

Federal Circuit Patent Bulletin: *Bayer Pharma AG v. Watson Labs., Inc.*

November 29, 2017

“[T]hat the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination.”

On November 1, 2017, in *Bayer Pharma AG v. Watson Labs., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Lourie, Moore,* O’Malley) reversed the district court’s judgment that the asserted claims of U.S. Patent No. 8,613,950, which related to an oral disintegrating tablet formulation of vardenafil for treating erectile dysfunction that Bayer markets as Staxyn, were not invalid for obviousness. The Federal Circuit stated:

A patent may not issue “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.” Obviousness depends on the following factual determinations: “(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness, if any.” . . .

The clear error in the district court fact finding that there was no motivation to formulate ED drugs in ODTs, is that it concluded that the record did not contain an indication that ED drugs would be good candidates for ODT formulations. This is simply not accurate. Watson relied on nine prior art references to support its assertion that there would have been a motivation to create an ODT formulation of vardenafil. . . . [S]ix references—Chang, Boolell, Fryburg, Bell-Huff,

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Furitsu, and Chen—are absent from the district court’s decision. While it is certainly not necessary for a district court to evaluate all references presented to it, nowhere here does it mention these key references in analyzing whether the prior art taught vardenafil ODT or whether a skilled artisan would have been motivated to formulate vardenafil ODT. These references are highly relevant to whether a person of ordinary skill in the art would have been motivated to formulate ODT vardenafil. And their express disclosures cause the district court factfinding regarding motivation to combine to be clear error. . . .

Watson produced a significant number of references to support its argument that a person of ordinary skill in the art would have been motivated to formulate an ODT formulation of vardenafil. While it may at times be unwise for a party to rely on numerous prior art references when challenging a patent on obviousness grounds, Watson’s approach was not untenable here. Watson produced these nine references to support a narrow point: they each “disclosed formulating vardenafil and other approved ED drugs into ODTs.” . . . Here, the motivation to formulate an ODT version of vardenafil is plainly evident from the face of multiple prior art references disclosing ODT formulations of ED drugs. No further rationale for developing vardenafil ODT was necessary. On review of the entire record evidence before the district court, we are left with the definite and firm conviction that the district court clearly erred when it found there would not have been a motivation to formulate vardenafil ODT. . . .

“A reference teaches away when it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” The district court did not find that a person of ordinary skill in the art would have believed vardenafil’s expected bitter taste and increased bioavailability would have likely rendered an immediate-release formulation unproductive. Instead, the district court’s analysis focused on whether a person of ordinary skill in the art would “necessarily have made an immediate-release ODT rather than a delayed-release ODT.” But the teaching away inquiry does not focus on whether a person of ordinary skill in the art would have merely favored one disclosed option over another disclosed option. In assessing whether prior art teaches away, that “better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes.” When there are only two possible formulations and both are known in the art at the time, the fact that there may be reasons a skilled artisan would prefer one over the other does not amount to a teaching away from the lesser preferred but still workable option. The district court’s finding that a person of ordinary skill in the art would have first pursued a delayed-release formulation over an immediate-release formulation is insufficient to support a finding of teaching away.

The evidence before the district court supports its finding that a person of ordinary skill in the art may have preferred a delayed-release formulation over immediate release—not that an immediate-release formulation was unlikely to be productive in vardenafil ODT. Rather than testify that a skilled artisan would have believed the taste of vardenafil is too bitter to formulate as an immediate-release ODT, Dr. Wicks merely testified that “the consideration would lead them to a delayed-release ODT.” . . . This testimony supports the district court’s finding that the taste and bioavailability of vardenafil raised concerns, and that a skilled artisan may have preferred a delayed-release formulation, but it does not support a finding of teaching away. While the district court did not clearly err in its fact finding that a skilled artisan would have had concerns over an immediate-

release formulation due to vardenafil's expected bitter taste and bioavailability, obviousness "does not require that the motivation be the best option, only that it be a suitable option from which the prior art did not teach away." We determine whether a skilled artisan would have found the claimed combination obvious weighing the four Graham factors, which includes the district court's fact findings regarding the bitter taste and bioavailability of immediate release formulations. . . .

Weighing all four Graham factors, we conclude claims 9 and 11 of the '950 patent would have been obvious. The repeated suggestion in the prior art to make an ODT formulation of an ED drug and the suggestion to use the combination of sorbitol and mannitol as excipients are strong evidence of a motivation to make the claimed combination. The parties agree that ODTs were known to exist as either immediate-release or delayed-release formulations. A skilled artisan motivated to formulate vardenafil ODT would have been faced with a design need for its release profile, and an immediate-release formulation would have been one of two options. While a skilled artisan may have preferred a delayed-release formulation over the claimed immediate-release formulation, "that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggests that the combination claimed . . . is the preferred, or most desirable, combination." Weighing this evidence together with the objective evidence of unexpected results and copying, we conclude that a skilled artisan would have found the claimed combination obvious. The district court's final judgment is reversed.