

## ***Almirall, LLC v. Amneal Pharmaceuticals LLC, 28 F.4th 265 (Fed. Cir. 2022)*** **(Lourie, Chen, Cunningham)**

BY R. WILSON "TREY" POWERS III, PH.D.

Almirall's patent claims recite: [a]bout 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer....

The Board instituted an IPR on the patent, where the primary reference disclosed "between about 0.2% to about 4% by weight" of various gelling agents. However, the primary reference did not disclose the specific claimed gelling agent. Instead, the Board relied on disclosures from secondary references—in two separate unpatentability grounds—for disclosure of the specific claimed gelling agent. Both secondary references also disclosed gelling agents at ranges overlapping the claimed range.

The Board determined that it would have been obvious to substitute the primary reference's gelling agent with the gelling agent disclosed in either of the two secondary references. The Board found that a skilled artisan would have had a good reason to pursue a replacement for the primary reference's gelling agent. For example, the Board credited expert testimony explaining that the primary reference's gelling agent had drawbacks such as grittiness and a propensity for agglomeration which would have been reduced with the secondary references' gelling agent. The Board also determined that a skilled artisan would have had a reasonable expectation of success in making the substitution. The Board found that the disclosed overlapping ranges support the conclusion that a skilled artisan would have expected that swapping one for the other would be successful and would perform the same function in the modified composition.

On appeal, Almirall argued that the gelling agent ranges in the primary reference do not create a presumption of obviousness because the primary reference disclosed a different gelling agent. Almirall argued that the presumption of obviousness regarding overlapping ranges only applies when a single reference discloses all claimed ranges. Almirall also

The court held that the Board's decision set forth factual findings of similarity between the two types of gelling agents that supported the conclusion that each of the primary reference's components encompasses, overlaps, or abuts the ranges recited in the claims.

argued that the Board's factual findings were unsupported by substantial evidence.

The Federal Circuit rejected those arguments. The court held that the Board's decision set forth factual findings of similarity between the two types of gelling agents that supported the conclusion that each of the primary reference's components encompasses, overlaps, or abuts the ranges recited in the claims. The court also noted that the Board found that expert testimony established that a skilled artisan would have been able to immediately appreciate that the two types of gelling agents at issue perform the same function and are interchangeable.

Ultimately, the court found that the case did not depend on overlapping ranges. Instead, the court determined that it was a simple case of substituting one known gelling agent for another. Specifically, each agent "may be effective at a different concentration in different formulations, but that is just a property of the particular known material, subject to conventional experimentation."

---

## RELATED CASES

- *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367 (Fed. Cir. 2022) (holding that an applicant's admission of what is in the prior art cannot constitute "prior art consisting of patents or printed publications" within the meaning of 35 U.S.C. § 311(b) and cannot be the basis for a ground in an IPR).
- *LG Electronics Inc. v. Immervision, Inc.*, 39 F.4th 1364 (Fed. Cir. 2022) (holding that a typographical or similar error in a prior art reference cannot be the basis for an invalidating prior art disclosure so long as a skilled artisan would disregard the erroneous information or mentally substitute the correct information).
- *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154 (Fed. Cir. 2022) (vacating and remanding Board decision concluding that there was no motivation to combine because the Board relied only on "generic industry skepticism," as opposed to evidence of skepticism specific to the invention or specific to the asserted combination of references).