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Federal Circuit Reverses Judge Sleet's Factual Findings for Failure to Address Unrebutted Evidence

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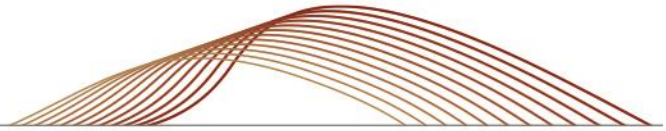
On November 1, 2017, the Federal Circuit reversed Judge Sleet's (District of Delaware) decision that Bayer's asserted patent was not invalid for obviousness. *Bayer Pharma AG, et al. v. Watson Labs., Inc., et al.*, No. 2016-2169 (Fed. Cir. Nov. 1, 2017). The Federal Circuit panel consisted of Judges Lourie, Moore, and O'Malley, and the opinion was authored by Judge Moore. According to the Federal Circuit, Judge Sleet failed to address several prior art references relied upon by defendants to argue motivation to combine prior art teachings. The Court also applied a stringent standard for proving a "teaching away" of a formulation i.e., it is insufficient to demonstrate a preference for one type of formulation design over another; the design of the claimed formulation must have been considered "unproductive" for the intended result. This opinion also joins a growing list of opinions from the Federal Circuit that have minimized the objective indicia of nonobviousness, even though they "may often be the most probative and cogent evidence in the record," in cases where a prima facie showing of obviousness was made. *See Merck Sharp & Dohme Corp. v. Hospira, Inc.*, No. 2017-1115 (Fed. Cir. Oct. 26, 2017) (Newman, J., dissenting) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).

I. Background

Bayer Pharma AG *et al.* ("Bayer") filed a Hatch-Waxman action against Watson Laboratories, Inc. ("Watson") for infringement of U.S. Patent No. 8,613,950 ("the '950 patent") based on Watson's submission of an Abbreviated New Drug Application ("ANDA") to market a generic version of Staxyn®, an erectile dysfunction ("ED") medication. Staxyn® is the compound vardenafil hydrochloride trihydrate formulated as an oral disintegrating tablet ("ODT").

Bayer asserted dependent claims 9 and 11, both of which depended from independent claim 8. Claim 8 is directed to a vardenafil tablet that: (1) is an ODT; (2) releases the drug in the mouth, i.e., immediate-release; and (3) has at least two sugar alcohols. Claim 9 further requires the sugar alcohols to be a mixture of sorbitol and mannitol, and claim 11 requires that one of the sugar alcohols be sorbitol.

Following a bench trial, Judge Sleet held that Watson failed to prove that claims 9 and 11 were invalid for obviousness. Specifically, Judge Sleet found that one of skill in the art would not have been motivated to create an ODT formulation of vardenafil and would not have used mannitol and sorbitol



as excipients. Judge Sleet also found that the prior art taught away from formulating vardenafil ODT as immediate-release. Finally, Judge Sleet credited Bayer's objective evidence of nonobviousness based on copying and unexpected properties.

II. The Federal Circuit's Reversal

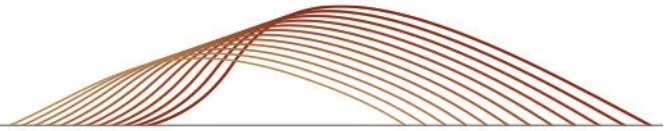
In reversing, the Federal Circuit determined that Judge Sleet clearly erred in several of his factual findings, including those underlying his conclusions of no motivation to formulate ED drugs as ODTs or to use sorbitol in addition to mannitol in an ODT formulation. The Court also held that the evidence underlying Judge Sleet's finding that the prior art taught away from a delayed-release formulation did not rise to the level of a teaching away. While the Federal Circuit did not disturb Judge Sleet's findings on objective indicia favoring nonobviousness, the Federal Circuit still concluded that the claimed formulations were invalid for obviousness.

Regarding the motivation to formulate ED drugs as ODTs, the Federal Circuit held that Judge Sleet clearly erred in finding that the record did not contain an indication that ED drugs would be good candidates for ODT formulations. According to the Federal Circuit, there were at least nine references in the record describing ODT formulations of ED drugs. The Court noted that six of those references were not discussed in the district court opinion and many were unchallenged by Bayer's expert. The Federal Circuit also criticized Judge Sleet for relying too heavily on the fact that ODT formulations of ED drugs were not commercially available in the relevant timeframe, as opposed to considering the teachings of the prior art *in toto*.

The Federal Circuit also disagreed with Judge Sleet's finding that the prior art taught away from an immediate-release formulation based on testimony from Bayer's expert that one of skill in the art would have expected a vardenafil ODT to have a bitter taste, which would have discouraged designing a formulation that releases the drug directly into a patient's mouth, and that an immediate-release formulation would have been expected to increase bioavailability, which may have been a problem for the target patient population of older men. The Federal Circuit, however, held that those facts did not establish a teaching away. While a skilled artisan may have preferred the design of a delayed-release formulation for an ED drug based on those facts, the Federal Circuit determined that a skilled artisan would not have believed an immediate-release formulation would have been "unproductive."

As to claims 9 and 11, Judge Sleet found that a skilled artisan would not have been motivated to use sorbitol in an ODT formulation based on testimony that every ODT on the market used only mannitol sugar alcohol and there were no known problems with using only mannitol in ODTs. In deeming that finding to be clearly erroneous, the Federal Circuit held that the analysis focused too heavily on commercially available products and failed to address the totality of the relevant prior art. In particular, the Court identified a number of references in the record demonstrating that the use of sorbitol and mannitol in ODT formulations was known. The Federal Circuit noted that the district court opinion did not explain why these references were not relevant to the obviousness analysis or cite any rebuttal testimony from Bayer's expert.

With respect to the objective indicia of nonobviousness, the Federal Circuit did not disturb Judge Sleet's findings that Watson's copying of the claimed invention and Staxyn's unexpected increased duration of action compared to another commercially available ED drug supported a conclusion of nonobviousness. Notably, other than stating that this real-world evidence was weighed along with the other *Graham* factors, the Court did not explain how this evidence influenced the obviousness determination.



III. Strategic Takeaways

This opinion implicates several strategic considerations. For example, the opinion reminds practitioners of the importance of addressing, if possible, all of your adversary's positions. Failure to do so, as was evident here, could result in a tribunal adopting the unrebutted positions. Moreover, an expert's otherwise credible testimony can be undermined by failure to address opinions proffered by the other side's expert.

In responding to an obviousness challenge, it is also risky to rely on the existence, or the lack thereof, of commercial products in the relevant timeframe to the exclusion of addressing the non-commercialized teachings of the prior art. In this case, Judge Sleet found that a skilled artisan would not have been motivated to formulate vardenafil as an ODT formulation because, *inter alia*, no commercially available ED drug was formulated as an ODT as of the '950 patent's priority date. While real-world facts may provide persuasive evidence of nonobviousness, e.g., objective indicia of nonobviousness, it is also critical to sufficiently rebut any significant assertions of products that a skilled artisan would have developed based on the teachings of the prior art.

This opinion also illustrates the stringent standard for establishing a teaching away in formulation prior art. Specifically, the standard requires more than the identification of preferred alternatives; it appears necessary to proffer evidence demonstrating that a skilled artisan would have considered the course of action leading to the claimed invention to be "unproductive" of the intended result.

Further, this opinion appears to buttress the concerns expressed by Judge Newman regarding the role of objective indicia of nonobviousness in her dissent from the recent *Merck Sharp & Dohme* decision. *See Merck Sharp & Dohme Corp.*, No. 2017-1115 (Newman, J., dissenting). According to Judge Newman, instead of being considered together with the other *Graham* factors in a nonobviousness analysis, certain opinions from the Federal Circuit appeared to relegate objective indicia of nonobviousness to rebuttal evidence once a prima facie showing of obviousness was made. *Id*. at 4-6. By not explaining how Judge Sleet's findings relating to real-world evidence factored in the Court's obviousness determination, this case seems to follow Judge Newman's stated concerns. It is therefore important to ensure that a court understands the significance of the objective evidence offered in a case.

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings New York lawyers:

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