

ALLERGAN, INC. v. SANDOZ INC., Appeal No. 2014-1275 (Fed. Cir. August 4, 2015).  
Before Lourie, Linn and Hughes. Appealed from E.D. Tex. (Judge Schneider).

Background:

Plaintiff owns patents relating to a drug to treat glaucoma. Defendant filed an abbreviated new drug application ("ANDA") for a generic version of the drug. In response, Plaintiff sued Defendant, asserting that the ANDA filing infringed Plaintiff's patents. The district court held a bench trial and concluded that the asserted claims would not have been obvious in view of the cited prior art and also concluded that the ANDA products infringed the asserted claims.

In reaching its conclusion of nonobviousness, the district court emphasized that the prior art (which disclosed very broad ranges that encompassed the specifically claimed amounts of the recited active compound and preservative) taught away from the claimed invention because the prior art taught that (1) the recited active compound lost efficacy as its concentration decreased; (2) the concentration of the recited preservative had no impact on the properties of the recited active compound; and (3) the recited preservative was cytotoxic and could cause corneal disorders, and therefore the prior art encouraged the removal of the recited preservative from formulations for treating the eye. In view of such evidence, the district court found that there would not have been a reason to pursue the claimed invention or a reasonable expectation of success if it were pursued. The district court also found that secondary consideration evidence (unexpected results, long-felt need, and commercial success) supported the conclusion of nonobviousness, and thus concluded that defendant failed to prove by clear and convincing evidence that the asserted claims would have been obvious. Defendant appealed.

Issue/Holding:

Did the district court err in concluding that defendant failed to prove by clear and convincing evidence that the asserted claims would have been obvious? No, affirmed.

Discussion:

The Federal Circuit determined that the district court's conclusion of nonobviousness was supported by underlying factual findings, which were not clearly erroneous. Although the prior art disclosed broad ranges that encompassed the recited amounts, the Federal Circuit determined that ample evidence of teaching away (e.g., Appellants' own expert summarized the prior art's widespread concern with respect to the recited preservative by describing the recited preservative as "a natural-born killer" that was "from Satan") and unexpected results (e.g., the record showed that the claimed amounts of the two different ingredients could and did materially and unpredictably enhance the properties of the claimed formulation) was of record, and that such evidence fully supports a conclusion of nonobviousness.

Accordingly, at least because the district court did not clearly err in finding (i) that the prior art taught away from claimed formulation, and (ii) that the claimed formulation exhibited unexpected results, the Federal Circuit affirmed the district court's conclusion of nonobviousness.