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CLIENT ALERT

The PTAB's Interpretation of a Prior Art Reference Is a Factual F

APRIL 26, 2019

Neptune Generics, LLC v. Eli Lilly & Company, Nos. 2018-1257, 2018-1258, 2018-1288, and 2018-1290 (Fed. Cir. Apr. 26, 2019)
The Patent Trial and Appeal Board (PTAB) considered three petitions for *inter partes* review (IPR) of the same patent. The PTAB found that in all three cases, the petitioners had not established that the patent was invalid as obvious. The patent is generally directed to treatment of a chemotherapy patient with a combination of vitamin B12 and folic acid prior to treatment with the anticancer drug pemetrexed. Such pretreatment lowers homocysteine levels, a marker for toxic effects of pemetrexed. The PTAB found that while pretreatment with folic acid was known, it would not have been obvious to also pretreat with vitamin B12.

The Federal Circuit affirmed, finding that each step of the PTAB's analysis was "supported by substantial evidence." The petitioners argued that the prior art explicitly disclosed the administration of folic acid with vitamin B12 to lower homocysteine levels that had been "elevated by any known cause." However, the Federal Circuit held that such an argument was "at heart, a challenge to the Board's factual findings," and that the PTAB's distinction of this statement was supported by substantial evidence. The petitioners also pointed out that the patentees themselves had indicated to the Food and Drug Administration (FDA) that "the prior art suggested that pretreating with folic acid and B12 was a no-risk, predictable way" to lower the toxic effects of pemetrexed. However, the Federal Circuit again held that the PTAB's factual finding would not be overturned, given the PTAB's conclusion that the patentees' contrary FDA statements were made "through the lens of what they had invented."
A copy of the opinion can be found here

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