

BRISTOL-MYERS SQUIBB CO. v. TEVA PHARMS. USA, INC., Appeal No. 2013-1306 (Fed. Cir. June 12, 2014). Before Prost, Plager, and Chen. Appealed from D. Del. (Judge Burke).

Background:

BMS owns a patent with a claim directed to an antiviral compound known as entecavir. Teva filed an ANDA for a generic version of entecavir with a Paragraph IV certification that its generic product would not infringe BMS's patent and/or that the patent was invalid or unenforceable. BMS sued Teva for patent infringement.

After a bench trial, the district court found that at the time of BMS's invention, 2'-CDG was a lead compound for the development of antiviral drugs. Based on the structural similarity between entecavir and 2'-CDG, the "totality of the prior art" on 2'-CDG, and other evidence presented by Teva, the district court found that a skilled artisan would have been motivated to make the modifications that would have obtained entecavir, with a reasonable expectation of success of creating a compound with beneficial antiviral properties. Although the district court found that evidence of commercial success, long-felt need, and unexpected results cut in favor of non-obviousness, the district court ultimately concluded that Teva proved by clear and convincing evidence that BMS's claim would have been obvious. BMS appealed.

Issue/Holding:

Did the district court err in holding that BMS's claim would have been obvious? No, affirmed.

Discussion:

The Federal Circuit reiterated its previous case law that to establish obviousness of a new chemical compound, the accused infringer must identify some reason that would have led a chemist to have modified a known compound. Generally, such a "known compound" analysis focuses on the identity of a "lead compound," which is a prior art compound that would have been a natural choice for further development efforts. Establishing the requisite reason to modify that lead compound can come from any number of sources, including a showing that the claimed and prior art compounds possess a sufficiently close relationship to create an expectation, in light of the totality of the prior art, that the new compound will have similar properties to the prior art compound. Whether a lead compound and a claimed compound have a sufficiently close relationship frequently turns on their structural similarities and differences.

The Federal Circuit held that based on the prior art and testimony, the district court properly found strong evidence of obviousness, because the record showed that a skilled artisan would have selected 2'-CDG as a lead compound and made the minor modification to arrive at entecavir. Also, the Federal Circuit found no clear error in the district court's fact findings regarding evidence of secondary considerations of nonobviousness. The Federal Circuit concluded that after considering all of the findings for and against obviousness, as well as Teva's burden of proof, it found no basis to disturb the district court's ultimate legal conclusion, and affirmed the judgment that BMS's claim is invalid as having been obvious.