

MYLAN PHARMACEUTICALS INC. v. MERCK SHARP & DOHME CORP., Appeal No. 21-2121 (Fed. Cir. September 29, 2022). Before Lourie, Reyna, and Stoll. Appealed from PTAB.

Background:

Mylan petitioned for *inter partes* review of claims in a Merck-owned patent. The independent claim was directed to a specific type of salt: sitagliptin DHP. The salt could be used as an enzyme inhibitor for treating diabetes. The dependent claims recited hydrate forms of the salt.

Mylan argued that the claims were both anticipated by and obvious over the prior art.

Mylan presented a prior art reference that described a genus of enzyme inhibitors for treating diabetes. Within that genus, the reference disclosed 33 species, including sitagliptin. It also disclosed that salts could be used, and mentioned 8 "particularly preferred" salts, including DHP. Mylan argued that one of ordinary skill in the art would "at once envisage" all the members of the reference's genus, including the claimed salt. The PTAB disagreed, and held that the claims were not anticipated.

Mylan also argued that the dependent claims directed to hydrate forms would have been obvious in view of other references, which described hydrates of pharmaceutical compounds, and also generally described salt selection and optimization procedures. However, the PTAB found that Mylan had provided no rationale for why one of ordinary skill would have been motivated to make the claimed monohydrate form of sitagliptin DHP, and also failed to show that one of ordinary skill in the art would have had a reasonable expectation of success in making the hydrate form of sitagliptin DHP. Thus, the PTAB held that the claims were not obvious.

Issue/Holding:

Did the PTAB err in holding that the Merck claims were not invalid over the prior art?
No, affirmed.

Discussion:

The Federal Circuit agreed with the PTAB on all counts.

With respect to the anticipation inquiry, the court held that one of ordinary skill in the art would not "at once envisage" the specific sitagliptin DHP claimed in the patent. The prior art reference did not provide any guidance to select sitagliptin from among the 33 enzyme inhibitors, or to use a phosphate salt of any type of enzyme inhibitor. Expert testimony established that there were 957 possible salts that could theoretically be formed from the various disclosed enzyme inhibitors and salts, some of which might not even exist. Additionally, evidence showed that salt formation is an unpredictable art that requires trial and error. Thus, the reference did not describe a "limited class" of compounds from which the claimed salt could be "at once envisaged."

Regarding the obviousness inquiry, the court pointed to evidence that skilled artisans would have avoided making hydrates due to known stability and solubility issues, as well as evidence of unpredictability in the process of hydrate formation. Additionally, Merck had provided evidence that its hydrate compound had unexpected properties. This was sufficient evidence to support a finding of nonobviousness.