

Keywords: Obviousness; old prior art; objective indicia; composition; claim construction.

General: Obviousness is less likely when problem to be solved not present in cited art that is old; objective indicia of non-obviousness may be enhanced by old prior art.

Leo Pharmaceutical Products, Ltd. v. Rea

U.S. Court of Appeals Federal Circuit

No. 2012-1520

Decided August 12, 2013

I. Facts

Leo Pharmaceutical Products owns U.S. Patent No. 6,753,013. The '013 patent relates to a treatment for skin diseases such as psoriasis. The background section of the '013 patent notes that psoriasis was historically treated with (1) a vitamin D analog and (2) a corticosteroid. These two types of compounds, however, have optimum stability values of pH that differ significantly from one another. As a result, physicians would prescribe two incompatible creams or ointments to be applied at different times of the day (e.g., morning and night). Patients often did not comply with this treatment regimen. The '013 patent describes and claims a composition that combines a vitamin D analog and a corticosteroid using a new set of solvents, such as POP-15-SE, and which is "storage stable and non-aqueous."

A third party challenged the '013 patent in an *inter partes* reexamination. In the reexamination, Leo amended the claims to include the term "storage stable" and ultimately appealed the examiner's rejections to the Board. The Board construed the term "storage stable," which is not expressly defined in the '013 specification. The Board relied on a specific stability test described in the '013 to define the term "storage stable." The Board then agreed with the examiner that the claims of the '013 patent were obvious based on three prior art references:

1. Turi (filed in 1977) — Describes a composition that combines a steroid with POP-15-SE to avoid additional preservatives. Specifically states that the claimed invention *does not contain water, gels, or alcohols*. No mention of storage stability concerns.
2. Dikstein (filed in 1984) — Describes compositions that combine a vitamin D analog with a corticosteroid that can treat psoriasis. Every composition includes almond oil or propylene glycol, and many contain water. No mention of storage stability concerns.

3. Serup (filed in 1993) — Describes compositions that combine a vitamin D analog with a corticosteroid to treat skin atrophy (a side effect of steroid treatment). Every composition is aqueous and contains almond oil or propylene glycol, and many contain water. No mention of storage stability concerns.

The Board also found that objective indicia of non-obviousness provided by Leo—namely, that the combination produced “unexpected results”—did not overcome the *prima facie* case of obviousness because Turi provided an explicit reason to use POP-15-SE as a solvent.

Leo appealed to the Federal Circuit.

II. Issue

1. Did the Board err in its construction of the claim term “storage stable?”
2. Did the Board err in holding that the claims were obvious based on Turi, Dikstein, and Serup?

III. Holding & Discussion

1. Yes, the Board erred in its construction of the claim term “storage stable.” The Federal Circuit noted that “storage stable” has an accepted and customary meaning that is broader than the example of the specific stability test described in the ‘013 patent. The court thus held that Board erred by narrowing the definition of “storage stable” to a single example test mentioned in the specification.

2. Yes, the Board erred in holding that the claims were obvious based on Turi, Dikstein, and Serup. The Federal Circuit reiterated that obviousness is a question of law reviewed *de novo* based on several factual inquiries:

- (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.¹

Invention itself can be the recognition of a problem. The court first emphasized that an invention itself can be the recognition of a problem. Here, the prior art either discouraged combining vitamin D analogs and corticosteroids in a single formulation, or attempted the combination without recognizing or solving the storage stability problems associated with the combination. Indeed, Leo cited other prior art during reexamination that expressly discouraged combining a vitamin D analog with a corticosteroid because of stability concerns. The Federal Circuit stated that this prior art taught away from mixing topical vitamin D drugs with other drugs. Moreover, although Dikstein and Serup describe a combination of vitamin D with corticosteroid, neither identifies the storage stability problem. Indeed, Leo provided experimental evidence that none of the prior art compositions would be storage stable—every composition of Dikstein and Serup include water, almond oil, alcohol, or propylene glycol.

¹ In re Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009).

Reliance on old prior art implies nonobviousness. The Federal Circuit further stated that old prior art implied nonobviousness. The court noted that Turi existed for 22 years and Dikstein 14 years before the '013 patent was filed. The court noted that storage stability tests on the Dikstein and Serup combinations could have lead to discovery of the problem, but if these discoveries were routine or easy, someone would have achieved the invention of the '013 patent soon after the disclosure of Dikstein or Serup. However, the court noted, the '013 invention did not appear for more than a decade after these references appeared. Indeed, Turi was available for 22 years before the '013 patent was filed, but nobody attempted to improve Turi with vitamin D (not even Serup). The Board stated that combining Turi with vitamin D after it had been publicly available for so long was straightforward only in hindsight. The court also emphasized that the '013 patent's combination would not have been "obvious to try."² That the prior art had been publicly available for so long implies that it would not be obvious to try—"the problem was not known, the possible approaches to solving the problem were not known or finite, and the solution was not predictable."

Objective indicia of unexpected results and long-felt need are enhanced when the prior art is old. The court observed that Leo provided objective indicia of unexpected results and that the record shows a long-felt need. In general, the court noted, objective indicia constitute an independent, non-cumulative part of the obviousness analysis.³ Here, Leo provided extensive evidence of unexpected results. In fact, the FDA approved Leo's formulation for Talconex® as being truly storage stable—something Leo's experiments showed did not result when Serup was combined with Turi (replacing Serup's solvent with POP-15-SE). The court also noted that the record shows a long-felt need: it took 22 years after Turi and 14 years after Dikstein for a storage-stable combination of vitamin D and corticosteroid to be developed.

IV. Conclusion

When the prior art is old and does not identify the problem to be solved, the invention is more likely to be nonobvious. Objective indicia may be enhanced when the prior art is old.

² "[W]here the prior art, at best gives only general guidance as to the particular form of the claimed invention or how to achieve it, relying on an obvious-to-try theory to support an obviousness finding is impermissible." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1073 (Fed.Cir. 2012).

³ *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed.Cir. 2008).