MERCK SHARP & DOHME CORP. v. HOSPIRA, INC., Appeal No. 2017-1115 (Fed. Cir. October 26, 2017). Before Newman, Lourie and Hughes. Appealed from D. Del. (Judge Andrews).

Background:

Merck owns the 150 Patent directed to a process for preparing a final formulation of a known compound (Ertapenem), the process being considered to increase the stability of the composition.

Merck sued Hospira in response to Hospira's ANDA filing for a generic version of Merck's product. While the court found that one of Merck's patents covering the compound itself had claims that were nonobvious and infringed, the district court found that the claims of the 150 Patent would have been obvious and thus, invalid. Notably, the district court found that although some of the steps, as well as the ordering of the steps, were not disclosed in the prior art, the claimed steps leading to the formulation were conventional manufacturing steps that would have been obvious from the prior art as a product of routine experimentation. The district court considered Merck's secondary considerations evidence of commercial success and copying, but ultimately found the evidence insufficient to overcome the obviousness finding.

Issue/Holding:

Did the district court err in finding the claims of the 150 Patent would have been obvious? No, affirmed.

Discussion:

The Federal Circuit acknowledged that features recited in the 150 Patent's claim such as simultaneously adding two components to a solution, a particular temperature range, a moisture content, and the particular order of the steps were not literally disclosed in the prior art. However, the Federal Circuit agreed with the district court that these features were all experimental details that one of ordinary skill would have utilized via routine experimentation with the principles of the prior art and thus would have been obvious.

The Federal Circuit held that Merck's evidence of secondary considerations, including commercial success and evidence of copying, was insufficient to overcome the evidence of obviousness of the claims. The Federal Circuit commented that the district court's dismissal of commercial success because Merck had another patent directed to the product itself was improper, because the mere fact that Merck owned an allegedly "blocking" patent should not discount commercial success evidence. However, the Federal Circuit still found the evidence insufficient to overcome the obviousness finding. The Federal Circuit also found the evidence of copying insufficient to outweigh the competing evidence of obviousness of the process.

Judge Newman dissented, arguing that the case should be remanded for proper consideration of obviousness utilizing the *Graham* factors. Judge Newman's concern was that the majority seemed to consider the fourth *Graham* factor (secondary considerations) only in the context of whether it is sufficient to rebut obviousness findings based upon the first three factors. Judge Newman indicated that secondary considerations should constitute independent evidence of nonobviousness, not just rebuttal evidence, and should be analyzed accordingly.