

The *KSR* Standard for
Obviousness:
A Pendulum Shift
to 20/20 Hindsight ?

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KSR International Co. v. Teleflex, Inc.

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- U.S. Supreme Court's unanimous decision drastically altered the evaluation of patentability
- A new standard for analyzing obviousness
 - “Obvious to Try” and “Common Sense” standards will be used as easy fallbacks to indicate obviousness
 - Essentially 20/20 hindsight will become the new standard for analyzing obviousness

Pre-KSR Landscape

35 U.S.C. §103

- The U.S. Patent Act sets forth the requirements of patentability and denotes that a patent may not be obtained
 - "*. . . if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.*"
- Further, the Act makes sure to eliminate a temptation of hindsight review by stating
 - "*[p]atentability shall not be negatived by the manner in which the invention was made.*"

Pre-*KSR* Landscape
Graham v. John Deere Co., 383 U.S. 1
(1966)

Parameters for Determining Obviousness

1. Scope and contents of the prior art
2. Level of ordinary skill in the art
3. Differences between claimed invention and prior art
4. Evaluation of evidence of secondary considerations
 - Commercial success
 - Long felt but unsolved needs
 - Failure of others
 - Existence of licenses
 - Unexpected results and skepticism of those in the art

Pre-*KSR* Landscape

TSM Test

- Subsequent to *Graham*, Federal Circuit created a two-pronged objective analysis of obviousness to rebut the tendency to use hindsight as a method of invalidating a patent
 - 1) a teaching, motivation, or suggestion to combine or modify prior art references
 - 2) coupled with a reasonable expectation of success viewed in light of the prior art
- Under the TSM test, a patent claim is only proved obvious if the prior art, the problem's nature, or the knowledge of the person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings
- Federal Circuit previously held that the TSM test was an absolute prerequisite to obviousness

Pre-*KSR* Landscape

TSM Test

- After Supreme Court decided to review the TSM test requirement, Federal Circuit issued two decisions which indicated a broader conception of the TSM test
 - DyStar Textilfarben v. Patrick - "Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense." 464 F.3d 1356, 1367 (2006)
 - Alza Corp. v. Mylan Labs, Inc. - "There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine" 464 F.3d 1286, 1291 (2006)

KSR International Co. v. Teleflex, Inc.

- Teleflex claimed that KSR infringed its patent on connecting an adjustable pedal assembly to an electronic throttle control
- KSR argued that merely combining the two elements was obvious and thus, not patentable
- The District Court agreed with KSR
 - Found the patent to be obvious in light of the offered prior art
- Federal Circuit vacated the District Court's decision
 - Highlighted the role the Teaching Suggestion Motivation (TSM) Test plays in resisting the temptation to engage in impermissible hindsight as an indicator of obviousness
- Supreme Court unanimously reversed the Federal Circuit's judgment
 - Held that the Federal Circuit's application of the TSM test was inconsistent with §103 and incorrectly analyzed the issue of obviousness

KSR International Co. v. Teleflex, Inc.

Supreme Court cited several errors by Federal Circuit:

- Question was not whether the combination was obvious to the patentee but whether the combination was obvious to one skilled in the art
 - Thus "any need or 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."
- Erroneous to assume a person of ordinary skill attempting to solve a problem would only be led to the elements of prior art designed to solve the same problem.
 - "**Common sense** teaches us that familiar items may have obvious uses beyond their primary purpose, and 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 International Co. v. Teleflex, Inc.

Supreme Court cited several errors by Federal Circuit (con't)

- Erroneous to conclude a patent claim cannot be proved obvious merely by showing the 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." When the combination leads to anticipated results, the fact that it was obvious to try that combination might show that it was obvious under §103.
- Federal Circuit "drew the wrong conclusions from the risk of courts and patent examiners falling prey to hindsight bias."
 - Rigid preventative rules that deny fact-finders recourse to "common sense" are unnecessary.

Effects of *KSR* Decision

- *KSR* is a knee-jerk reaction to past cases which each suggested that patents were being upheld as valid for vague or unsupportable reasons
 - *eBay Inc v. MercExchange LLC*, 547 U.S. 388 (2006)
 - *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 1166 (2006)
- *KSR* gives lip service to the dangers of hindsight
 - Warns of hindsight bias, but rejects the idea that there can be bright line rules that might assist in protecting against such bias
- "Common Sense" analysis undoubtedly will lead factfinders down a very subjective path
 - What may be common to one is not necessarily common to another
 - Factfinders making a prima facie case for obviousness by merely saying that it is "common sense" is not the objective test set forth in 35 U.S.C. § 103
- "Obvious to Try" is the antithesis of the TSM test
 - The "obvious to try" standard is ambiguous and invokes hindsight
 - Patentee will now be faced with demonstrating that it was not obvious to do something and proving the negative at times can be quite difficult

USPTO Obviousness Guidelines under 35 U.S.C. § 103 in light of *KSR*

- A. Combining prior art elements according to known methods to yield predictable results
- B. Simple substitution of one known element for another to obtain predictable results
- C. Use of known technique to improve similar devices (methods or products) in the same way
- D. Applying a known technique to a known device (method or product) ready for improvement to yield predictable results
- E. "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- F. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art
- G. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference teaching to arrive at the claimed invention

Obviousness Decisions Post-*KSR*

- 21 Published Federal Circuit cases, which conducted an obviousness inquiry utilizing the analysis and legal framework of *KSR*
 - 15 invalidated/rejected based on obviousness (71%)
 - 6 upheld (29%)
- In most cases, the reliance on *KSR* to invalidate patents is essentially a hindsight evaluation of the claims
- Some may argue that the Federal Circuit's cases are in line with the USPTO Guidelines
- A valid argument can be made that the Federal Circuit is conducting a 20/20 hindsight review of the patent and prior art

Obviousness Decisions Post-*KSR*

- *PharmaStem Therapeutics, Inc. v. Vic Cell, Inc.*, 491 F.3d 1342 (Fed. Cir 2007)
 - Challenged medical discovery patent for process of collecting umbilical cord blood for use in adult stem cell reconstruction
 - Court invalidated patent based on USPTO Guideline “A” – Combination of Elements
 - Completely ignored that the invention was achieved through "scientific skepticism, despite the extensive research that was being conducted by many scientists in this field."
- *Pfizer, Inc. v. Apotex, Inc.*, 488 F.3d 1377 (Fed. Cir. 2007)
 - Invalidated drug patent as "obvious to try" (USPTO Guideline “E”)
 - Ignores that methodical experimentation is fundamental to scientific advance, and particularly for biological and medicinal products, where small changes can produce large differences
- *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008)
 - Upheld claims for certain drugs based on "obvious to try" standard, but recognized the dangers of hindsight review
 - Allowed use of TSM test, but only in "flexible manner"
 - "A retrospective analysis of the inventor's path to an invention – which seems to follow logical steps – ignores an inventor's insights, willingness to confront and overcome obstacles, and even serendipity."

The Pendulum-Shift Resulting from *KSR*

- *KSR* Framework Hinders the Advancement of Patentability
 - Ignores U.S. Patent System aim at issuing patents based on novel inventions awarding scientific, creative, and innovative development
- Shifting the Burden of Proof
 - Proving validity now fully shifts to the inventor to come forth with substantial evidence that it was **not** "obvious to try" something
- Statutory Standard has been Completely Disregarded
 - 35 U.S.C. §103 no longer addresses what **would have been** obvious

The Pendulum-Shift Resulting from *KSR*

- Current "Common Sense" Analysis
 - The focus now is on what is claimed to be common sense and attempts at trying different inventions in addressing the obviousness question
 - Opens the opportunity to inject hindsight into the evaluation
- A Legislative Response is the Only Recourse
 - Congress must consider the ramifications of *KSR* and adopt future patent reform
 - Swing the pendulum back from a 20/20 hindsight review to a system which rewards innovation, creativity, and societal advancement