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CLIENT ALERT

A Substantially Equivalent Disclosure Can Be Sufficient to Provide Written Description; in an Obviousness Analysis, the Motivation to Combine Is Not Necessarily Linked With the Potential for FDA Approval

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Nalpropion Pharmaceuticals, Inc. v. Actavis Laboratories FL, Inc., No. 2018-1221 (Fed. Cir. Aug. 15, 2019)
The Federal Circuit affirmed a rejection of a Section 112 written description challenge, but disagreed with a finding that certain claims would not have been obvious.

With respect to the written description challenge, the patent claim at issue related to a pharmaceutical method of treating obesity, where one component had a specific profile when subjected to a USP Apparatus 2 Paddle dissolution test. The specification, in contrast, only explicitly disclosed profiles obtained using a USP Apparatus 1 Basket dissolution test. The Federal Circuit noted these differences, but stated that "it is not necessary that the exact terms of a claim be used in haec verba in the specification, and equivalent language may be sufficient." Here, the district court (D. Del.) had considered expert testimony and found that the USP 1 and USP 2 tests are substantially equivalent. The Federal Circuit concluded by stating that while "as a general matter written description may not be satisfied by so-called equivalent disclosure, in this case, buttressed by the district court's fact-finding, and where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps, we affirm the district court's conclusion. Rigidity should yield to flexible, sensible interpretation."

With respect to the obviousness challenge, the Federal Circuit rejected an argument that there was no motivation to combine the prior art references, because one of the references disclosed a compound with weight-loss properties that were "too insignificant to obtain FDA approval as a weight loss drug." Instead, the Federal Circuit credited the "real-world fact" that skilled artisans did combine the compounds disclosed in the references because one compound was known to be a well-tolerated and safe antidepressant. The court also rejected the district court's unexpected results finding because "the inventors only combined two drugs known to affect weight loss" and therefore combining prior art disclosing these two compounds "for this known purpose as claimed in the patents yields no unpredictable result."

Judge Prost dissented, stating that the majority "adds what appears to me to be a new rule to this court's long-standing written description jurisprudence . . . that a 'substantially equivalent' disclosure may satisfy the written description requirement when the relevant claim limitation recites only 'resultant dissolution parameters rather than operative claim steps.'" Judge Prost premised her dissent on three primary reasons: (i) the majority did not give enough credit to the fact that the USP 2 test was a claim limitation; (ii) the majority's substantially equivalent rule was inconsistent with precedent; and (iii) the finding of equivalence between USP 1 and USP 2 was clear error.

A copy of the opinion can be found here.

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