

Extrinsic Evidence, Including Testing, of Non-Prior Art Embodiments Can Be Used to Demonstrate Inherency; for Purposes of Obviousness, a Reasonable Expectation of Success Is Not Needed if the Missing Limitation Is Necessarily Present in the Prior Art

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The patentee sought to enforce a claim to a pharmaceutical composition, which “when stored in a glass container for at least five months exhibits no more than about 2% decrease in the concentration of [the pharmaceutical].” After the alleged infringer stipulated to infringement, the only dispute was whether the “about 2%” limitation was inherent when the product was stored as claimed, and was therefore not a patentable advancement over the prior art.

The district court found that the stability limitation was inherent and concluded that the asserted claim was invalid as obvious because “the inclusion of an inherent, but undisclosed, property of a composition does not render a claim to the composition nonobvious.” The district court further held that one of ordinary skill would have had a reasonable expectation of success that prior art compositions would exhibit the required level of stability when stored as claimed. The court relied on evidence regarding the stability of 21 samples of the composition, none of which were prior art.

The Federal Circuit affirmed, noting that “[e]xtrinsic evidence can be used to demonstrate what is ‘necessarily present’ in a prior art embodiment even if the extrinsic evidence is not itself prior art.” Thus, the alleged infringer’s expert was free to analyze non-prior art samples as long as they met the remaining elements of the asserted claim.

The Federal Circuit also held that there was no need to reach any conclusion regarding a reasonable expectation of success. The district court “engaged in a thorough and extensive analysis of the stability data in the record to reach its factual finding that the about 2% limitation was necessarily present in the prior art.” Thus, the subsequent analysis of a reasonable expectation of success was “unnecessary.” This is because “[i]f a property of a composition is in fact inherent, there is no question of a reasonable expectation of success in achieving it.”

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