Keywords: Claim construction, ordinary meaning, dictionary, ambiguous, intrinsic record, "hydrosol"

General: Because words often have multiple dictionary definitions, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor.

Novartis Pharm. Corp. v. Eon Labs Manuf. Inc.
70 U.S.P.Q.2d 1438 (Fed. Cir. 2004)
Decided April 2, 2004

I. Facts

Cyclosporin, an important immunosuppressant drug, is not very soluble in water and is, therefore, difficult to administer in a formulation that will be readily absorbed by the aqueous environment of the human body. In response, the Novartis '382 patent explains that dissolving cyclosporin in a water-miscible solvent and then adding a comparatively large amount of water results in a hydrosol – an aqueous dispersion of very small solid particles of cyclosporin that is more readily absorbed by the body. Accordingly, claim 1 of the '382 patent recites, *inter alia*, "a hydrosol which comprises solid particles of a cyclosporin."

Novartis filed suit against Eon for contributory infringement of the '382 patent. The accused infringer, Eon, did not sell cyclosporin in the form of a hydrosol. However, when Eon's capsules, which have cyclosporin dissolved in a small amount of ethanol, were ingested, a hydrosol of cyclosporin formed in the aqueous environment of the user's stomach. Therefore, Novartis asserted that Eon was liable for *contributory* infringement arising from the ultimate consumer's use of the Eon capsules.

The district court disagreed, construing the term "hydrosol" to require a synthetic pharmaceutical preparation, i.e., it does *not* encompass a dispersion of solid particles of cyclosporin that *only forms in the stomach of a patient*. Apparently, the district did not use a dictionary to define "hydrosol," but looked only to the intrinsic record which indicated that the claimed hydrosol was intended to be administered via intravenous injection. The district court held there was no direct infringement and granted summary judgment to Eon, dismissing Novartis's claims of induced and contributory infringement.

On appeal, Novartis argued that the plain meaning of hydrosol includes products formed inside the stomach and that this definition should control the outcome of the case.

II. Issue

Did the district court err in construing the claim term "hydrosol" to not encompass a dispersion of solid particles of cyclosporin that only forms in the stomach of a patient?

III. Discussion

No. Affirmed. The claim term "hydrosol" of the '382 patent does *not* encompass formation of hydrosol in the user's stomach. Instead, "hydrosol", as claimed, is limited to medicinal products prepared outside of the body.

Initially, the Federal Circuit noted that neither party suggested that hydrosol has a specialized meaning inconsistent with the ordinary dictionary definition. Therefore, the Federal Circuit examined "general purpose dictionary definitions." Indeed, the Federal Circuit examined several dictionaries (and the definitions of several words) to determine the ordinary meaning(s) of hydrosol. The court deduced two pertinent definitions of hydrosol: a *broad* definition encompassing formation in the stomach, and a *narrow* definition not encompassing formation in the stomach. The choice between these two definitions would determine the outcome of the case.

After concluding that the plain meaning of the claim term "hydrosol" is ambiguous, the Federal Circuit looked to the intrinsic record to determine "which of the available, relevant definitions should be applied to the claim term at issue." The specification and prosecution history described hydrosol in terms of a pharmaceutical composition, and did not mention of the term in any other context. Therefore, the court concluded that the narrower definition of "hydrosol" applied; that is, the term "hydrosol" is limited to a *medicinal preparation* consisting of a dispersion of solid particles in a liquid colloidal solution prepared *outside the body*. The decision of the district court was, therefore, affirmed.

Dissent

The majority used multiple dictionaries to find a perceived ambiguity in the meaning of the "hydrosol" as claimed. Of course, the ordinary meaning of hydrosol is *not* restricted to hydrosols made in any particular place, whether in a factory or in a human stomach. For certain, the ordinary meaning of "hydrosol" carries no manufacturing site limitation with it. That being so, one would have thought that the majority would have applied settled law to allow the term it full breadth, unless the patentee had made an explicit disclaimer or clear disavowal of scope to alter the ordinary broad meaning of the term. Established law precludes narrowing a claim term simply because the specification and file history describe examples of embodiments that reflect the use of the contested term in a specific way.

Dictionaries are fine tools to assist in the exercise of claim interpretation, for sure, but in this case the majority has simply overworked the use of dictionaries to a point of error. Here, proper use of dictionaries would fit comfortably (as it should) with precedent that recognizes that medicinal preparations made in the body can infringe valid claims.

Claim Construction by the Majority

A *Webster's* dictionary defines "**hydrosol**" as "a sol in which the liquid is water." In turn, the same dictionary defines a "**sol**" as "a dispersion of solid particles in a liquid colloidal *solution*." (Emphasis added).

[The dissent points out that, for the majority, this definition of sol from this particular chosen dictionary is crucial, for it permits the court to move to a further degree of separation away from the word "hydrosol" to investigate the meaning of "solution." The dictionaries referenced by the dissent do not use the word "solution" to define "sol" but define "sol" as "a fluid colloidal system."]

The term "**solution**" has two pertinent definitions. These are "(1): a liquid containing a dissolved substance" and "(2): a liquid and usu. aqueous *medicinal preparation* with the solid ingredients soluble." (Emphasis added).

1. The first definition can include a hydrosol formed in the stomach.
2. The second definition cannot include hydrosol formed in the stomach because the court deduced that "medicinal preparation" is a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body. "**Medicinal**" means "of or relating to medicine" and the relevant definition of "**medicine**" is a "substance or preparation used in treating disease." Medical dictionaries define "**preparation**" in terms of a substance that is made prior to being administered.

There are two viable definitions of hydrosol (which lead to different outcomes of the case).

IV. Conclusion

Even where the intrinsic record does not explicitly disclaim or vary the scope of a claim term from its ordinary meaning (as is the case here with "hydrosol"), the intrinsic record may be helpful in guiding a choice between competing dictionary definitions of a claim term.