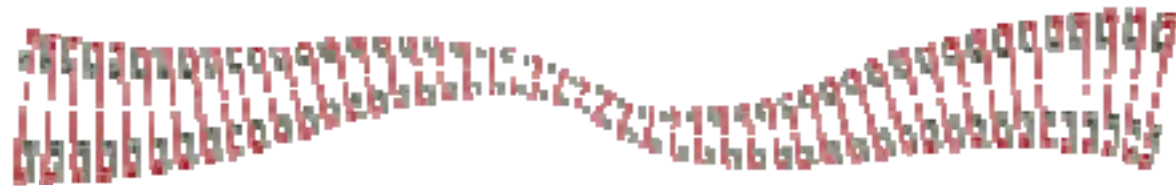


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Presents
Roadblocks to Patentability

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Obviousness (35 U.S.C. 103(a))

- In order to obtain a patent, an invention must be non-obvious in addition to being novel.
- The test for non-obviousness is an objective inquiry into whether “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.”

The pre-KSR rule

- Under the Teaching-Suggestion-Motivation (TSM) test, a claimed invention is obvious when there is a teaching, suggestion, or motivation to combine prior art teachings. The teaching, suggestion, or motivation may be found in the prior art, in the nature of the problem, or in the knowledge of a person having ordinary skill in the art.

KSR International Co. v. Teleflex Inc.

- Graham vs. Deere established the objective framework for applying Sec. 103
 - (1) Determination of the scope and content of the prior art
 - (2) Identification of any differences between the prior art and the claims at issue
 - (3) Determination of the level of ordinary skill in the pertinent art, that warrants the award of a patent.
 - (4) Review of any relevant secondary considerations, such as commercial success, long felt but unresolved needs and failure of others

KSR cont'd.

- According to the Supreme Court, the TSM test is one of a number of valid rationales that could be used to determine obviousness. It is not the only rationale that may be relied upon to support a conclusion of obviousness.

Secondary Considerations

- (1) the invention's commercial success
- (2) long felt but unresolved needs
- (3) the failure of others
- (4) skepticism by experts
- (5) praise by others
- (6) teaching away by others
- (7) recognition of a problem
- (8) copying of the invention by competitors

PTO Hypotheticals

- Combining prior art elements according to known methods to yield predictable results.
- Simple substitution of one known, equivalent element for another to obtain predictable results.
- Use of known technique to improve similar devices (methods, or products) in the same way.
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results.
- “Obvious to try” – choosing from a finite number of predictable solutions.
- TSM Test.

Case Law

- Where there are no persuasive reasons to start with a lead compound and then modify that lead compound to form the claimed drug, the claimed drug will be held to be non-obvious
 - *Takeda* – prior art disclosed a series of compounds that could have served as lead compounds, but the one closest to the drug claimed exhibited significant toxicity, there was no reasonable expectation that the claimed drug would be less toxic than the prior art
 - *Ortho-McNeil and Eisai*

Case Law cont'd.

- Prima facie obviousness of a claimed compound in view of a prior art racemic mixture can be rebutted where the claimed compound showed unexpected benefits, and that the claimed compound and its non-superimposable mirror image would have been difficult for a person of ordinary skill in the art to separate.
- Prima facie obviousness of a purified form of a prior art mixture will not be rebutted where the potency of the purified form was expected.
 - *Forest and Aventis*

Case Law cont'd.

- Listing prior art references and concluding with a stock phrase, “to one skilled in the art it would have been obvious to perform the claimed method” does not support a finding of obviousness. The kind of motivation required by the patent laws is not a generalized motivation to develop a method, but rather the motivation to combine particular references to reach the claimed method.
 - *Innogenetics*

Case Law cont'd.

- An invention is nonobvious when one of ordinary skill in the art would not infer a negative interaction from a prior art reference, and thus would have had no reason to make a claimed modification that reduced that negative interaction
 - *Omeprazole*

Case Law cont'd.

- Where a person skilled in the art would have had reason to attempt to make the composition or carry out the claimed process, and would have had a reasonable expectation of success in doing so, then the claimed composition or process will be held to be obvious
 - *Daiichi and Kubin*

Consequences of KSR

- Forces everyone who has grown comfortable with the TSM litmus test shortcut to return to full and proper *Graham* analyses when assessing the obviousness of patent claims.
- It had the practical and immediate effect of making patents more difficult to obtain.
- Recent article in Nature Biotechnology.

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