

IPR tricks of the trade: Don't forget to show prior art is analogous in obviousness challenge to patentability

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In inter partes reviews (IPRs), a petitioner may challenge the validity of issued claims as being obvious over one or more prior art references. A claim is unpatentable if it would have been obvious to a person of ordinary skill in the art at the time of invention based on the teachings of the references cited by the challenger.

Obviousness is a question of law based on underlying factual findings. One of those factual findings is whether the prior art is analogous to the claimed invention. A reference qualifies as prior art for an obviousness determination *only* when it is analogous to the claimed invention. Whether prior art is analogous is not always the focus of an obviousness challenge. Nevertheless, failing to show that a reference is analogous to the challenged claims is a mistake. The U.S. Court of Appeals for the Federal Circuit in *Sanofi-Aventis Deutschland GmbH v. Mylan Pharma, Inc.*, Appeal No. 21-1981 (Fed. Cir. May 9, 2023) reminded practitioners of the importance of addressing and deciding this threshold factual issue.

Two separate tests exist to determine what art is analogous:

- (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

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There are a number of issues to consider when engaging in an analogous art analysis. First, one must not be overly rigid in defining the "problem" at hand. Obviousness is an expansive test that does not collapse the obviousness inquiry to "only consider art within the inventor's field of endeavor."

Second, the analysis must be performed from the correct point of view. The patent challenger "must compare the [prior art] to the challenged patent." It is not enough to establish that two or more references are analogous to one another — the challenger must

show that the references are each analogous to the claims being challenged.

Third, while an IPR petitioner "is not required to anticipate and raise analogous art arguments in its petition," the issue must be addressed if raised by the patent owner. A petitioner "can use its reply to 'respond to arguments raised'" by the patent owner, but the petitioner must address the argument under the correct legal framework.

It is important for practitioners to address the analogous art inquiry. The test is not a complicated one, but failing to address it properly — either in the first instance or in response to an argument questioning whether prior art is analogous — carries significant consequences.

In *Sanofi*, Mylan filed an IPR petition against Sanofi's claims directed to a drug delivery device for dosage control that included a "spring washer" with several "fixing elements." Mylan argued that the challenged claims were obvious over a combination of two prior art references. The petition stated that one reference "addresses a problem analogous to that addressed" in the second reference. Mylan did not argue that either of the references was analogous to the patent at issue.

Sanofi argued, after institution of trial, that the lead prior art reference was not analogous to the challenged patent because — while the reference and the patent both addressed various mechanical components — the prior art related to cars and not drug delivery devices. Sanofi also argued that the reference was not reasonably pertinent to the problem of the challenged patent.

The Patent Trial and Appeal Board (PTAB), nevertheless, found the lead reference to be analogous because the reference addressed a problem that was also addressed by the inventors of the challenged patent.

On appeal, the Federal Circuit found that the PTAB improperly expanded Mylan's arguments. Mylan's IPR petition only argued that the two asserted references were analogous to one another. Mylan did not address whether either reference was analogous to the challenged patent. Mylan did not take the opportunity to respond to Sanofi's analogous art argument on the merits and instead faulted Sanofi for allegedly applying an incorrect legal standard.

Under the specific facts of this case, the Federal Circuit concluded that Mylan did not establish obviousness because it failed to show that the prior art references were analogous to the challenged patent.

Sanofi is not an isolated occurrence. The PTAB regularly engages in an analogous art analysis either when denying institution or rejecting an obviousness challenge at final written decision.

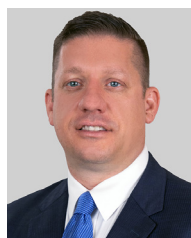
The takeaway here is that it is important for practitioners to address the analogous art inquiry. The test is not a complicated one, but

failing to address it properly — either in the first instance or in response to an argument questioning whether prior art is analogous — carries significant consequences. If the PTAB decides the issue in denying institution, the PTAB's conclusions are the final word as institution decisions are not appealable as a matter of law. If, on the other hand, the PTAB determines the issue in its final written decision, an appeal may present its own challenges. While the Federal Circuit reviews legal issues *de novo*, underlying factual findings are reviewed for substantial evidence, which is a higher and more difficult standard to overcome.

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