

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

March 28, 2014

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On March 28, 2014, in *Shire Dev. LLC v. Watson Pharm., Inc., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Rader, Prost, Hughes*) reversed and remanded the district court's judgment that Watson's Abbreviated New Drug Application for generic LIADA® infringed U.S. Patent No. 6,773,720, which related to a controlled-release oral pharmaceutical composition containing 5-aminosalicylic acid (mesalazine or mesalamine) for treating inflammatory bowel diseases. The Federal Circuit stated:

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 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." This court reviews the application of prosecution disclaimer de novo.

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 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 evidence and are impermissibly broad.

[T]he district court erred by construing "'lipophilic matrix' [as] a matrix that includes at least one lipophilic excipient." That construction erroneously focuses on the lipophilic properties of an excipient in the matrix, rather than the properties of the matrix itself. 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. The Background of the Invention explains that a lipophilic matrix is one "in which the main component of the matrix structure" exhibits certain lipophilic properties. And, the specification teaches that a lipophilic matrix "generally entail[s] non-linear, but esponential [sic] release of the active ingredient." Thus, a "lipophilic matrix" is more than just a matrix with at least one lipophilic excipient— the matrix itself must exhibit lipophilic characteristics. The '720 patent teaches that this occurs when "the main component of the matrix structure" is lipophilic.

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 acknowledged that the applicants described their matrices as "separate" to distinguish over the prior art references, but found that "no where in the prosecution history, claims, or specification does the term 'separate and distinct' appear." Explaining that the prosecution history is an ongoing negotiation and that there must be clear and unambiguous disavowal, the district court could not "say that the claim was clearly limited or disclaimed during the prosecution." The district court correctly found no prosecution disclaimer because the statements in the prosecution history were not "unambiguous disavowals." . . .

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. . . .

Shire argues that the intrinsic evidence does not describe any particular degree of separation and thus, such a construction would create ambiguity. Shire's argument misses the point. A court must identify "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention." Whether or not a composition infringes when there is a trace of hydrophilic molecules in the inner volume because of the mixing step inherent in the manufacturing process, for example, is a question for the fact finder. That this question may need to be resolved does not compel a claim construction that departs from the customary and ordinary meaning of the claims, i.e., that the matrices must be "separate" such that they retain their claimed properties and are consistent with their respective Markush group limitations.

Accordingly, we reverse the district court's constructions of "inner lipophilic matrix" and "outer hydrophilic matrix," and subsequent infringement determination, and remand for proceedings consistent with this opinion.