USPTO's Recently Updated Guidelines Pertaining to Obviousness Provide Useful Tools for Practitioners

The United States Patent and Trademark Office (USPTO) recently published updated guidelines for the evaluation of obviousness—the 2010 KSR Guidelines Update (2010 Update)—in light of Federal Circuit decisions issued since the Supreme Court's 2007 landmark decision in KSR Int'l Co. v. Teleflex Inc. Unlike the 2007 KSR Guidelines, which substantially increased the examiners' arsenal by supplementing the prior teaching-suggestion-motivation (TSM) test with six additional rationales for rejecting claims as obvious, the 2010 Update provides a more balanced picture of the obviousness inquiry that will assist both practitioners and examiners in arguing obviousness. More particularly, the 2010 Update provides a number of examples from actual cases—cases that found claims obvious and cases that found claims nonobvious—that examiners and practitioners can use to help support their positions. In announcing the updated guidelines, USPTO Director David Kappos stated, "[n]ow that a body of post-KSR case law is available to guide office personnel and practitioners as to the boundaries between obviousness and nonobviousness, this update can be used to compare and contrast situations in which claimed subject matter was found to have been obvious with those cases in which it was determined not to have been obvious." Although arguing nonobviousness remains more challenging than under the previous TSM test, the 2010 Update provides practitioners new tools to wield in navigating the post-KSR obviousness landscape.

Though the Supreme Court's decision in KSR demanded a more flexible approach to the obviousness inquiry than the previous TSM test, the 2010 Update impels examiners to provide an explicit, reasoned analysis as to why the invention would have been obvious to a person of ordinary skill in the art at the time of the invention. According to the 2010 Update, “[t]his requirement for explanation remains even in situations in which Office personnel may properly rely on intangible realities such as common sense and ordinary ingenuity.” For example, in the now frequently cited standard for rejecting claims as obvious for combining prior art elements according to known methods to yield predictable results, the guidelines urge examiners to identify a reason why it would have been obvious to combine the known elements, especially when the combination requires a greater expenditure of time, effort, or resources than the teachings of the prior art:

Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may nevertheless be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so.
Indeed, the 2010 Update cites the Federal Circuit’s affirmation of the district court’s determination of nonobviousness in *In re Omeprazole Patent Litigation* to support the requirement that an examiner must present a recognized reason to make the proposed combination in the face of additional effort. In *In re Omeprazole Patent Litigation*, despite the findings that subcoatings for enteric drugs were known and there was no evidence of undue technical hurdles or a lack of a reasonable expectation of success, the Federal Circuit stated:

> [T]he formulation was nevertheless not obvious because flaws in the prior art formulation that had prompted the modification had not been recognized. Thus there would have been no reason to modify the initial formulation, even though the modification could have been done. Moreover, a person of skill in the art likely would have chosen a different modification even if he or she had recognized the problem.

Further, the 2010 Update provides that “merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness.” Rather, the examiner must also demonstrate that the results flowing from the combination would have been predictable to a person of ordinary skill in the art. In *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, the Federal Circuit noted that the “predictable result” discussed in *KSR* refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. In this case, the plaintiff successfully overcame the rationale that the combination of references leads to a predictable result because the alleged reason to combine the references ran contrary to the teachings of the prior art such that the person of ordinary skill in the art would have been deterred from the proposed combination. Thus, though patent practitioners have been forced to modify their analysis in light of *KSR*, *DePuy Spine* makes clear that the patent bar can still rely on familiar nonobviousness arguments (e.g., teaching away) to overcome § 103 rejections.

The 2010 Update additionally addresses the emergence in the wake of the *KSR* decision of the oft maligned “obvious to try” rationale. Though the guidelines attempt to assuage the fears of practitioners, the contours of this standard remain hazy, especially in technology areas outside of the chemical arts. Nonetheless, the cited post-*KSR* decisions indicate that an “obvious to try” rationale is only appropriate when there is a recognized problem or need, there are a finite number of identified, predictable solutions to the recognized problem or need, and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success. Indeed, the 2010 Update provides that “[c]ourts appear to be applying the *KSR* requirement for ‘a finite number of identified predictable solutions’ in a manner that places particular emphasis on predictability and the reasonable expectations of those of ordinary skill in the art.”

We anticipate that the growing body of post-*KSR* case law will continue to shift the contours of the obviousness analysis. We will continue to stay abreast of developments regarding the obviousness inquiry and will keep our readers well-informed of new developments.
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This advisory was prepared by Nutter's Intellectual Property practice. For more information, please contact your Nutter attorney at 617.439.2000.

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