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Patent Litigation

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Dissent: Deferential Review by Federal Circuit Falls Short of Purpose of Providing Optimum Determination of Patent Validity

In *Merck & CIE v. Gnosis S.P.A., Gnosis Bioresearch S.A., Gnosis U.S.A. Inc.* [Case No. 2014-1779 (Fed. Cir. Dec. 17, 2015)], the Federal Circuit affirmed the Patent Trial and Appeal Board's (PTAB) decision that the contested claims were invalid for obviousness, determining that the PTAB's factual findings were supported by substantial evidence, and agreeing with the PTAB's conclusion of obviousness. However, in dissent, Judge Newman asserted that the Federal Circuit's substantial evidence standard of review for the PTAB's factual findings in America Invents Act (AIA) trial decisions is not appropriate under the AIA, and that based on a review without deference, the PTAB's decision in this case should be reversed.

The patent at issue relates to methods of using folates to reduce excessive levels of homocysteine in the human body, which are known to cause cardiovascular, ocular, neurological, and skeletal disorders. The reviewed patent is owned by Merck, and licensed to Pamlab, which sells several pharmaceutical products covered by the patent. The PTAB determined that all of the contested claims were obvious in light of three prior art references. The PTAB found that all of the limitations of the claims were disclosed in these references, and that there was a motivation to

combine references to arrive at the claimed invention.

In making its determination, the PTAB also considered objective indicia of non-obviousness; however, the PTAB concluded that Merck failed to demonstrate an adequate nexus between the novel features of the patent and the evidence of commercial success, licensing, copying, and industry praise. The PTAB further determined that the evidence of a long-felt, unmet need was unpersuasive, and therefore afforded the evidence of objective considerations little weight.

As for the standard of review, the court reviewed the PTAB's factual findings for substantial evidence, and reviewed the PTAB's conclusion of obviousness *de novo*. [Slip Op. at 7.] The court determined that the PTAB's findings were supported by substantial evidence and, that on balance, they provide strong evidence of obviousness. [Slip Op. at 17.]

In dissent, Judge Newman elaborated on an argument she had raised in an earlier *inter partes* review (IPR) appeal that the substantial evidence standard should not be applied in appeals of PTAB trial decisions, stating that "it is incorrect for this court... to review the PTAB decision under the highly deferential 'substantial evidence' standard" and that it is "our assignment to determine whether the PTAB ruling is correct in law and supported by a preponderance of the evidence." [Dissent at 4.] Judge Newman's dissent does not, however, address why she previously joined other Federal Circuit judges in applying the substantial evidence standard in other IPR appeals. [See *Belden Inc. v. Berk-Tek LLC*, Case No. 2014-1575, -1576 (Fed. Cir. Nov. 5, 2015).]

"Correctness, Uniformity, Finality, and Expedition"

Judge Newman reasoned that the AIA's new post grant procedures (1) were created to respond to the belief that the Patent Office was making mistakes and (2) were directed towards the goals of "correctness, uniformity, finality, and expedition" with respect to the patent system. [Dissent at 4, 5.] Judge Newman asserts that, on appeal, the way to ensure the AIA's goals are met is to have the Federal Circuit look at the entirety of the evidence and review PTAB decisions for correct applications of the standard of proof required by the AIA. [Dissent at 3, 5.] Deferential review, according to Judge Newman, "falls short of the legislative purpose of providing optimum determination of patent validity." [Dissent at 5.] In this case, had the Federal Circuit assured that the PTAB's factual findings were supported by a preponderance of the evidence, Judge Newman believes the court would not have affirmed the PTAB's decision. [Dissent at 13.] This appears to be an argument in support applying a *de novo* standard of review to the PTAB's findings, but Judge Newman does not specifically call it that.

Absent *en banc* review (an unlikely event), the Federal Circuit will continue to review the PTAB's factual findings for substantial evidence in AIA trial appeals, however Judge Newman presents some interesting arguments as to whether the court should continue to do so, or whether the goals of the AIA would be better served by evaluating on appeal whether the preponderance of the evidence supports the PTAB's findings.

In a companion case before the same Federal Circuit panel, addressing three related patents, *South Alabama Medical Science Foundation v. Gnosis S.P.A., Gnosis Bioresearch S.A., Gnosis U.S.A. Inc.* [Case Nos. 2014-1778, 2014-1780,

2014-1781, p. 8 (Fed. Cir. Dec. 17, 2015)], the court likewise affirmed the PTAB's ruling that the contested claims were obvious, and Judge Newman dissented, stating, "[f]or the reasons discussed in my dissenting opinion in *Gnosis I*, obviousness

was not established by a preponderance of the evidence."

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