

Pharmaceutical Patent Life Cycle Management after *KSR International v. Teleflex*

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The full impact of the U.S. Supreme Court's decision in *KSR International v. Teleflex* (S.C. 2007) cannot be predicted at this time. Instead, it will be determined by patent examiners and courts in the coming months and years. Nevertheless, *KSR* has undoubtedly created some uncertainty regarding the test for obviousness and will likely require pharmaceutical / biotech patent attorneys and their clients to evolve their patent practices.

It is clear that the Court in *KSR* rejected the "rigid approach" which the Federal Circuit has used on occasion to determine obviousness – a strict application of the teaching, suggestion, or motivation test (the TSM test). The Court directed its primary criticism of the TSM test to instances where it has been applied too rigidly, not to the test conceptually, and actually stated that the test "captured a helpful insight" for use in determining obviousness. Thus, the TSM test likely will still be used in some instances to determine obviousness, but its application will change.

After *KSR*, it is less clear what will be considered to be obvious or non-obvious and how this determination should be made. In attempting to provide some guidance, the Supreme court stated: "[I]f 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." Thus, defining properly the person of ordinary skill will continue to be important. In this regard, the Court interestingly noted that "a person of ordinary skill is also a person of ordinary creativity, not an automaton."

Further, the Supreme Court also held that the Federal Circuit erred in its holding that a patent claim cannot be proved obvious merely by showing that a combination of elements was "obvious to try." When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp according to the Court. When this occurs and leads to the anticipated success, the court held, that "it is likely the product [is] not of innovation but of ordinary skill and common sense." These statements about the "obvious to try" test and "creativity" with regard to combining known elements seem to indicate that claims covering improvements on known inventions or incremental improvements will be rejected or invalidated as being obvious more often than they otherwise would have been under the previous application of the TSM test.

One key area that will likely be impacted is the practice of obtaining patents covering improvements on known drugs. Obtaining patents on existing products, combined, used or made in new ways provides pharmaceutical / biotech companies with extended patent coverage for their key commercial products. This strategy, known as Patent Life Cycle Management, maximizes profitability of drugs.

Since patent term is, in general, limited to 20 years from the date of filing of the first non-provisional application, companies seek patent protection on other inventions which use the initial chemical composition in an improved form. For example, a company may seek patent protection on an improved formulation using known components, including a drug whose patent may be expiring, which unexpectedly provides quicker absorption into the blood. Assuming this new patented formulation covers the product sold, the patent protection can be extended from the date of expiration of the compound patent to the date of patent expiration of the patent covering the improved formulation, usually well after the expiration of the compound patent.

There is a palpable fear that post-*KSR* patent examiners and courts will be able to reject or invalidate patent claims by showing that the drug was known, the formulary elements were known, and then inferring that it is obvious for one of ordinary skill of the art to combine them to achieve the desired results. As a result, it may become difficult to obtain improvement patents and/or defend their claims in court.

However, on the positive side for the patent applicant and patentee, the Supreme Court in *KSR* stated 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.” Insightfully, the Court noted that inventions in most, if not all, instances rely upon building blocks “long since uncovered.” Thus, claimed discoveries will generally be combinations of what is already known. These statements should be helpful in showing that improvement patents are still patentable inventions, even if they combine known elements.

The key to obtaining an improvement patent on a known drug in the future will likely be a persuasive, well-supported showing of unexpected results or other secondary indicia. In its discussion of *United States v. Adams*, 383 U.S. 39, 40 (1966), the Court in *KSR* indicated that the presence of unexpected results may support conclusions that the invention is not obvious. The Court also pointed out that *Teleflex* had “no secondary factors to dislodge the determination that claim 4 is obvious.” Thus, the Supreme Court left the door open for practitioners to continue to argue the presence of secondary indicia as set forth in *Graham v. John Deere*, 383 U.S. 1, 18 (1966):

Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

After *KSR*, prudent biotech / pharmaceutical companies and patent attorneys should consider, prior to filing an application, what their response to a rejection of obviousness will be. Some options for improving the applicant's response include: (1) doing a cursory search of the potential prior art; (2) locating lab notebooks or experimental data that demonstrate any difficulty to successfully combine the elements of the improvement patent; (3) obtaining data showing how commercially successful the improvement has been; and/or (4) considering if the product met a long-felt need.

To maximize the persuasive power of this information, it will likely need to be presented in expert/inventor declarations during prosecution. Accordingly, it will be prudent to obtain and submit this information on the inventor's opinions and experiences in developing the improvement early on in prosecution. The presentation of this information, even if submitted in a declaration, can be further enhanced by interviewing the case with the Examiner to show in detail why the improvement is non-obvious.

In summary, to obtain a patent or a ruling of validity when faced with an obviousness rejection post-*KSR*, pharmaceutical / biotech companies should expect to be required to engage their inventors in discussions and arguments with examiners and judges to a greater extent than in the past and be prepared to provide arguments showing that secondary indicia exist.

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