

SANOFI-AVENTIS DEUTSCHLAND GMBH v. MYLAN PHARMACEUTICALS INC.,
Appeal No. 2021-1981 (Fed. Cir. May 9, 2023). Before Reyna, Mayer, and Cunningham.
Appealed from the Patent Trial and Appeal Board.

Background:

Mylan petitioned for *inter partes review* of all claims of Sanofi's patent directed to a medical device injector pen, arguing that a combination of three prior art references rendered obvious Sanofi's patent. In the petition, Mylan argued that a secondary reference in the combination was analogous art because it addressed a problem analogous to a problem addressed in the primary reference. Sanofi, on the other hand, argued that the secondary reference was not analogous art because it relates to cars, instead of drug delivery devices, and because it was not reasonably pertinent to a problem addressed by Sanofi's patent. The PTAB sided with Mylan, finding that the secondary reference was reasonably pertinent to Sanofi's patent and that all of Sanofi's patent's claims were unpatentable. Sanofi appealed.

Issue/Holding:

Did the PTAB err in finding that the secondary reference was analogous art? Yes, reversed.

Discussion:

On appeal, Sanofi argued that the PTAB had improperly raised new issues in its analysis of whether the secondary reference was reasonably pertinent to a problem addressed by Sanofi's patent, since Mylan had only presented arguments concerning the secondary reference's relevance to the primary reference. In response, Mylan argued that it had met its burden by showing that (i) the problems addressed by the primary reference and Sanofi's patent were essentially the same, and (ii) the skilled artisan would have found it obvious to modify the primary reference based on the secondary reference.

In response, the Federal Circuit explained that the analogous art test is whether the reference is in the same field of endeavor as the patent at issue, or whether the reference is reasonably pertinent to the particular problem addressed by the patent at issue. The Federal Circuit emphasized that this analysis is between a reference and the challenged patent, rather than between the reference and another cited reference.

In rejecting Mylan's arguments, the Federal Circuit found that Mylan had failed to show the secondary reference was analogous to the patent because Mylan argued a problem addressed by the primary reference and Sanofi's patent that was different from the problem that Mylan relied on to argue that the secondary reference was analogous to the primary reference. The Federal Circuit also rejected Mylan's argument that the comparisons Mylan made between the secondary reference and Sanofi's patent addressed the analogous art issue, since these comparisons related to the similarities between the challenged claims and the secondary reference, instead of how the secondary reference was analogous to Sanofi's patent.