

## Prior Art Ranges for Similar Compounds Can Establish a Prima Facie Case of Obviousness

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*Valeant Pharmaceuticals International, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 2018-2097 (Fed. Cir. Apr. 8, 2020)

Patentee sued for infringement of a patent claiming a stable pharmaceutical solution of methylnaltrexone with a pH of about 3.0 to 4.0. The district court granted summary judgment in favor of patentee, on the basis that: (1) the key prior art references did not teach methylnaltrexone formulations, but only formulations of similar compounds; and (2) the claimed pH range would not have been obvious to try. On appeal, the Federal Circuit reversed and remanded for further proceedings.

The Federal Circuit noted that the claimed pH range “clearly overlaps with the pH range in the record art, but none of the references disclosed the same drug as the one claimed.” Nevertheless, the court held that “prior art ranges for solutions of structurally and functionally similar compounds that overlap with a claimed range can establish a prima facie case of obviousness,” thus shifting the burden to the patentee to show that the invention would not have been obvious. The court reasoned its previous cases have established the principle that “[w]hen compounds share significant structural and functional similarity, those compounds are likely to share other properties, including optimal formulation or long-term stability.” Here, “[b]ecause these three molecules [the claimed and prior art compounds] bear significant structural and functional similarity, and because the prior art of record teaches pH ranges that overlap with the pH recited in the [asserted claim], [alleged infringer] has at least raised a prima facie case of obviousness sufficient to survive summary judgment.”

The Federal Circuit also disagreed with the district court’s obvious-to-try analysis as being “inconsistent with precedent.” Specifically, the “bounded range of pH 3 to 4 presents a finite number of narrower pH ranges for a skilled artisan to try,” not an infinite number as the district court had suggested. Moreover, “there is no requirement that for a variable to be obvious to try, it must be the first variable a person of skill would alter.” A factfinder could also draw the inference that trying a pH of 3–4 would lead to a stable formulation: “Absolute predictability that the proposed pH range would yield the exact stability parameters in the claim is not required.” These errors were more notable here where “pH is in fact the only variable in [the asserted claim], not one of many variables that can be experimented with.”

A copy of the opinion can be found [here](#).

2 Min Read

## Author

[Sharon Lin McIntosh](#)

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