

Objective Evidence Based on Unclaimed Species Insufficient Nexus

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Gnosis SpA v. South Alabama Medical Science Foundation

In the final written decision of an *inter partes* review, the **Patent Trial and Appeal Board (PTAB)** found all claims at issue unpatentable, concluding that the prior art provided strong evidence of obviousness, which was not overcome by the objective evidence presented due to lack of sufficient nexus to the claimed subject matter. The PTAB found that the objective evidence presented was either tied to a prior art element in the claim or pertained to an **unclaimed embodiment/species**, with no indication that other embodiments encompassed by the claims would perform similarly. ***Gnosis SpA v. South Alabama Medical Science Foundation***, IPR No. IPR2013-00016 (PTAB, June 20, 2014) (Kamholz, APJ).

The patent claims at issue relate to dietary folate supplementation and are directed to a method of **increasing intake of folate** by administering a composition comprising substantially chirally pure **5-methyl-(6S)-tetrahydrofolic acid (5-methyl-(6S)-THF)** and a **nutritional substance** comprising a vitamin other than ascorbic acid. The PTAB agreed with Gnosis that the challenged claims would have been obvious over the asserted prior art references, Serfontein and Marazza. According to the PTAB, Serfontein calls for a “suitable active metabolite of folate” in oral preparations to correct folate deficiency, Marazza specifically identifies chirally-pure 5-methyl-(6S)-THF as an active metabolite of folate suitable for oral use to increase folate levels, and the similar purpose and disclosure of the references provides sufficient rationale for combining them. The patentee’s arguments against the combination of Serfontein and Marazza, and against the use of reduced folates, were found unpersuasive for lack of credible evidence, among other reasons.

The patent owner also relied on various types of objective evidence based on five marketed products, each including substantially chirally-pure 5-methyl-(6S)-THF in combination with various other active ingredients, which are not specifically recited in the claims. The patentee emphasized that the combinations of active ingredients and the “unique” aspects of the products’ formulations account for their success. The PTAB disagreed with the patentee’s position that that nexus is sufficiently established when the product or method on which the evidence is based is covered by the patent. The Board cited ***In re Kao*** ([*IP Update*, Vol. 14, No. 6, Endo Finds Pain Relief from Board’s “Erroneous Reasoning”](#)) to not only require a showing that *novel elements in the claim account for the objective evidence*, but also that the *objective evidence be reasonably commensurate in scope*

with the claim. The latter may be established by providing adequate basis to support the conclusion that other embodiments falling within the claim will behave in the same manner.

Here, the PTAB determined that the causal relationship between the claimed subject matter and commercial success, licensing, copying or long-felt need was tenuous, because the evidence was based on the unique formulations of the marketed products and therefore tied to combinations of elements not found in the claims at issue. According to the PTAB, by arguing the special advantages of the unique formulations, the patentee had implicitly suggested that other formulations within the scope of the claims would not necessarily offer the same benefits. PTAB also concluded that the evidence of unrecognized problem, unexpected results, skepticism and praise lacked nexus to the claims because they were tied to 5-methyl-(6S)-THF, a claim element known from the prior art and, hence, ineligible to establish the required nexus.

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