

Federal Circuit Patent Bulletin: *Insite Vision, Inc. v. Sandoz*

April 9, 2015

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On April 9, 2015, in *Insite Vision, Inc. v. Sandoz*, the U.S. Court of Appeals for the Federal Circuit (Prost, Newman, Linn*) affirmed the district court's judgment that U.S. Patents No. 6,861,411, No. 6,239,113, No. 6,569,443, and No. 7,056,893, which related to treating eye infections by the topical administration of azithromycin marketed as Azasite®, were not invalid as obvious. The Federal Circuit stated:

A patent is invalid "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." As patents are "presumed valid," § 282, a defendant bears the burden of proving invalidity by "clear and convincing evidence." Obviousness is a question of law, based on underlying factual determinations including: "the scope and content of the prior art"; "differences between the prior art and the claims at issue"; "the level of ordinary skill in the pertinent art"; and "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc." "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." . . .

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The obviousness inquiry entails consideration of whether a person of ordinary skill in the art "would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and . . . would have had a reasonable expectation of success in doing so." "In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention." "Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." And, here, the district court recognized that an overly narrow "statement of the problem [can] represent[] a form of prohibited reliance on hindsight, [because] [o]ften the inventive contribution lies in defining the problem in a new revelatory way."

Whether a person of ordinary skill in the art would narrow the research focus to lead to the invention depends on the facts. [I]f the prior art would motivate a person of skill in the art to make the claimed invention, even if that was not based on "the same motivation that the patentee had," the patent would have been obvious. But whether the prior art would so motivate a skilled artisan is a question of fact.

Here, the district court did not clearly err in finding that the problem faced by one skilled in the art was broader than merely seeking to use azithromycin to treat conjunctivitis. The district court found that azithromycin's characteristics-including that molecules in its class were "known to be bacteriostatic, to have a limited spectrum of activity, and to require multiple doses per day to penetrate tissue,"- would make it a poor choice for treating ocular infections. . . .

The district court concluded that it would not have been obvious to a person of ordinary skill in the art to formulate a topical azithromycin formulation for ophthalmic treatment of any infection as recited in the asserted claims of the '411 patent. The district court thoroughly and properly considered all of the evidence presented and the various arguments raised by the parties in ruling the asserted claims to be not invalid. We agree.

First, the district court did not clearly err in finding that there were "innumerable" options for ophthalmic treatments, including fluoroquinolones. Fluoroquinolones "were known to be a better option than azithromycin, " because they "were bactericidal[,] could act on a broad range of bacteria [and] were known to penetrate ocular tissue." Furthermore, the district court did not clearly err in determining that those of skill in the art would have been concerned that azithromycin might not penetrate ocular tissue based on its high molecular weight, charge and insolubility in water. Even Sandoz's expert, Dr. Reed, admitted that compounds with high molecular weights and charged compounds might not penetrate ocular tissue.

The district court also did not clearly err in crediting Dr. Asbell's testimony that a person of ordinary skill in the art "would not assume that delivering high concentrations of a drug to the eye topically would ensure that the drug would penetrate the ocular tissue simply because the drug was successful when administered systemically." Dr. Asbell's testimony is supported by the fact that oral azithromycin was delivered to the eye at least in part through phagocytosis—a bloodstream dependent process—which would not occur when azithromycin was administered topically. . . . For all of the above reasons, this court concludes that Sandoz has not met its clear and convincing burden and therefore affirms the district court's determination that the asserted claims of the '411 patent are not invalid.