

Schwarz Pharma, Inc. v. Paddock Labs., Inc.

No. 07-1074, Federal Circuit (Michel, Lourie,* Moore)

“An alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment” and that it would be inappropriate to apply an insubstantial differences or function/way/result test in order to determine foreseeability.

On October 12, 2007, the Federal Circuit affirmed the district court’s summary judgment that Paddock did not infringe U.S. Patent 4,743,450, which related to hypertension (high blood pressure) treatment with pharmaceutical compositions of angiotensin converting enzyme (ACE) inhibitors combined with stabilizers, when it filed an Abbreviated New Drug Application (ANDA) for approval to market generic tablets containing moexipril hydrochloride (MH) and magnesium oxide (MgO). The Federal Circuit stated:

[T]he district court did not err in holding that Schwarz’s claim of infringement under the doctrine of equivalents was barred by prosecution history estoppel. [T]he original claims did recite a metal containing stabilizer, in claim 1, and an alkaline earth metal salt, in claim 16. Warner-Lambert thus presumptively surrendered subject matter encompassed by those terms when it amended those claims and deleted those broader terms. [I]t cannot be maintained, as argued by Schwarz, that the ‘450 specification defined alkaline earth metal salt to mean only borate, silicate, and carbonate salts. . . . The use of the terms “alkali or alkaline earth metal salt” and “metal containing stabilizer” in the original claims reflects and is consistent with the breadth of that statement. The reference to borates, silicates, and carbonates reflects preferences, not limitations inconsistent with both the original claims and broader language in the specification. Also, the amendment was made in response to an obviousness rejection by the examiner and thus is presumed to have been made for reasons of patentability. We therefore hold that the presumption of surrender applies to MgO because it clearly falls within the territory between the language of the original and the amended claims of the ‘450 patent.

[I]t is Schwarz’s burden to rebut the presumption that MgO was surrendered as an equivalent when the claims of the ‘450 patent were amended. As to foreseeability, . . . “an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment” and that it would be inappropriate to apply an insubstantial differences or function/way/result test in order to determine foreseeability. On appeal, Schwarz does not seriously

dispute that MgO was known as a stabilizer by those of skill in the art at the time of the amendment, but rather insists that MgO had to have been known as a stabilizer against the specific degradation pathway of cyclization or for the specific drug category of ACE inhibitors in order to have been foreseeable as an equivalent. We disagree.

While care must be taken not to sweep too broadly in defining the field of an invention, Schwarz attempts to define the field of invention too narrowly. The language of original claim 1 (and that of issued claim 1 as well) began with the words “[a] pharmaceutical composition which contains,” and the language of a claim defining an invention defines the field within which foreseeability may be considered. The scope of the claim thus supports the district court’s treatment of the field of invention as pharmaceutical compositions rather than being limited to pharmaceutical stabilizers that inhibit cyclization in ACE inhibitors. We therefore conclude that, because MgO was known as a stabilizer in the field of pharmaceutical compositions, Schwarz has failed to rebut the presumption of surrender by demonstrating that MgO was not a foreseeable equivalent. . . .

We also do not agree with Schwarz that the presumption of surrender is rebutted because the narrowing amendment was no more than tangentially related to the use of MgO. [T]he use of MgO is directly implicated by the amendment of the claim language at issue because the language amended concerns the types of stabilizers covered by the claims and excludes MgO. The fact that the inventors may have thought after the fact that they could have relied on other distinctions in order to defend their claims is irrelevant and speculative; the inventors chose to distinguish over the Veber patent by narrowing the range of claimed stabilizers to exclude the one disclosed in Veber, as well as others. . . . We cannot say in such a case that the amendment was no more than tangentially related to the equivalent at issue. In fact, quite the opposite appears to be true; the narrowing amendment was directly related to the range of equivalents that Schwarz now seeks to recapture.

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