ENDO PHARMACEUTICALS INC., v. ACTAVIS LLC, Appeal No. 2018-1054 (Fed. Cir. May 3, 2019). Before Wallach, Clevenger and Stoll. Appealed from D. Del. (Judge Andrews).

Background:

Endo sued several drug manufacturers that had filed Abbreviated New Drug Applications to market generic versions of the patented drug oxymorphone, which was licensed to Endo. Representative claim 1 recites: "A hydrochloride salt of oxymorphone comprising less than 0.001% of 14-hydroxymorphinone."

The district court construed the claim term "14-hydroxymorphinone" to mean "14-hydroxymorphinone hydrochloride" when read in view of the specification and based on testimony from Actavis's expert. This claim construction barred prior art disclosing the non-salt form of 14-hydroxymorphinone from being applied to the asserted claims. The district court also found that a person of ordinary skill in the art would not have a reasonable expectation of success in combining the prior art, despite an FDA communication mandating that opioid manufacturers reduce ABUK impurities (which include 14-hydroxymorphinone) in oxymorphone to below 0.001%. The district court subsequently ruled that the asserted claims were valid and had been infringed, which the defendant drug manufacturers appealed.

Issues/Holdings:

(i) Did the district court err in its claim construction? No, affirmed.

(ii) Did the district court err in holding that the claimed composition was not obvious? No, affirmed.

Discussion:

The Federal Circuit held that the district court correctly construed "14-hydroxymorphinone" as "14-hydroxymorphinone hydrochloride" because: (i) the plain language of the asserted claims recite 14-hydroxymorphinone *as part of* the hydrochloride salt form of the claimed compound, and not as a separate non-salt component; and (ii) Actavis's expert acknowledged that a person of ordinary skill in the art would recognize, based on Example 3 in the specification, that "14-hydroxymorphinone" corresponded to the hydrochloride salt form (i.e., 14-hydroxymorphinone hydrochloride).

The Federal Circuit agreed with the district court that the skilled artisan would not have a reasonable expectation of success in combining the prior art. The Federal Circuit found that one of ordinary skill in the art would not have reasonably believed that the disclosed methods of the prior art were fruitful avenues to achieve an oxymorphone purity level of less than 0.001% with respect to 14-hydroxymorphinone hydrochloride. The Federal Circuit also found that the FDA communication simply outlines a goal without actually teaching how a reduction of impurities in oxymorphone below 0.001% is accomplished. Thus, the Federal Circuit ruled that the FDA communication would not have been enough to overcome these deficiencies of the prior art.

Judge Stoll dissented because the FDA communication discloses all the features of representative claim 1, and would have constituted motivation for the skilled artisan to have modified the prior art to arrive at the asserted claims. Judge Stoll emphasized that a reference does not need to teach how to achieve the claimed invention in order to provide a motivation to combine.