

## **IP Alert | Federal Circuit to PTAB: Explain Your Rationale**

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In early November, Merck Sharp & Dohme Corp. and Wyeth LLC presented oral arguments to the U.S. Court of Appeals for the Federal Circuit on an appeal from two inter partes reviews (IPRs) related to a vaccine to prevent pneumococcal diseases, such as pneumonia, meningitis, bacteremia, sepsis, and middle ear infection.

On Nov. 26, the court issued its non-precedential decision to vacate and remand the two IPRs to the Patent Office's Patent Trial and Appeal Board (PTAB) for further proceedings.<sup>[1]</sup> It found the PTAB's decision "too cryptic to survive judicial review."

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Click [here](#) to read a previous Banner Witcoff IP Alert that summarizes the oral hearing and provides additional background information.

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Although the court did not cite the Administrative Procedure Act (APA) in its decision, its reasoning was consistent with Merck's assertion that the PTAB had violated 5 U.S.C. §§ 706(2)(A) and (E) of the APA in failing to explain its rationale. The court found that the record contained disputed issues of fact. Yet, rather than addressing those issues, the PTAB's final written decisions avoided them. Specifically, the court found conflicting evidence relating to whether a person of skill in the art would have been motivated to combine 13 serotypes into conjugates with CRM<sub>197</sub> protein and whether the potential for "immune interference" would have dissuaded the person of skill in the art from making the 13-conjugate combination. The court stated that the PTAB's differing conclusions on

obviousness of claims that only differed by the number of serotype conjugates in the combination underscored the need for further explanation. The court also instructed the PTAB on remand to consider a reference that it had disregarded as merely cumulative.<sup>[2]</sup> Merck's expert relied on the reference, a memorandum from Ireland's Environmental Protection Agency, which indicated that Wyeth in 2003 intended to produce a 13-valent conjugate vaccine with only the CRM<sub>197</sub> protein as the conjugate protein.

Merck had argued that the phenomenon of immune interference was irrelevant to obviousness because the PTAB construed the Wyeth claim as not requiring any specific level of immunogenicity. The court rejected that argument. It found immune interference relevant to motivation to conjugate all 13 serotype polysaccharides to a single carrier protein—CRM<sub>197</sub>.

Throughout the oral arguments and the opinion, the court made clear that the mere fact that the Peña reference did not show that a vaccine it was testing was successful was not sufficient to render the claimed subject matter non-obvious.

Obviousness, the court stated, does not require that the prior art show success.

We will have to wait to see if the PTAB explains its initial decision more fully or, upon reconsideration in view of the court's guidance, changes its opinion of the patentability of claim 18.

The court's decision will likely embolden appellants in the future to attack PTAB decisions for failure to comply with the APA, in addition to attacking the merits of the decision.

Click [here](#) to read the court's non-precedential decision, and [here](#) to download a PDF of this article.

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<sup>[1]</sup> Merck Sharp & Dohme Corp. v. Wyeth LLC, (2018-2133, -2134) (Fed. Cir.) (Nov. 26, 2019)

<sup>[2]</sup> See footnote 4.

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