred to in Horisawa was lurasidone hydrochloride (the active ingredient in the challenged claims). Ex. 1002, ¶ 109. The petition then alleged: "Claims 1-75 are obvious over Saji patent (EX. 1009) in view of the prior art." The only other discussion of Horisawa in the actual obviousness analysis was in the form of a brief citation.

In its patent owner response, Sumitomo objected that the petition failed to state the obviousness ground clearly and with particularity. However, in spite of the petition's failure to define the ground clearly, its cursory mention of Horisawa, and the lack of expert testimony, the Board, in its final written decision, made extensive findings related to Horisawa and how a POSA would interpret it. The Board also found that Horisawa was

prior art, even though the petition explicitly stated that "Ground 3 ***does not*** hinge on Horisawa being prior art."

The issue of whether Horisawa qualified as prior art was never squarely presented during the proceeding. The Board's decision to rely on Horisawa, and to treat it as prior art in its obviousness analysis, represented an improper new ground of unpatentability. See *EmeraChem Holdings, LLC v. Volkswagen Group of America, Inc.*, 859 F.3d 1341 (Fed. Cir. 2017).

The oral hearing focused primarily on the priority issue and included a discussion of the jurisdictional issue. Nevertheless, in an abrupt about-face, the Board dodged the jurisdictional issue and decided only Ground 3 in its Final Written Decision, finding claims 1-75 unpatentable as obvious.

The Board's belated shift from priority to obviousness resulted in a poorly reasoned obviousness decision that relied on a ground never squarely raised in the petition. Precedential Opinion Panel review is warranted to correct this error and to ensure application of uniform standards consistent with *Cuozzo, ICU Medical*, *SAS*, *Magnum Oil*, and *EmerChem*. Sumitomo is available to provide additional briefing on this issue, as well as the legal standards governing the priority analysis, should the panel so desire.

Respectfully submitted,
Dorothy Whelan, Reg. No. 33,814
Counsel for Patent Owner

Dorothy Whelan :: Sr. Principal :: Fish & Richardson P.C.
612 337 2509 direct :: 651 230 7163 mobile :: whelan@fr.com
fr.com :: Bio :: LinkedIn :: Twitter