

S. ALA. MED. SCI. FOUND. v. GNOSIS S.P.A., Appeal Nos. 2014-1778, -1780, -1781 (Fed. Cir. December 17, 2015). Before Newman, Plager, and Hughes. Appealed from the Patent Trial and Appeal Board.

Background:

In an *inter partes* review, the Patent Trial and Appeal Board (PTAB) held that a patentee's claims directed to a method of increasing a human subject's dietary folate uptake were obvious over the prior art. The method included administering a particular combination of a folic acid stereoisomer with a vitamin. The PTAB held that there was "strong evidence" that one of ordinary skill in the art would have been motivated to combine the teachings of the applied references to arrive at the claimed method. The PTAB did not heavily weigh the patentee's evidence of secondary considerations, reasoning that there was an insufficient nexus between the evidence and the merits of the claimed invention.

The patentee appealed, arguing that the PTAB applied an overly strict nexus requirement.

Issue/Holding:

Did the PTAB err in holding that the patent claims were obvious? No, affirmed.

Discussion:

After confirming that the claimed methods would have been *prima facie* obvious, the Federal Circuit considered the patentee's evidence of secondary considerations. The court noted that for objective evidence of secondary considerations to be afforded substantial weight, there must be a nexus between the evidence and the merits of the claimed invention. There is no nexus when the secondary considerations result from something other than what is novel in the claim.

The court discounted the patentee's evidence of commercial success and industry praise, holding that there was no nexus between this evidence and the novel feature of the claims. The patentee had identified specific products that were commercially successful and received praise. However, these products contained active ingredients not recited in the claims. The court determined that there was an insufficient showing that the commercial success and industry praise were due to the specific combination of compounds recited in the claims.

However, the Federal Circuit held that the PTAB erred in its analysis of the patentee's licensing evidence. The PTAB had concluded that the patentee failed to show a nexus between the claimed invention and the products manufactured under the licenses. The Federal Circuit clarified that the relevant inquiry is whether there is a nexus between the invention and the licensing activity itself. The patentee is not required to establish a nexus between the manufactured product and the claimed invention, although such evidence may be probative of whether there is a nexus.

Despite identifying this error in the PTAB's analysis, the Federal Circuit agreed with the PTAB's ultimate conclusion of obviousness in view of the weight of the remaining evidence.