

Federal Circuit Patent Bulletin: *Shire Dev., LLC v. Watson Pharms., Inc.*

June 4, 2015

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On June 3, 2015, in *Shire Dev., LLC v. Watson Pharms., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Chen, Hughes*), on remand from the Supreme Court of the United States, reversed and remanded the district court's judgment that Watson infringed U.S. Patent No. 6,773,720, which related to a controlled-release oral pharmaceutical composition for treating inflammatory bowel diseases marketed by Shire as LIALDA®. The Federal Circuit stated:

We review the district court's ultimate interpretation of the patent claims de novo. "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law, and [we] will review that construction de novo." If, on the other hand, a district court resolves factual disputes over evidence extrinsic to the patent, we "review for clear error those factual findings that underlie a district court's claim construction." In this case, we review the district court's constructions de novo, as the intrinsic evidence fully determines the proper constructions.

When construing asserted claims, claim terms are given "their ordinary and accustomed meaning as understood by one of ordinary skill in the art." Intrinsic evidence, such as "the specification, . . . may shed contextual light" on the ordinary and customary meaning of a claim term. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the

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invention will be, in the end, the correct construction.

In addition to the specification, this court looks to the prosecution history. For example, “where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.” “However, while the prosecution history can inform whether the inventor limited the claim scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the PTO. Therefore, the doctrine of prosecution disclaimer only applies to unambiguous disavowals.” We review the application of prosecution disclaimer *de novo*.

We have also held that a court may look to extrinsic evidence, such as dictionaries and expert testimony, to “shed useful light on the relevant art” and for a variety of other purposes. But “a court should discount any expert testimony ‘that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.’

The district court construed “inner lipophilic matrix” to mean “a matrix including at least one lipophilic excipient, where the matrix is located within one or more other substances.” Similarly, the district court construed “outer hydrophilic matrix” as “a matrix of at least one hydrophilic excipient, where the matrix is located outside the inner lipophilic matrix.” These constructions do not reflect the ordinary and customary meaning of the claim terms in light of the intrinsic evidence and are impermissibly broad. . . .

A review of the intrinsic evidence as a whole reveals that the district court’s construction of “inner lipophilic matrix”—and thus, “outer hydrophilic matrix”—is overly broad. Looking first to the language of the claims, “lipophilic” is an adjective that modifies matrix. The parties stipulated that “lipophilic” means “poor affinity towards aqueous fluids.” Thus, the matrix—not just an excipient within the matrix—must exhibit the stipulated-to lipophilic characteristic. This conclusion is bolstered by the specification.

In construing the matrix terms, the district court rejected Watson’s position that the inner matrix and outer matrix must be “separate and distinct.” Watson based its arguments on alleged disclaimers by the applicants during the prosecution. . . . The district court correctly found no prosecution disclaimer because the statements in the prosecution history were not “unambiguous disavowals.” During prosecution, Shire carefully characterized the prior art as not having separate matrices but never actually stated that the claimed invention does have separate matrices. Although the prosecution history statements do not rise to the level of unmistakable disavowal, they do inform the claim construction.

The prosecution history, the structure of the claim itself, the ordinary meaning of the claim terms, including the Markush group limitations, and the patent’s description of the invention compel a claim construction which requires that the inner lipophilic matrix is separate from the outer hydrophilic matrix. [T]he logical reading of the claim requires separation between the matrices because the matrices are defined by mutually exclusive spatial characteristics—one inner, one outer—and mutually exclusive compositional characteristics—one hydrophilic, one lipophilic. According to the ordinary and customary meanings of these characteristics, one matrix cannot be both inner and outer in relation to a second matrix. Nor can one matrix be both hydrophilic

and lipophilic. Thus, considering “matrix” is properly construed as “a macroscopically homogenous structure in all its volume,” the construction of “inner lipophilic matrix” requires the inner volume to be separate from the outer volume. . . .

On remand from the Supreme Court, Shire argues that because the district court “heard” testimony from various expert witnesses during a Markman hearing and at trial, we must defer to the district court’s constructions of the appealed terms. The Supreme Court held that we “should review for clear error those factual findings that underlie a district court’s claim construction.” The Court did not hold that a deferential standard of review is triggered any time a district court hears or receives extrinsic evidence. Here, there is no indication that the district court made any factual findings that underlie its constructions of “inner lipophilic matrix” and “outer hydrophilic matrix.”