Most individuals reading this publication are well-versed in at least the basic concepts of the standard for patentability in the US. Very basically, in order to obtain a patent, the claimed invention must be considered new, useful, and unobvious. The consideration as to whether something is new (novelty) involves, e.g., whether there is one piece of prior art, be it an earlier patent, earlier publication, or earlier use that discloses all of the claimed features of the invention in question. This article addresses the standards for determining obviousness, and how those standards may have been affected by a recent Supreme Court decision.

**THE BASICS**

Obviousness is a legal conclusion based on the factual inquiries set forth in Graham v. John Deere Co., 383 US 1, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. See McNeil-PPC, Inc., v. L. Perrigo Company, 337 F.3d 1362 (Fed. Cir. 2003). A court must also consider any secondary indicators of non-obviousness that are asserted by the applicants, including (1) commercial success; (2) unexpected results; (3) long felt but unsolved need; and (4) failure of others. See Graham v. John Deere Co. of Kansas City, 303 US 1, 17-18 (1966).

Typically, a determination of obviousness by a patent examiner or a court is not based on one piece of prior art. Rather, such a determination is based on a combination of prior art (e.g., two or more earlier patents/publications). One of the classic arguments that patent practitioners have used to argue in favor of patentability when faced with a combination of two or more prior art references concerns a lack of motivation to combine: that is, a patent claim is only proved obvious if the prior art, the problem’s nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings. Thus, an argument for patentability based on “a lack of motivation to combine the teachings of these references” is found quite often in the file histories of US patents. The argument follows that without such motivation to combine the teachings of those references, a person having ordinary skill in the art would simply not recognize the benefits of combining such teachings. For example, if the prior art references that are to be combined are directed at solving different problems, it is often argued that one of ordinary skill in the art seeking to solve the problem addressed by the claimed invention would not be motivated to prior art directed at solving a different problem. Or, if each reference solves the problem addressed in the claimed invention in a different way, there might be no motivation to combine such disparate work to solve the problem. As another example, it is often argued that the two references that the examiner seeks to combine are in entirely different scientific fields; and so there would be a lack of motivation for the person having ordinary skill in the art to look outside that art for a solution to the problem.

Until now, the law was reasonably clear: “[i]t is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion in the prior art, to combine the elements.” See Ruiz v. AB Chance Co., 234 F.3d 654 (Fed. Cir. 2000) quoting Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953 (Fed. Cir. 1997). This rule has sometimes been referred to as the “TSM” test (teaching, suggestion, or motivation). The suggestion or motivation could be explicit or implicit. See Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120 (Fed. Cir. 2000) “the suggestion to combine need not be express, and may come from the prior art, as filtered through the knowledge of one skilled in the art.” In other words, the suggestion to combine the disclosures of two or more prior art references in order to establish prima facie obviousness required some suggestion for doing so, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Jones, 958
F.2d 347, 351 (Fed., Cir. 1992).

Have these seemingly well-settled rules for determinations of obviousness/nonobviousness now been eliminated by the Supreme Court? In its recent decision in KSR International v. Teleflex Inc., 127 S. Ct. 1727 (April 30, 2007), the Supreme Court sent shockwaves throughout the patent community, and indeed throughout the scientific community with its holding that the Federal Circuit (which hears all appeals from patent litigations) had been applying a flawed analysis with respect to the obviousness inquiry. The Supreme Court, in reversing a Federal Circuit decision which employed the TSM test to uphold a patent, held that the Federal Circuit “addressed the obviousness question in a narrow, rigid manner that is inconsistent with §103 and this Court’s precedents.”

THE KSR DECISION

In KSR, Teleflex sued KSR for infringement of its US Patent No. 6,236,565 entitled “Adjustable Pedal Assembly With Electronic Throttle Control.” The patent litigation involved an adjustable mechanical pedal that KSR developed for Ford, for which KSR added a modular sensor. Teleflex, a rival to KSR in the design and manufacture of adjustable pedals, asserted the ‘565 patent against KSR. Claim 4 of the ’565 patent, which was at issue, claimed a vehicle-controlled pedal apparatus. It includes a pivot for pivotally supporting an adjustable pedal assembly, and an electronic sensor responsive to the pivot for providing a signal that corresponds to pedal arm position. The position of the pivot remains constant. The electronic sensor transmits the position of the pedal to a computer that controls the engine throttle.

There was a robust amount of prior art involved in the obviousness consideration. The prior art included an accelerator pedal that interacts with the throttle via a mechanical link; computer-controlled throttles that open and close valves in response to electronic signals rather than through movement of the pedal; pedals that could be adjusted to change their location in the footwell (for different-size drivers); a patent (Asano) that described a support structure that housed the pedal such that even when the pedal is adjusted relative to the driver, one of the pedal’s pivot point stays fixed; a patent (Redding) that describes a different, sliding mechanism where both the pedal and the pivot point are adjusted; a patent that taught that it was preferable to detect the pedal’s position in the pedal assembly, not in the engine (and described a pedal with an electronic sensor on a pivot point in the electronic assembly); and finally a patent (Smith) that taught that the sensor should be put on a fixed part of the pedal assembly. In addition, the prior art included patents for self-contained modular sensors to be taken off the shelf and attached to mechanical pedals, and patents that describe placement of sensors on adjustable pedals.

The District Court granted summary judgment in KSR’s favor. Following Graham’s direction, the Court found that the Asano patent taught everything contained in Claim 4 except the use of a sensor to detect the pedal’s position, which the Court recognized was taught in patents describing self-contained modular sensors. The District Court determined that the level of ordinary skill in pedal design was an undergraduate degree in mechanical engineering or equivalent experience. The District Court then applied the TSM test and reasoned that the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals; that the prior art patents regarding the placement of sensors on adjustable pedals provided the basis for such developments; and finally that the Smith patent taught locating the sensors on the fixed structure of the pedal. The District Court was further swayed by the fact that the USPTO had not had the opportunity to consider the Asano patent in its patentability determination.

Relying mainly on the TSM test, the Federal Circuit reversed the District Court’s decision. It held that unless the “prior art references address[ed] the precise problem that the patentee was trying to solve” the problem would not motivate an inventor to look at these other references (119 Fed. Appx. at 288). The Federal Circuit found that the Asano pedal was designed to solve a “constant ratio problem” whereas the asserted ‘565 patent sought to provide a simpler adjustable electronic pedal. In similar fashion, the Federal Circuit found that the other prior art patents did not necessarily go to the issue of motivation to attach electronic control on the support bracket of a pedal assembly. When viewed in this manner, the Federal Circuit determined that such prior art would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano, and therefore did not render the ‘565 patent obvious.

The case was appealed to the Supreme Court, which began by rejecting the “rigid” approach of the Federal Circuit. The Decision addressed the Supreme Court’s prior decisions concerning obviousness, including Graham:

“The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her
skill…Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue …As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”

While noting that the TSM test is not necessarily inconsistent with the Graham analysis, the Supreme Court wrote a fairly scathing opinion concerning errors in the nonobviousness analysis made by the Federal Circuit. It stated that the Federal Circuit was in error by holding that courts and patent examiners should look only to the problem the patentee was trying to solve in order to determine whether there was motivation to combine. Under the correct analysis, any problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

Second, the Supreme Court found error in the Federal Circuit’s assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem.

The Supreme Court then found error with respect to the Federal Circuit’s hindsight analysis. It determined that the Federal Circuit found, in error, that a patent claim cannot be proved obvious by merely showing that the combination of elements was “obvious to try.” It reasoned that when there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill in the art, all in order to determine whether there is skill and common sense. In that instance, the fact that a combination was obvious to try might show that it was obvious under §103. Thus, while noting that the fact-finders should be aware of the improper use of hindsight, the Supreme Court determined that the “obvious to try” standard nonobviousness was not always correct.

Finally, the Supreme Court noted that because it had made its incorrect decision in KSR, the Federal Circuit had made further decisions that appeared to be more consistent with the Supreme Court’s earlier precedents. Those cases required the use of “common knowledge and common sense” in the TSM test, and found that motivation could be found implicitly in the prior art.

WHERE DO WE GO FROM HERE?

There are many messages that might be taken from the Supreme Court’s decision in KSR. It is impossible to predict how this decision will affect the future. Does the KSR Decision mean that all previously granted patents in which the combination of prior art was overcome by an argument/determination that there was a lack of motivation (to combine the references) should now be considered invalid? Certainly, given the popularity of the TSM test, that would throw a huge amount of uncertainty into the marketplace. Nevertheless, the KSR Decision does indeed make suspect all patent claims granted by virtue of a “rigid” TSM consideration.

The underlying theme throughout the KSR Decision is the invocation of terms “common knowledge” and “common sense.” The Supreme Court was clearly annoyed at the application a rigid test that would not take into account a common sense analysis of combining elements used in the same field, albeit for overcoming different problems.

Another disturbing feature of KSR to future cases is the Supreme Court’s statements concerning the “obvious to try” standard. It now appears that the obvious to try standard is indeed permissible as long as it would be obvious to one of ordinary skill in the art using their common knowledge or common sense.

How does this effect pharma? There are important differences between the inventiveness considered in KSR as opposed to pharma. First, mechanical inventions, such as that in KSR, are predictable. It is often the case that inventions in the world of pharma are much less predictable. Likewise, the level of skill of the person of ordinary skill in the mechanical art in KSR is well below that typically found in pharma. But does a higher-educated formulator have “more” common knowledge or common sense? Can that higher-educated person apply solutions from more fields than his counterpart in the mechanical arts? Will litigants now have to provide evidence not only directed at what level of education/experience one skilled in the art of the invention is, but also what their common knowledge is? How does one determine what the level of common sense in the art is?

While the long-term effects are not yet known, we can at least speak to the present. Already, the Federal Circuit has quoted the KSR mantra of a lack of a rigid formula for determining obviousness, and the use of common sense of those skilled in the art to demonstrate why some combinations would have been obvious where others would not. See, eg, Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc., F.3d (Fed. Cir. 2007). ♦