OREXO AB v. ACTAVIS ELIZABETH LLC, Appeal No. 2017-1333 (Fed. Cir. September 10, 2018). Before Newman, Hughes, and Stoll. Appealed from D. Del. (Judge Robinson). (Obviousness)

Background:

Plaintiff owns a patent directed to an abuse-resistant pharmaceutical composition for the treatment of opioid dependence. The scope of the claims of the patent at issue encompasses a product having the brand name Zubsolv®, approved by the FDA for treatment of opioid dependence. Defendant filed an Abbreviated New Drug Application ("ANDA") for a generic counter-part of Zubsolv®, accompanied by a Paragraph IV certification, leading to this Hatch-Waxman litigation.

The district court found that all the ingredients in the claims were generally known, and held that although the specific formulation was not shown or suggested in any reference (the parties even acknowledged that the claimed product was new), a skilled artisan would obviously have selected these components from the prior art and reformulated them as in the claims at issue. In support of its ruling, the district court stated that there is "nothing in the prior art which would have discouraged a person of ordinary skill from following the path set out in the various references". The district court also found that the prior art sought to improve bioavailability, that interactive mixtures were known to improve bioavailability, and therefore that the improved results of the claimed formulation were inadequate to serve as probative evidence of unexpected results, as the observed improvement was merely a difference in degree, not a difference in kind. Thus, the district court held the asserted claims invalid as obvious over the prior art. Plaintiff appealed.

Issue/Holding:

Did the district court err in holding the asserted claims invalid? Yes, reversed and remanded.

Discussion:

The Federal Circuit found that the record did not contain clear and convincing evidence of a teaching or suggestion to use the recited particles as a carrier for the recited opioid product in substitution therapy, or that the actual beneficial results (e.g., enabling reduced dosage and enhanced efficacy in substitution therapy products, deterring abuse) would be obtained. The Federal Circuit also found that the claimed invention's novel structure and arrangement unexpectedly improves bioavailability over the closest prior art and thus the district court erred in discounting the enhanced bioavailability of the claimed formulation as a difference in degree, not a difference in kind.

Therefore, because there was no suggestion that the specified elements should be selected and combined and that the designated formulation would be less subject to abuse than prior formulations for substitution therapy, the Federal Circuit concluded that, on the entirety of the record, defendant did not establish obviousness by clear and convincing evidence. Accordingly, the Federal Circuit reversed the district court's judgment of invalidity, and remanded for further proceedings.