

# KSR'S EFFECT ON PATENT LAW

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## INTRODUCTION

The Supreme Court in *KSR International Co. v. Teleflex Inc.* clarified its 1966 decision in *Graham v. John Deere*, avoiding the sea change to a synergy-based standard that many had expected—and perhaps feared. *KSR* has raised the bar set in *Graham* for seeking patent protection—by providing a flexible test for obviousness—while simultaneously making it easier for accused infringers to defend themselves. Moreover, *KSR* will change the strategies of both patent prosecutors and litigators.

Before *KSR*, the Supreme Court's last major decision on nonobviousness under 35 U.S.C. § 103 was *Graham*, in which the Court established three factual inquiries for use in determining *prima facie* obviousness: (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, and (3) the level of skill in the art. This *prima facie* case could be rebutted by objective evidence of non-obviousness, such as commercial success, long-felt but unsolved needs, and failure of others.

In applying the three *Graham* factors, the Federal Circuit has used the “teaching, suggestion or motivation” (“TSM”) test. A court using this Federal Circuit standard to determine obviousness would require a showing of some teaching, suggestion or motivation to combine the teachings found in the prior art references. This standard was designed to avoid finding claims obvious based on impermissible hindsight. Many decisions suggested that the motivation must come from the prior art itself rather than from the knowledge of a person having ordinary skill in the art (“PHOSITA”). Other cases, notably several decided after the Supreme Court granted certiorari in *KSR*, applied a more flexible approach and held that motivation to combine the information contained in the prior art can be found implicitly.

## I. THE TSM TEST BEFORE AND AFTER *KSR*

The high tech industry, among others, sharply criticized the TSM test. First, these critics argued that the Federal Circuit—not the Supreme Court—created the TSM test and, in doing so, improperly added an additional step to the *Graham* analysis. Second, the critics claimed that even if the TSM test

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was a justified application of *Graham*, the Federal Circuit applied the test too rigidly, making it difficult to invalidate bad patents and thereby stifling innovation. The pharmaceutical industry, on the other hand, supported the TSM test as a way to protect chemical patents against impermissible hindsight analysis, since chemical inventions may involve only minor structural differences over the prior art and yet still produce unexpected results.

When the Supreme Court granted certiorari in *KSR*—by way of a unanimous non-precedential opinion—many observers predicted the Supreme Court would take the opportunity to reverse the Federal Circuit and overhaul nonobviousness law, in part by scrapping the TSM test. This prediction seemed prescient when, at oral argument, Justices described the TSM test as “gobbledygook” (perhaps a first in Supreme Court jurisprudence) and as “worse than meaningless.”

In *KSR*, the Court found four errors in the Federal Circuit’s nonobviousness jurisprudence:

1. The TSM test, while a helpful tool and not necessarily inconsistent with *Graham*, was applied too rigidly by the Federal Circuit, which looked only at the problem the patentee sought to solve;
2. The Federal Circuit wrongly assumed that a PHOSITA would consider only pieces of prior art designed to solve the same problem identified by the inventors;
3. The Federal Circuit erroneously held that a claim cannot be obvious merely because it would be “obvious to try.” Where there is a design need or market pressure to solve a problem and only a “finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options”; and
4. The rigid application of TSM “den[ied] factfinders recourse to common sense.”

The “common sense” of a PHOSITA will now be sufficient to support a finding of motivation and courts must consider whether a claimed invention is “more than the predictable use of prior art elements according to their established functions.”

Although the Court broadened the scope of the obviousness inquiry, it did not reject the spirit behind the TSM test. There still must be an “articulated reasoning with some rational underpinning to support the legal conclusion” of obviousness. The *KSR* Court understood that the TSM test sought to accomplish a worthy goal. The problem with *Graham* was that it did not provide courts guidance on how to articulate coherently the reason why the factual findings in the first three prongs would prompt a PHOSITA to make the claimed invention without resort to impermissible hindsight. The “articulated reasoning” approach provides a consistent, objective analysis framework. Determining if there is an articulated reason requires analysis of a number of factors, pro and con, such as teaching away, reasonable expectation of success, whether the results are simply from routine

experimentation, etc. These factors fill in the gaps of the *Graham* test and also guard against hindsight bias.

## II. POST-KSR DECISIONS

The Federal Circuit issued a number of decisions while *KSR* was being considered and after its release. These were a mix of chemical and electrical/mechanical cases, the reasoning of which hints at how the Federal Circuit will apply *KSR*.

The first “combination” case decided post-*KSR* was *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.* Relying on the new standard, the Federal Circuit affirmed a finding of obviousness. The court found that a PHOSITA exercising common sense would have added a limitation that was missing from the two prior art references in order to achieve the goal of the patent. Under *KSR*, combining old elements according to their established functions is obvious, and thus the patent was invalid despite evidence of substantial commercial success.

The Federal Circuit’s treatment of chemical and pharmaceutical patents illustrates the difficulties surrounding the TSM test. In *Takeda Chemical Industries, Inc. v. Alphapharm Pty., Ltd.*, decided after *KSR*, the Federal Circuit rejected an “obvious to try” argument. Alphapharm argued that selecting “compound b” and altering it to arrive at the claimed invention were obvious steps. Takeda showed that compound b was one of hundreds of millions of compounds disclosed in the art and that references taught away from its use. The Federal Circuit held that, in chemical cases, it remains necessary to identify some reason why a chemist would “modify a known compound in a particular manner.” Alphapharm had failed to identify such a reason. The court also noted that, even if Alphapharm had succeeded in its *prima facie* case, secondary considerations would have rebutted their showing. These considerations included the district court’s finding that nothing in the prior art “suggest[ed] making the specific molecular modifications to compound b that are necessary to achieve the claimed compounds.”

This decision appeared to retreat from the earlier, heavily criticized result in *Pfizer, Inc. v. Apotex, Inc.* There the Federal Circuit, pre-*KSR*, had reversed the district court and invalidated a patent, holding that substituting different forms of salt was the result of routine experimentation and thus obvious to try. The Federal Circuit rejected the district court’s findings that results of the substitution were unexpected and that there was no reasonable expectation of success. As in *Leapfrog*, commercial success could not save the patent. Hopes that *Pfizer* would be quietly retired in favor of *Takeda* were dashed, however, when the court denied a petition to rehear *Pfizer* en banc (albeit with three judges dissenting). *Pfizer*’s continued vitality was demonstrated yet again when the court cited *Pfizer* in *Pharmastem Therapeutics, Inc. v. Viacell, Inc.* But while *Pfizer* remains good law, it is not necessarily inconsistent with *KSR*. The criticism of *Pfizer* is that it *misapplies*—not that it ignores—the reasonable expectation of success doctrine, which is always a consideration in “obvious to try” challenges.

### III. LESSONS FOR PROSECUTION

*KSR*'s gloss on the TSM test has already influenced patent prosecution, the administrative process of obtaining a patent from the U.S. Patent and Trademark Office ("PTO"). The PTO has drafted guidelines stating that the *Graham* factors still provide the basis for evaluating obviousness and that examiners must articulate a reason for an obviousness determination. The PTO has trained its examiners on these guidelines, which will be published in the Federal Register. The Board of Patent Appeals and Interferences ("BPAI") has issued a series of decisions that may serve as a template for examiners. The BPAI decisions emphasize *KSR*'s instruction that combinations must be more than the "predictable use of prior art elements according to their established functions" and that the obviousness analysis can "take account of the inferences and creative steps" of a PHOSITA rather than relying on "precise teachings directed to the specific subject matter of the challenged claim."

These guidelines and decisions indicate that applicants now must show why the steps taken by the applicant were not readily apparent. Reciting unexpected or superior results, functions or properties in the specification can show the examiner that the invention goes beyond a combination of known elements yielding predictable results. The guidelines and decisions also suggest applicants should avoid characterizing the field of the invention and avoid identifying problems recognized in the art to be solved in patent applications. An adverse party can use such statements against the patentee during litigation. Likewise, the patent application should avoid a detailed discussion of the prior art if possible, lest a court later seize upon it as evidence of a high level of skill in the art.

### IV. LESSONS FOR LITIGATION

It will be some time before recognizable post-*KSR* trends emerge from the Federal Circuit's obviousness opinions. But *KSR* and post-*KSR* Federal Circuit decisions do provide some early guidance. A party challenging the validity of a patent should argue that the invention is merely an art-recognized solution to an art-recognized problem. The precise tactics for this strategy will vary according to the field of the invention, the quality of the prior art, and other factors. Meanwhile, a few general approaches to attacking patents are also clear:

- Establish a high level of skill in the art. The higher the level, the more technical the line of reasoning on which the claim can rely and the higher the threshold will be for the PHOSITA's "common sense;"
- Argue that the prior art had the same "goal" as the patent-in-suit;
- Argue that the invention is merely the optimization of a variable as a result of routine experimentation;
- Identify known reasons for improvement in the industry and argue that it would have been obvious to substitute an element in the prior art with

another to achieve desired results—making it cheaper, stronger, etc.; and

- Argue that the invention would have been “obvious to try” because only a finite number of identified, predictable ways exist by which to achieve the goal of the patent.

On the other hand, patentees will face some new challenges in fighting off an obviousness attack. For the next several years, most patent litigations will involve patents that were prosecuted before *KSR* and, therefore, might contain statements about the field of the invention and detailed discussions of the prior art. But the inclusion of these statements will not necessarily be fatal. To defend against obviousness, patentees can employ the following approaches:

- Argue that the prior art is non-analogous. For art to be analogous, it must be in the field of the applicant’s endeavor or reasonably pertinent to the problem to be solved. Although *KSR* broadened the second prong of this analysis, it did not eliminate the analogousness requirement; therefore, a patentee should argue that the art taken from outside the same field of endeavor of the patent relates to solving a different problem than the patent-in-suit solved;
- Argue hindsight or a failure to articulate a reason for the combination or both. Hindsight based on statements in the patent or patent application cannot be the reason for combining references—the patent cannot be used as a road map for creating hindsight obviousness;
- Argue that the results or the properties of the patent are either unexpected or superior so as to avoid the “combination of old elements” trap;
- Demonstrate how the prior art teaches away from the claimed invention; and
- Rely on secondary considerations, while recognizing that the Federal Circuit’s post-*KSR* decisions have given mixed weight to them.

## CONCLUSION

The early crop of cases post-*KSR* seem to show that demonstrating a reasonable expectation of success when combining the information contained in the prior art is the key to establishing whether an apparent reason with rational underpinnings exists. A patent that combines known elements by known methods and that yields predictable results has every expectation of successfully being patented, but such a formulaic patent is vulnerable to attack. The truly inventive patents—where there was not a reasonable expectation of success and they have unexpected results or properties—will survive under *KSR*.