VALEANT PHARMACEUTICALS INTERNATIONAL, INC. v. MYLAN PHARMACEUTICALS INC., Appeal No. 2018-2097 (Fed. Cir. April 8, 2020). Before Lourie, Reyna and Hughes. Appealed from D.N.J. (Judge Chesler).

Background:

Plaintiff owns a patent directed to stable pharmaceutical preparations useful for reducing the side effects of opioids. The patent is listed in the Orange Book for Relistor®. Defendant filed an ANDA seeking approval from the U.S. Food and Drug Administration to market a generic version of Relistor®, and Plaintiff sued Defendant alleging that Defendant's proposed product would infringe the patent. Defendant conceded that its ANDA product would infringe the asserted claim of the patent but maintained that the asserted claim was invalid as obvious over stable solutions of similar compounds (with similar anti-opioid activities).

Plaintiff moved for summary judgment that the asserted claim would not have been obvious, and the district court granted Plaintiff's motion. The district court rejected Defendant's expert testimony and cited references as insufficient, largely because the references did not teach formulations of the exact active compound but instead taught formulations of similar but different active compounds (the main structural difference between the relevant compounds was the identity of a functional group attached to a particular nitrogen atom). The district court also rejected Defendant's theory that the claimed conditions necessary to arrive at the recited stable pharmaceutical preparation (i.e., a specific pH range between about 3.0 and about 4.0) would have been obvious to try as the recited pH range was just one of a finite number of pH options disclosed in the art—holding that given any two unequal numbers (here a range between pH 3 and 7), the quantity of number ranges falling between the two is infinite, not finite. Plaintiff appealed.

Issue/Holding:

Did the district court err in granting summary judgment? Yes, reversed and remanded.

Discussion:

In reversing the district court's grant of summary judgment, the Federal Circuit 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. However, the Federal Circuit also stated that the holding of this case "should not be misconstrued to mean that molecules with similar structure and similar function can always be expected to exhibit similar properties for formulation." But, on the present record, the district court's grant of summary judgment was in error.

In this regard, the Federal Circuit concluded that the asserted claim would have been obvious because the pH range in the asserted claim overlaps with suitable pH ranges taught in the art for similar compounds that shared significant structural and functional similarities. That is, because in this case a person of skill in the art can expect these compounds with common properties are likely to share other related properties (including optimal formulation for long-term stability), it would have been obvious for a person of skill in the art to try to use such disclosed pHs when formulating and/or pursuing stable solutions of the recited active compound. Therefore, the Federal Circuit determined that the record supported that Defendant had at least raised a *prima facie* case of obviousness sufficient to survive summary judgment.

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