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CLIENT ALERT

Federal Circuit Limits Pharmaceutical Claim Construction Because of Prosecution History and Written Description

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AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al., No. 21-1729 (Fed. Cir. Dec. 8, 2021)

Following claim construction and a bench trial on invalidity, the Federal Circuit vacated the stipulated judgment of infringement, finding the district court's claim construction too broad, but affirmed the district court's determination that the asserted patent was not obvious. AstraZeneca's asserted patent for the Symbicort pressurized metered-dose inhaler claims a formulation that includes a 0.001% concentration of polyvinylpyrrolidone ("PVP"). The Federal Circuit first considered whether the claimed concentration should be construed to mean within one significant figure of 0.001% (i.e., 0.0005% to 0.0014%) or precisely 0.001%, with only minor deviations permitted. Although the court agreed that the ordinary meaning would be to read it within one significant figure, the Federal Circuit held that the claim term must be assessed in light of the entire patent, including the written description and prosecution history.

The asserted patent's written description emphasized the importance of stability in formulating the pharmaceutical. It included the inventors' testing showing that even a concentration of 0.0005%—a concentration that AstraZeneca's proposed significant-figure construction would permit—would negatively impact the stability of the claimed formulation. The Federal Circuit was also persuaded by the prosecution history, which shows that the inventors claimed increasingly narrow concentrations until they finally arrived at the claimed 0.001% concentration. The prosecution history also shows that the inventors had previously qualified the claimed concentration by preceding it with the word "about." The Federal Circuit observed that the claims as issued did not have the qualifier preceding the 0.001% concentration. Given the written description and prosecution history, the Federal Circuit determined that the asserted patent claims a precise 0.001% concentration, with only a 5% margin of error permitted. This results in a range that is significantly narrower than AstraZeneca's proposed significant-figure margin of error, which allowed for variations as much as 50%. As a result, the court vacated the stipulated judgment of infringement and remanded for further proceedings to determine whether Mylan's product infringes the asserted patent under the proper claim construction.

The court also considered Mylan's appeal of the district court's factual findings underlying the nonobviousness determination. The Federal Circuit relied on precedent demonstrating that prior art teaching away from a claimed invention can render that invention nonobvious. *See In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012). Prior art teaches away from a claimed invention if a skilled artisan would be discouraged from following the prior-art

reference after reading that reference. *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (quoting *Galderma Lab'ys, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013)).

The prior art at issue asserted that a 0.001% concentration of PVP was not suitable in aerosol pharmaceuticals. Mylan argued that, contrary to the district court's finding, the prior art did not teach away from the concentration but merely expressed a preference without discrediting the 0.001% concentration. The Federal Circuit determined that the prior art did not need to explicitly disparage the concentration. It is sufficient for the district court to rely on expert testimony that a skilled artisan would find the prior-art data disparaging, as the district court below did. The Federal Circuit therefore affirmed the lower court's judgment of no invalidity.
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