

ALERT

Federal Circuit Patent Bulletin: *Par Pharm., Inc. v. TWi Pharm., Inc.*

December 3, 2014

"A party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art."

On December 3, 2014, in *Par Pharm., Inc. v. TWi Pharm., Inc.*, the U.S. Court of Appeals for the Federal Circuit (O'Malley,* Wallach, Hughes) vacated and remanded the district court's judgment that U.S. Patent No. 7,101,576, which related to using nanosized formulations of the drug megestrol acetate to increase the body mass in a human patient suffering from anorexia, cachexia, or loss of body mass, was invalid for obviousness. The Federal Circuit stated:

Under § 103, a patent may not issue "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Obviousness is a question of law based on underlying factual determinations, including: (1) the scope and content of prior art; (2) differences between prior art and claims; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. A party asserting that a patent is obvious "must 'demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.'" Our obviousness inquiry "must be expansive and flexible." . . .

Both Par and TWi appear to agree that essentially all of the substantive limitations in the independent claims are present in the various prior art references identified by the district court. The point of contention is whether the specific food effect limitations are also disclosed in the prior art. Both TWi and the district court claim that these limitations are an inherent property of the formulation disclosed by the obvious combination of prior art elements. We do not find any clear error in the district court's conclusion that TWi failed to prove by clear and convincing evidence that a food effect for micronized megestrol was known in the art. . . . Because the prior

art failed to disclose a known food effect in megestrol, both TWi and the district court rely on the doctrine of inherency to disclose the food effect limitation. We conclude that the district court erred in its inherency analysis under our precedent.

“The inherent teaching of a prior art reference” is a “question of fact.” We have recognized that inherency may supply a missing claim limitation in an obviousness analysis. We have, however, also explained that the use of inherency, a doctrine originally rooted in anticipation, must be carefully circumscribed in the context of obviousness. . . . Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

[T]he concept of inherency must be limited when applied to obviousness, and is present only when the limitation at issue is the “natural result” of the combination of prior art elements. . . . A party must, therefore, meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis—the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art. The district court, however, did not require that TWi present evidence sufficient to prove inherency under this standard.

Dr. Beach, TWi’s expert, testified that an improvement in bioavailability “necessarily results in a decrease in any food effect,” and TWi presented evidence that a reduction in particle size improves bioavailability. Therefore, per the district court, the reduced particle size would, ipso facto, lead to a reduced food effect. The district court’s analysis, however, ignores the claim limitations at issue. . . . The district court’s broad dicta regarding the effect of particle size on bioavailability and food effect are not commensurate with the actual limitations at issue. While it may be true that a reduction in particle size naturally results in some improvement in the food effect, the district court failed to conclude that the reduction in particle size naturally results in “no substantial difference” in the food effect.

Although the district court applied the incorrect standard for inherency in its obviousness analysis, we cannot, on the record before the court, conclude that TWi failed to present evidence sufficient to demonstrate that the claimed food effect limitations necessarily are present in the prior art combinations. There are simply no findings of fact addressing that question, and we decline to make such findings in the first instance. We therefore vacate the district court’s inherency analysis and remand for the district court to determine if TWi has presented clear and convincing evidence that demonstrates the food effect as claimed is necessarily present

in the prior art combination.

Although the district court erred in its inherency analysis, we agree with its analysis of the motivation to combine and reasonable expectation of success. After determining that claimed elements are present in the prior art, proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. “The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.” The presence or absence of a reasonable expectation of success is also a question of fact. “What a reference teaches and whether it teaches toward or away from the claimed invention are questions of fact.”

[W]e are not limited to the same motivation that may have motivated the inventors. [T]he district court did not err in looking to motivations beyond the food effect. The district court also did not err in finding alternate motivations due to the viscosity and interpatient variability problems with micronized megestrol. . . . The district court thus did not err in finding a motivation to combine megestrol with nanoparticle technology due to the known viscosity and interpatient variability problems with micronized megestrol. . . .

The reasonable expectation of success requirement for obviousness does not necessitate an absolute certainty for success. Thus, we conclude that the district court did not err in finding that TWi proved a reasonable likelihood of success in combining megestrol with nanoparticle technology. . . .

A prior art reference teaches away when it “suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” We find that the district court did not err in concluding that [the prior art Graham reference] does not teach away from combining megestrol with the NanoCrystal technology. Graham merely “caution[ed] a person skilled in the art that rapid absorption with rapid elimination and low blood plasma concentrations may cause Megace OS to be ineffective.” Graham never mentioned nanoparticle technology, and never stated that further size reductions would lead to more rapid elimination of megestrol. . . .

“Unexpected results are useful to show the ‘improved properties provided by the claimed compositions are much greater than would have been predicted.’” [U]nexpected results do not have to derive explicitly from the motivation to combine to be relevant. . . . It is true that unexpected results can, in appropriate circumstances, be sufficient standing alone to preclude a finding of obviousness. Whether that is true, however, will necessarily turn on the precise nature of those results and the strength of other evidence weighing in favor of an obviousness determination.