

PAR PHARMACEUTICAL, INC. v. TWI PHARMACEUTICALS, INC., Appeal No. 2014-1391 (Fed. Cir. Dec. 3, 2014). Before O'Malley, Wallach, Hughes. Appealed from D. Md. (Judge Blake). (Obviousness-Inherency)

Background:

Par's patent covered a method for increasing body mass by administering nanosized megestrol particles, wherein there is substantially no difference in the absorption of nanosized megestrol particles when taken with or without a food ("food effect"). TWi filed an ANDA seeking approval to market a generic version of the nanosized particles, alleging that Par's patent claims are invalid for obviousness. Par sued for infringement.

At trial, the district court concluded that Par's patent was invalid for obviousness because the prior art taught (1) microsized megestrol particles for increasing body mass and (2) methods for transforming microsized particles into nanosized particles. The district court found that one of ordinary skill would have been motivated to have combined the prior art because the art taught that nanosized particles have a reduced viscosity (which increases patient compliance) and increased bioavailability, and that one of ordinary skill would have had a reasonable expectation of success in combining the references. The district court acknowledged that the art did not teach the claimed food effect. However, the district court concluded that this feature was an inherent result from the obvious nanosized megestrol particles, and that the unexpected food effect was insufficient to overcome the otherwise strong evidence of obviousness. Par appealed.

Issue/Holding:

Did the district court properly conclude that Par's patent was invalid for obviousness?
No, vacated and remanded.

Discussion:

The Federal Circuit agreed with the district court that the prior art taught microsized megestrol particles for increasing body mass and methods for transforming microsized particles into nanosized particles. The Federal Circuit also agreed that that one of ordinary skill in the art would have been motivated to have combined the references. The Federal Circuit also agreed that Par's unexpected results were insufficient to overcome the strong evidence of obviousness from combining the references.

However, the Federal Circuit disagreed with the district court's inherency analysis regarding the recited food effect. The Federal Circuit noted that the inherency of an advantage (here, substantially no food effect) and its obviousness are different questions, and that obviousness cannot be predicated on what is unknown. In order to prove inherency under obviousness, the claimed feature must be established to be the natural result of the combination of elements in the prior art.

At trial, TWi introduced evidence that nanosized particles improve bioavailability, and that an improvement in bioavailability necessarily results in a decrease in the food effect. However, the Federal Circuit found this evidence to be a generality, and thus insufficient to establish the inherency of the recited "substantially no difference" in food effect. The Federal Circuit concluded that to establish inherency, the evidence must show that the reduction in particle size naturally results in "no substantial difference" in the food effect. Because there were no findings of fact regarding the "no substantial difference" in the food effect, the Federal Circuit remanded the case to the district court for further findings on this issue.