

IN RE EFTHYMIPOULOS, Appeal No. 2016-1003 (Fed. Cir. October 18, 2016). Before Prost, Newman, and Bryson. Appealed from the PTAB.

Background:

The applicant's claims are directed to a method of treating influenza by administering zanamivir by inhalation through the mouth alone. The claims were rejected as having been obvious over a first reference disclosing intranasal administration of zanamivir to treat influenza, and a second reference disclosing administration of a compound similar to zanamivir by inhalation for treatment and prevention of influenza. The examiner noted that there are only two possible inhalation methods (oral and nasal) and concluded that treating influenza by oral inhalation of zanamivir would have been obvious in view of other references teaching the availability of inhalers, the fact that oral inhalation delivers more drug to the lungs, and the fact that influenza infects the lungs. The Board affirmed the examiner's rejections, noting that the second reference's disclosure of "inhalation" is reasonably understood to disclose inhalation by the nose alone, the mouth alone, or both. The Board also considered the applicant's evidence of unexpected results, finding the evidence unpersuasive. The applicant appealed.

Issue/Holding:

Did the Board err in affirming the Examiner's rejection of the claims? No, affirmed.

Discussion:

The court agreed with the Board's characterization that it would have been obvious to administer zanamivir by inhalation through the mouth in view of the references' disclosures.

The appellant argued that a person of skill would not have expected administration through the mouth alone to have been effective because oral inhalation delivers more drugs to the lower respiratory tract and, at the time of the invention, it was thought that delivery of anti-influenza drugs to the upper respiratory tract was needed to be effective. The court rejected this argument based on the prosecution of record, which noted that it was known at the time of the invention that influenza can also attack the lower respiratory tract, and that oral inhalation delivers more drugs to the lungs as compared to nasal inhalation. The court concluded that a person of ordinary skill would have a reasonable expectation of success in combining the two references.

The court also found that the Board did not improperly disregard evidence of unexpected results presented through expert testimony. The court found that the Board properly concluded that the claimed method would not necessarily yield an unexpectedly superior result because the expert's study showed only that "adding intranasal administration of zanamivir did not obviously improve" the results using oral administration alone. The court also noted the Board's consideration of another study, concluding that it was also unpersuasive because its findings were not statistically significant and because it dealt only with prevention of influenza.

In a dissenting opinion, Judge Newman asserted that the results of the two studies should not have been disregarded simply because they did not directly compare nasal administration to oral inhalation. Additionally, Judge Newman characterized the proposed combination of references as an "obvious to try" rationale and argued that the references do not support this rationale because they do not disclose administration through oral inhalation alone as being among a finite set of options to try.