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Federal Circuit Patent Bulletin: *Senju Pharm. Co. v. Lupin Ltd.*

March 20, 2015

"[I]t was not clear error for the district court to conclude that the unexpected results evidence . . . relied upon during reexamination did not withstand scrutiny by [experts before] the district court."

On March 20, 2015, in *Senju Pharm. Co. v. Lupin Ltd.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Plager,* Moore) affirmed the district court's judgment that Lupin infringed U.S. Patent No. 6,333,045, which related to gatifloxacin, an aqueous liquid pharmaceutical eye drop composition, with added disodium edetate (EDTA) marketed by Allergan as Zymar®, and that the '045 patent was invalid for obviousness. The Federal Circuit stated:

An obviousness inquiry assesses "the differences between the subject matter sought to be patented and the prior art" to ascertain whether "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." "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Thus, a defendant asserting obviousness in view of a combination of references has the burden to show by clear and convincing evidence that a person of ordinary skill in the relevant field had reason to combine the elements in the manner claimed. In addition to showing a reason to combine the elements in the manner claimed, a defendant must also demonstrate that a person of ordinary skill would have a reasonable expectation of success in combining the elements. . . .

We conclude that the district court properly found that corneal permeability is not relevant in the discussion of composition claims 12-16 because these claims do not contain the corneal permeability limitation found in method claim 6 . . . . We do not find persuasive appellants' argument that it is necessary to consider corneal permeability when analyzing claims 12-16 because the claimed compositions embody the method of reexamined claim 6. . . . In composition claims 12-16 of the '045 patent, there is no limitation denoting the function of the composition and we decline to import this limitation into the claims. . . . In the present case, there were sufficient reasons to improve upon the '456 and '465 patents by utilizing gatifloxacin, as disclosed

in the '470 patent . . . . All three of these patents relate to quinolones and their derivatives for use as antibacterial agents, and we conclude that the district court properly determined that combining them would have been obvious to one of ordinary skill in the art. . . . Many of appellants' arguments on the lack of reasons to combine the teachings of these three patents rely on the fact that they do not disclose anything about corneal permeability of gatifloxacin solutions. [T]his is not a limitation of claims 12-16 and, therefore, is not relevant to the obviousness determination. . . .

With respect to claim 6, we conclude that the district court properly held this claim invalid as obvious in light of the '456, '465, and '470 patents, along with the Grass 1985, Grass 1988-I, Grass 1988-II, and Rojanasakul references. We find that the district court applied correct legal standards, accepting that the '045 patent was entitled to a presumption of validity; that appellees had to establish the underlying factual proofs of obviousness by clear and convincing evidence; and that the court properly considered all of the relevant evidence.

Though the district court did not specifically cite to Kompella and Mitra in its opinion, this is not fatal because neither the Mitra nor the Kompella reference actually teach away from utilizing a lower EDTA concentration at the claimed pH level. While both references find success at higher EDTA concentrations, they do not provide any indication that lower EDTA concentrations would not also work. Because the district court was not required to directly address these references and the references do not provide evidence of teaching away from the '045 patent disclosure, the district court did not commit clear error in its analysis. . . .

Appellants focus on the use of 0.01 w/v% EDTA to increase corneal permeability as the distinguishing feature of claim 6. However, this feature does not sufficiently distinguish claim 6 from the prior art. The asserted references demonstrate that one of ordinary skill in the art would have known that using 0.01 w/v% EDTA would result in an increase in corneal permeability. . . . Appellants improperly focus on the percentage change in permeability over the control, which was zero for both methanol and glycerol, to conclude that the data showed no increase in corneal permeability. In reality, though the percent changes were not statistically significant, appellees set forth expert testimony that a person of ordinary skill would have recognized from the data that 0.01 w/v% EDTA would increase corneal permeability. . . . On the evidence before us, that determination by the district court falls well within the wide discretion the court has to weigh expert credibility. Ordinarily, and absent compelling reason otherwise, an appellate court defers to such credibility determinations. . . .

Appellants argue that the district court engaged in an improper post hoc analysis of appellants' evidence of unexpected results, concluding that the claims were obvious before fully considering evidence of unexpected results and without making any finding of the results a skilled artisan would have expected. Appellants point out that a complete administrative record-including the Senju studies and the Grass 1985 and Grass 1988-I references-was before the PTO at the reexamination and that the examiners' decision to grant the amended and new claims "'carries with it a presumption that [each] Examiner did his duty and knew what claims he was allowing.'" Thus, appellants argue, the district court erred in failing to give weight to the PTO's factual findings on validity and unexpected results. . . .

These determinations, much like many of the obviousness determinations, were based on credibility judgments on which, on the evidence before us, we defer to the district court. We further conclude that the district court properly applied a presumption of validity, considering both the evidence of obviousness and the evidence of unexpected results, to find that appellees set forth clear and convincing evidence of invalidity in this case. We agree that it was not clear error for the district court to conclude that the unexpected results evidence that Senju relied upon during reexamination did not withstand scrutiny by Lupin's experts and the district court. Ultimately, the district court properly concluded that the theories presented during reexamination proved too weak when challenged in a judicial forum to rise to the level of unexpected results sufficient to rebut a strong case of obviousness.