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Review of Developments in Intellectual Property Law

SNIPPETS ALERT: Supreme Court Modifies Standard for Obviousness in *KSR v. Teleflex*

I. Introduction

It is not hyperbole to say that the U.S. Supreme Court's decision on April 30 in *KSR Int'l Co. v. Teleflex Inc.* was the most anticipated patent law decision of the year, and the most significant since *eBay v. Mercexchange*, 126 S.Ct. 1837 (2006). It came as no surprise that the Court reversed the Federal Circuit, something it has done in all but a single case over the past ten years. In doing so, the Court limited but did not eliminate the Federal Circuit's "teaching-suggestion-motivation" (TSM) test for determining whether an invention was obvious under 35 U.S.C. § 103.

The Court's decision moved the patentability pendulum incrementally, but decidedly, against patentees, and made obtaining a patent more difficult than it has been under the Federal Circuit's obviousness jurisprudence. It is evident from the Supreme Court's language that different technologies will be differently affected by the application of the Court's obviousness rubrics, but how much more difficult it will be to obtain a patent or prevent infringement remains to be seen.

The case arose over Teleflex's patent for an automotive gas pedal having an electronic sensor in place of the conventional mechanical linkage used to regulate speed and acceleration. The District Court granted summary judgment against the patentee, finding that the invention was an obvious variation of the prior art, assessed under both the Supreme Court's *Graham v. John Deere* standard and the Federal Circuit's TSM test. 86 S. Ct. 684. The Federal Circuit reversed, saying that the

District Court had not applied its TSM test with particularity to establish that the art provided sufficient motivation to achieve the claimed invention.

The Supreme Court identified four errors committed by the Federal Circuit in applying its test. The Court held that the Federal Circuit did not give sufficient consideration to the motivation arising from unsolved problems in the art that would be recognized by one of ordinary skill, but rather focused too greatly on the problem the inventor was attempting to solve. The second and related Federal Circuit error was limiting its consideration of the prior art to the problem that the art was intending to solve. The Court stated that "familiar items may have obvious uses beyond their primary purposes," analogizing an obvious invention to the fitting together of pieces of a puzzle. Third, the Court held that, in certain (albeit limited) circumstances, what is obvious to try can also be obvious under the law. Finally, the Court found the Federal Circuit had put too much emphasis on avoiding hindsight, and that this preoccupation substituted rigid preventive rules for what it termed "common sense."

As it has throughout its obviousness jurisprudence, including *United States v. Adams*, 383 U.S. 39; *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969); and *Sakraida v. AG Pro, Inc.*, 425 U.S. 273 (1976), the Supreme Court in this opinion exhibits its philosophical bias against patents on inventions that lack a sufficient amount of "innovation." The Court's analysis would exclude from patentability inventions

that are combinations of previously-known elements unless there is some evidence that the desirability of the combination would not be evident to the ordinarily skilled (and, according to the Court, ordinarily creative) worker.

As a result, it is certain that obtaining or defending patents based on incremental improvements in the art will be much harder to do. In this regard, the effects of this decision will fall more heavily on technologies where such incremental combination patents are more prevalent, or where the outcome of the combination is more predictable. Conversely, the effect of the decision should be less burdensome in arts that are inherently unpredictable.

How the Supreme Court's *KSR* ruling will be applied is not immediately clear. However, there are some contours of the new order that can be immediately discerned, and these are set forth below. We provide here a first set of practice tips, arranged in sections relating to patent prosecution and patent litigation.

II. Patent Prosecution

A. Generally

KSR is not expected to have a devastating effect on the ability of applicants to obtain patents. While certainly making it easier for an examiner to demonstrate an "apparent reason to combine...known elements", the Court nonetheless insisted that the examiner's analysis be explicit, and left undisturbed the requirement that the prior art references

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when combined must teach or suggest all the claim limitations. *KSR* at 14; MPEP § 2143. Thus, by (1) holding examiners to their burden and (2) emphasizing what many already consider best practices when drafting, practitioners should generally be able to avoid being thwarted by § 103 rejections that include a rationale for combining references made possible by *KSR*.

First, in responding to § 103 rejections, it is often possible to leverage the interdependency of claim elements – especially method steps – to identify elements not found in the prior art. Often the best starting point is to take a step back, and think about what is accomplished by the invention that is not accomplished by the prior art, even taken together. Essentially, as before *KSR*, practitioners should argue on a common-sense level about differences between the prior art and the claimed invention. To that end, practitioners should of course highlight (1) any instances of teaching away and (2) any unpredictable results. See *KSR* at 12.

Furthermore, it is incumbent after *KSR* to refuse to accept conclusory assertions by examiners that it would have been obvious to combine certain references. That is, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR* at 14. Thus, the Court left undisturbed the requirement that an examiner must present a “convincing line of reasoning supporting a rejection.” MPEP § 2144. The court reinforced this by stating that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR* at 14. And if the examiner does provide a rationale for combining references to achieve the invention, practitioners should of course consider whether this rationale can be defeated on its merits.

So how to best arm yourself against post-*KSR* rejections during the drafting phase? Again, the focus should be on what the invention accomplishes that the prior art does not. Identify this new functionality when receiving invention disclosures, and include it in the written description. Tell a convincing story. And when drafting claims, look for ways to link elements together in a way that highlights that new function. These interrelationships between claim elements will reduce the likelihood that an examiner will be able to identify those elements in the prior art. In general, avoid claiming a list of stand-alone prior art elements, since “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR* at 13.

B. The Biological, Chemical, and Pharmaceutical Arts

The Supreme Court’s emphasis on its own obviousness jurisprudence included the traditional reliance under *Graham v. John Deere* on the “secondary” or “objective” indicia of obviousness, including long-felt need, failure of others, and commercial success. The Court’s analysis also included by implication the traditional notion that evidence of surprising and unexpected results is evidence of non-obviousness. These considerations inure to the benefit of patentees and patent applicants in the biotech/pharma sphere, since these are inherently unpredictable arts.

For biotechnology claims, a few examples will suffice to illustrate the point. Although it may be “obvious to try” to obtain an antibody for a novel antigen, for example, it is certainly not predictable either that an antibody can be obtained, or that said antibody will have a specified minimum affinity for its cognate antigen. Thus, including in the definition of a claimed antibody an affinity



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minimum is one way to show non-obviousness. Similarly, it should be difficult to make out a *prima facie* case of obviousness for a novel gene (at least one for which the entire amino acid sequence is unknown). Claims to disease-related genetic markers such as single nucleotide polymorphisms should also be non-obvious, since their identities will be unrecognized in the art.

For pharmaceuticals, the situation is slightly different. Claims to purified enantiomeric species (such as S-omeprazole) should remain patentable in the absence of any related molecules in the art for which the connection between stereoisomer and biological activity is known. Novel formulation patents may face more difficulties, unless there is evidence of an unexpected property (such as increased bioavailability or shelf-life) associated with the formulation. Combination medications may also be more difficult to protect, if there is no advantage in administering the drugs in combination rather than separately.

Diagnostic claims are also in some jeopardy, particularly for instances where there is a correlation between a disease with a known feature of the disease. This is likely to provoke an obviousness challenge relying on the Court's "common sense" standard, insofar as identifying the presence or amount of a disease marker would be expected to be associated with the disease or the severity thereof.

For biotech/pharma patent claims that are rejected on obviousness grounds, successful responses will need to incorporate elements either not found or recognized in the art, or that show unexpected results. The unpredictability in this art, and the extent that other applications of patentability requirements (such as 35 U.S.C. § 112, 1st paragraph) circumscribe the scope or

require disclosure of such distinguishing features, provide the applicant's best arguments for non-obviousness.

C. The Electrical and Mechanical Arts

With respect to patent prosecution in the electrical and mechanical arts, it would seem that system and apparatus claims may encounter the most difficulty in overcoming § 103 rejections made possible by KSR, due to their tendency to make use of "off-the-shelf" components that have a finite number of known functions. For example, consider a claim directed to a circuit that solves a problem identified in the field at the time of invention, where each circuit element (resistors, transistors, diodes, etc.) functions in its known way. After KSR, examiners should have an easier time cobbling together a set of references that disclose each circuit element, and assert that it would have been obvious to a given engineer to try the finite available options to solve the known problem.

Method claims may suffer from similar difficulty after KSR, though likely not to the same extent. For example, if a particular method for establishing a communication session across a network involves steps such as "sending a SIP INVITE message" or "validating a password," these steps may be seen by examiners as effectively being "off-the-shelf" method steps, known to those in the industry. Again, after KSR, examiners will be more able than before to piece together method steps disclosed in various references, asserting that these steps perform their known functions, rendering the claim obvious in light of a known problem.

III. Patent Litigation

As a first observation, after KSR, accused infringers will likely assert obviousness based on combinations of more prior art references than they would have prior to

KSR. The Supreme Court supported such an approach by stating that courts should look at the "interrelated teachings of multiple patents," and that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." KSR at 14, 16-17.

Secondly, patentees may want to devote greater attention and emphasis on establishing the level of ordinary skill in the art, both in an effort to create a genuine issue of material fact that can preclude a summary judgment determination of obviousness, and more broadly because determining whether a combination is a "predictable variation" of the prior art is evaluated from the perspective of a person of ordinary skill in the art.

Interestingly, patentees may now face somewhat of a "Catch-22" when determining what should be the level of ordinary skill in the art. In particular, under KSR, patentees facing an obviousness challenge may (somewhat strangely) want to argue that the level of ordinary skill is low, because a highly-skilled artisan would presumably find many more combinations to be obvious. On the other hand, because the amount of disclosure a patent specification must contain in order to be enabling is inversely proportional to the pertinent level of ordinary skill (i.e., low level of skill means that more detailed disclosure is required), patentees must be careful not to argue in favor of a level of ordinary skill any lower than is commensurate with the particular specification at issue, to avoid opening up a secondary battle line on the issue of enablement.

Third, summary judgment will be a greater obstacle for a plaintiff to overcome. In KSR, the Supreme Court noted that while district courts "can and should" consider expert testimony to "resolve or keep open certain
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questions of fact,” obviousness is ultimately a legal determination. *KSR* at 23. Defendants will use this language to argue that even if there are open questions of fact, because obviousness is a legal question, the district court should still grant summary judgment. To combat such an argument, plaintiffs should spend additional time working with experts to keep open as many issues of fact as possible. Furthermore, patentees may want to, earlier in the litigation, present marketplace performance data that might otherwise have been withheld until a damages phase in order to establish commercial success, a secondary consideration that can prevent a determination of obviousness.

With respect to pharma/bio/chem patent litigation in particular, *KSR* may significantly alter the balance of power in favor of accused infringers. For example, where an active ingredient is not itself novel as a chemical compound, a pharmaceutical formulation or preparation containing that active ingredient is arguably a combination of prior art elements, each of which (except perhaps the active pharmaceutical ingredient) is functioning in its expected manner (e.g., emulsifiers, dispersants, wetting agents, granulating agents). At a minimum, patentees in the pharm/bio/chem area can expect that claims of this type will be subjected to a greater number of obviousness attacks, and that such attacks will be based on a greater number and variety of references.

IV. Conclusions

A significant caveat in any analysis of the *KSR* decision is that the Supreme Court did not overturn the TSM test; rather, the Court disapproved of the manner in which the Federal Circuit applied the TSM test. Indeed, the Court stated that the TSM test represented “a helpful insight,” and further, that “[t]here is no necessary inconsistency

between the idea underlying the TSM test and the *Graham* analysis.” Moreover, the Court noted (but did not opine with regard to) more recent Federal Circuit case law that applied the TSM test less rigidly, and left to the Federal Circuit the further development of the proper application of the test consistent with the Court’s opinion. Thus, although the *KSR* decision has certainly changed how obviousness law is applied, the Court did not effect the type of sea change envisioned and feared by patent holders, applicants and the patent bar. Accordingly, the suggestions contained herein will need to be reassessed as the case law in this area continues to develop.

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