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PTAB Trial Standard Of Review Requires Affirmance Despite Contrary Evidence

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In Merck & Cie v. Gnosis S.p.A., the ***Federal Circuit*** affirmed the decision of the ***USPTO Patent Trial and Appeal Board (PTAB)*** that held the challenged claims obvious in an *Inter Partes Review (IPR)* proceeding. Although the court recognized evidence that undermined the obviousness finding and acknowledged objective evidence of nonobviousness, the court determined that the PTAB's factual findings were adequately supported by substantial evidence, such that the decision should be affirmed. In her dissent, Judge Newman questions whether that is the correct standard of review for a PTAB trial decision.

The Patent At Issue

At issue were claims 8, 9, 11, 12, 14, 15, and 19–22 of Merck's U.S. Patent No. 6,011,040, directed to methods of "preventing or treating disease associated with increased levels of homocysteine . . . comprising administering … L-5-MTHF."

The PTAB found all of the contested claims obvious in view of three references:

> EP 0 595 005 (Serfontein), cited for teaching the use of "folate or a suitable active metabolite of folate," along with vitamins B6 and B12 to treat high levels of homocysteine.
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> U.S. Patent No. 5,194,611 (Marazza), cited for "identif[ying] L-5-MTHF as a 'natural metabolite' that may be used "as at least one active compound" in a treatment for folate deficiency," and for disclosing a method of obtaining L-5-MTHF from an enantiomeric mixture.
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> Ubbink et al., *Vitamin B-12, Vitamin B-6, and Folate Nutritional Status in Men with Hyperhomocysteinemia*, 57 Am. J. Clinical Nutrition, 47, 47–53 (1993) (Ubbink), cited for reporting the association between elevated levels of homocysteine and a number of disease conditions, and treatment using a vitamin supplement containing folic acid.

As summarized by the Federal Circuit:

> The Board found that, because of the close similarity of purpose and disclosure between Serfontein and Marazza, a person of ordinary skill in the art would have been motivated to combine the two references to arrive at a method of treating elevated levels of homocysteine with L-5-MTHF …. Further, the Board found a person of skill would have been motivated to use this method in the situation disclosed in Ubbink, in which the elevated homocysteine levels are associated with certain enzyme deficiencies. …. The Board also considered objective indicia of nonobviousness. The Board concluded that Merck failed to demonstrate an adequate nexus between the novel features of the ’040 patent and the evidence of commercial success, licensing, copying, and industry praise. It also found that the evidence of long-felt but unmet need, unexpected results, and industry skepticism was unpersuasive.

The Federal Circuit Decision

The Federal Circuit Decision was authored by Judge Hughes and joined by Judge Plager. Judge Newman dissented.

The court’s analysis begins with a reminder of the factual findings underlying the question of obviousness:

> Obviousness is a question of law based on underlying findings of fact. *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). The factual findings include: “(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.” *Id.*; *see also Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

With that in mind, the court cites *In re Gartside*, 203 F.3d 1305, 1313 (Fed. Cir. 2000), for the rule that “In appeals of Board decisions, these factual findings are reviewed for substantial evidence.”

Applying that deferential standard of review to the PTAB findings at issue, the court found them all to be supported by substantial evidence. The court acknowledged that Merck had presented ***some*** evidence in support of its arguments that “the prior art teaches away from this combination by suggesting: (1) administering 5-MTHF would actually increase levels of homocysteine, (2) 5-MTHF would be too unstable for therapeutic use, and (3) L-5-MTHF is a poor substrate for polyglutamation, a process that facilitates retention and use of L-5- MTHF in the cell. Nevertheless, the court also found substantial evidence to support the PTAB findings to the contrary.

At to point (1), the court stated:

> The prior art does not ***unambiguously teach*** that administration of 5-MTHF would increase homocysteine levels.

At to point (2), the court stated:

> Nor does the prior art ***compel*** a finding that a person of ordinary skill would have thought 5-MTHF was too unstable for therapeutic use.

As to point (3), the court noted conflicting views in the scientific literature, and also noted scientific literature indicating that "5-MTHF would nonetheless be effective for lowering homocysteine levels."

Merck also challenged the PTAB decision for failing to make "an express finding that a person of ordinary skill would have a reasonable expectation of success" in combining the cited references, but the court was willing to overlook that omission because "the Board addressed Merck's arguments against a reasonable expectation of success in the context of its teaching away arguments."

Turning to the issues surrounding the objective indicia of nonobviousness, the court found substantial evidence to support the PTAB's findings that "the nexus between the merits of the invention and the evidence of commercial success, licensing, copying, and industry praise was weak."

In this regard, the court noted that one group of commercial products was combination products that included other active ingredients (*e.g.*, B vitamins). Even though some claims at issue recite such combinations, the court noted that "[t]hese products go further and contain a specific combination of specific forms of B-vitamins and other active ingredients" and that "Merck failed to establish that the commercial success of these products was due to the claimed method—using L-5-MTHF and 'at least one B-vitamin'—as opposed to the specific formulations in the mixed products."

Don't all commercial products necessarily contain "specific combination of specific forms of [ingredients]"?

With regard to the single-ingredient products, which were approved "for use as a supplemental treatment of major depressive disorder and schizophrenia," the court found substantial evidence supported the PTAB's finding that the use of 5-MTHF for treating major depressive disorder and schizophrenia was known in the prior art, and therefore Merck "could not show a sufficient nexus between the commercial success of the Deplin® products and the novel features in the asserted claims."

But the Deplin® products include L-5-MTHF, as specified in the claims.

With regard to Merck's evidence of licensing, the court noted that the cited licensing agreement "also covered several other patents, including one that "claims the stable form of L-5-MTHF used in Pamlab's products more precisely than the '040 patent." Thus, "[i]t is therefore difficult to determine the extent to which the licensing agreement was a result of the novel features in the '040 patent, as opposed to the other patents involved."

Does this mean that a license encompassing a portfolio of patents only can support non-obviousness of the patent that most specifically claims the commercial product(s)?

Thus, although the court acknowledged that “another factfinder may have reasonably evaluated Merck’s evidence of objective indicia of nonobviousness differently in the first instance,” the PTAB’s findings were “supported by substantial evidence.”

Judge Newman’s Dissent

In her dissent, Judge Newman questions the court’s application of the “substantial evidence” standard of review to PTAB trial decisions.

Judge Newman states that Congress’s purpose in creating PTAB trials was “to restore an effective and balanced system of patents, whereby valid patents may reliably be confirmed and invalid patents efficiently invalidated.” Because the American Invents Act (AIA) “does not permit subsequent review of the PTAB’s validity/invalidity decision in any other tribunal, whether by appeal or direct review or as a defense or offense in litigation,” Judge Newman believes that the court’s focus should be on reaching the correct result, not affording deference to an agency decision.

Judge Newman points out the irony in affording deferential review to PTAB decision when the purpose of PTAB trials is to provide an efficient mechanism for correcting USPTO mistakes:

> The substantial evidence standard originated with appeals of jury verdicts, in recognition of the role of credibility at trial. …. “Substantial evidence” was incorporated into the Administrative Procedure Act in recognition of the expertise of specialized agencies. …. Here, however, a new system was created to respond to the belief that the agency was making mistakes. …. This new system is directed at correcting mistakes. Deferential review by the Federal Circuit falls short of the legislative purpose of providing optimum determination of patent validity.

According to Judge Newman,

> [T]he court’s role in an appeal of a PTAB trial decision] is to determine whether the PTAB ruling is correct in law and supported by a preponderance of the evidence. The panel majority errs in importing into these proceedings the Administrative Procedure Act standard that applies to initial patent examination decisions.

Turning to the case at hand, Judge Newman reviews Merck’s arguments and supporting evidence in detail, and explains why, in her view, the PTAB decision was not supported by a preponderance of the evidence, but rather was lacking evidence on many points.

It will be interesting to see if Merck–or another party receiving an unfavorable decision in a PTAB trial–pursues the standard of review issue to the Supreme Court.

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