



UNITED STATES PATENT AND TRADEMARK OFFICE

Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex



Cases Post-KSR

Takeda Chemical Industries v. Alphapharm Pty, Ltd.,
492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007)

Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491
F.3d 1342, 83 USPQ2d 1289 (Fed. Cir. 2007)

Forest Laboratories v. Ivax Pharmaceuticals, 501 F.3d
1263, 84 USPQ2d 1099 (Fed. Cir. 2007)



Cases Post-KSR

Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 84 USPQ2d 1285 (Fed. Cir. 2007)

Aventis v. Lupin, 499 F.3d 1293, 84 USPQ2d 1197 (Fed. Cir. 2007)

McNeil-PPC, Inc. v Perrigo Company, 443 F. Supp. 2d 492 (S.D. N.Y. June 5, 2007), aff'd by Fed. Cir. in April 2008 without published decision



Cases Post-KSR

In re Omeprazole Patent Litigation, 490 F. Supp. 2d 381 (S.D. N.Y. June 1, 2007), aff'd by Fed. Cir. in June 2008 in a non-precedential decision

Ortho-McNeil v. Mylan, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008)

Eisai v. Dr. Reddy's, 533 F.3d 1353, 87 USPQ2d 1452 (Fed. Cir. 2008)

Sanofi-Synthelabo v. Apotex, 550 F.3d 1075, 89 USPQ2d 1370 (Fed. Cir. 2008)



Cases Post-KSR

Boston Scientific Scimed v. Cordis, 554 F.3d 982, 89
USPQ2d 1704 (Fed. Cir. 2009)

In re Kubin, 561 F.3d 1351, 90 USPQ2d 1417 (Fed. Cir.
2009)

Procter & Gamble v. Teva, 566 F.3d 989, 90 USPQ2d
1947 (Fed. Cir. 2009)

Bayer Schering v. Barr, 575 F.3d 1341, 91 USPQ2d
1569 (Fed. Cir. 2009)



Outcome

Unobvious: 7

Obvious: 7



The 2010 KSR Guidelines Update . . .

IS effective as of its publication on September 1, 2010 in the Federal Register (75 Fed. Reg. 53643).

IS accessible, together with other post-KSR obviousness training materials for examiners, at http://www.uspto.gov/patents/law/exam/ksr_training_materials.jsp.

IS a summary of some, but not all, precedential Federal Circuit decisions concerning obviousness since KSR.

DOES provide examples of obvious and nonobvious claims.



The 2010 KSR Guidelines Update . . .

IS NOT a new USPTO policy with respect to obviousness.

IS NOT a replacement for the 2007 KSR Guidelines.

DOES NOT identify any new obviousness rationales.

DOES NOT provide any per se rules. Each case must be decided on its own facts.



Structure of the 2010 KSR Guidelines Update

Section 1 – purpose of the document

Section 2 – review of the law of obviousness

Section 3 – impact of the KSR decision

Section 4 – examples from cases discussing obviousness

A. "Combining Prior Art Elements"

B. "Substituting One Known Element for Another"

C. "The 'Obvious to Try' Rationale"

Section 5 – cases discussing consideration of evidence

Appendix – summary of "teaching points" from the cases



Important Points

In 2007, the Supreme Court's KSR decision reaffirmed that the familiar Graham v. Deere analysis, requiring evaluation of

1. the scope and content of the prior art;
2. the difference between the prior art and the claimed invention;
3. the level of ordinary skill in the art; and
4. secondary considerations,

was still the proper way to evaluate any question of obviousness.

Nothing has happened since 2007 to change that!



Important Points

As explained in the 2007 KSR Guidelines, every obviousness rejection requires

- (a) appropriate findings of fact;**
- (b) a reasoned explanation; and**
- (c) a legal conclusion of obviousness.**

This is so regardless of the rationale or line of reasoning used to formulate the rejection.



Important Points

No examiner may choose to disregard the Supreme Court's decision in KSR or the associated examiner guidance materials when determining whether or not an obviousness rejection should be made.

If properly formulated, a rejection that relies on a traditional pre-KSR-style "motivation statement" is an appropriate rejection in light of the KSR decision.



Important Points

The cases in the 2010 KSR Guidelines Update were chosen to provide examples of both obvious and nonobvious claims. The technologies and rationales included are those most thoroughly discussed in the cases since 2007. Many other cases are already available, and even more will become available as decisions are rendered. While important new decisions are routinely added to the MPEP, Office personnel are encouraged to keep up with current trends in the law by attending end-of-year case reviews, and by accessing cases via USPQ or the Federal Circuit's Web site.



Important Points

- 1. Any determination of whether or not a claimed invention is obvious requires the examiner to consider and weigh all evidence that has properly been made of record.**
- 2. If an applicant presents evidence in support of the nonobviousness of a claim, the examiner must reweigh all evidence. Evaluating an applicant's evidence only for its "knockdown" effect is not appropriate.**
- 3. Even if evidence is entitled to little weight, it should still be considered and addressed by the examiner.**



Important Points

An Appendix listing the example cases along with one or more "teaching points" drawn from each case is included with the 2010 KSR Guidelines Update.

Examiners should use the teaching points as a quick way to locate examples that may be particularly relevant to them.

The teaching points are not a substitute for reading the complete discussion of a case. Reading the entire court decision will also be informative, and is recommended particularly when the facts of the case are very similar to those in the application before the examiner.



A. Combining Prior Art Elements: SUMMARY

- It can be important for an examiner to identify a reason to combine prior art elements.
- Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so.
- Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.



A. Combining Prior Art Elements:
**4.1. In re Omeprazole Patent Litigation,
536 F.3d 1361 (Fed. Cir. 2008)**

The claimed pharmaceutical formulation including two layers of coatings over the active ingredient omeprazole (marketed as Prilosec®) was not obvious, even though –

- the coating materials and methods for applying them were known
- a formulation of omeprazole and a single-layer coating was known
- using a coating and a subcoating was known generally, although not specifically for omeprazole



A. Combining Prior Art Elements:

4.1. In re Omeprazole Patent Litigation

Why was the claimed formulation nonobvious over the references applied?

1. The patentee had discovered that the single-coating prior art product was subject to degradation, and that the degradation could be reduced by adding a subcoating.
2. Absent prior recognition of the problem, there would have been no reason to add a subcoating. Even though the modification would have been technically feasible, it would have amounted to extra effort and expense for no expected return without the patentee's discovery of the problem.



A. Combining Prior Art Elements: 4.1. In re Omeprazole Patent Litigation

Teaching point: Even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown.



B. Substituting One Known Element for Another: SUMMARY

- The substitution rationale applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention.
- A person of ordinary skill in the art must have been technologically capable of making the substitution.
- The result obtained must have been reasonably predictable.



C. Obvious To Try: SUMMARY

- Although the case law in this area is developing quickly in the chemical arts, the rationale has been applied in other art areas as well.
- "Obvious to try" is not a new line of reasoning since KSR. The Federal Circuit in In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009), stated that KSR resurrects its own wisdom in In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988), concerning differentiation between proper and improper applications of this line of reasoning.
- Courts appear to be applying the KSR requirement for "a finite number of identified predictable solutions" in a manner that places particular emphasis on predictability and the reasonable expectations of those of ordinary skill in the art.



C. Obvious To Try:

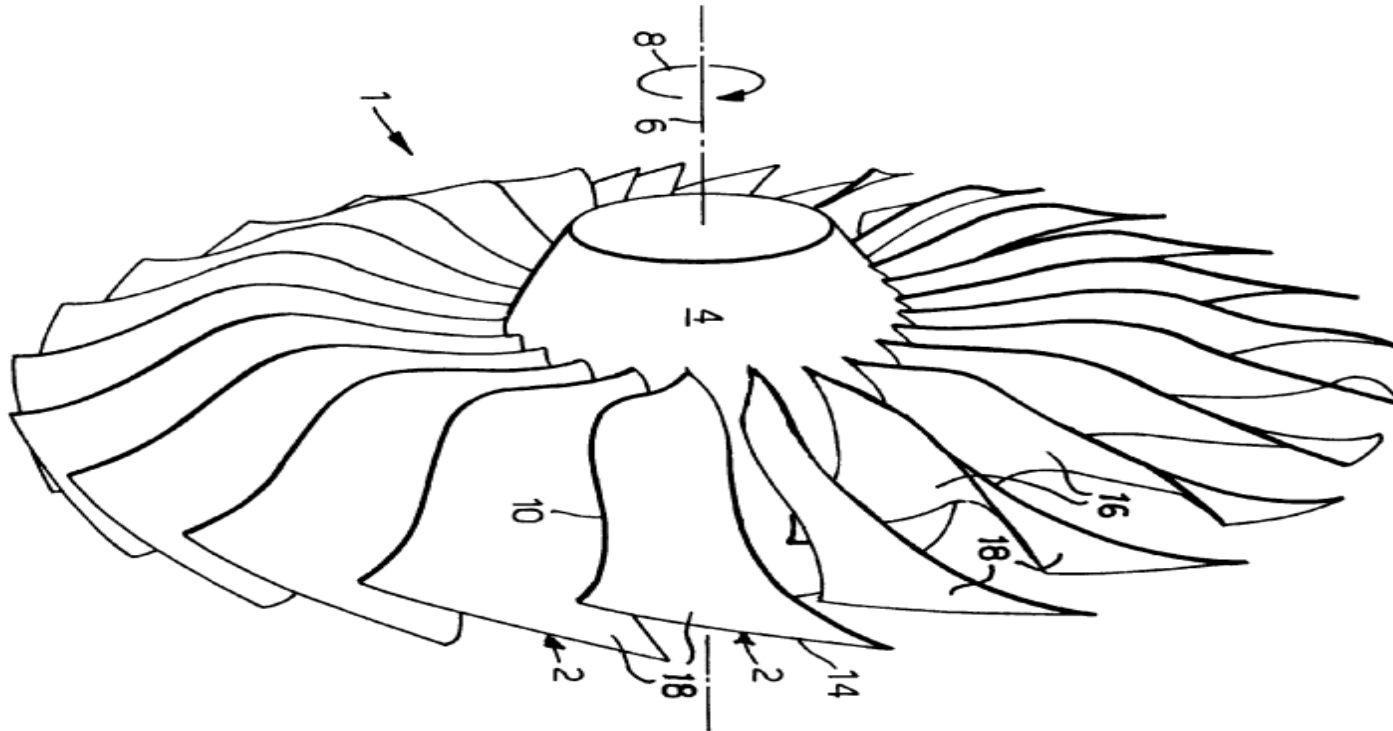
4.19. Rolls-Royce, PLC v. United Techs. Corp., 603 F.3d 1325 (Fed. Cir. 2010)

The claimed fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region, was nonobvious over the prior art applied, even though –

- United had argued that it would have been obvious for a person of ordinary skill in the art to try a fan blade design in which the sweep angle in the outer region was reversed as compared with prior art fan blades from rearward to forward sweep, in order to reduce endwall shock.



Obvious To Try: 4.19. Rolls-Royce, PLC v. United Techs. Corp.





C. Obvious To Try:

4.19. Rolls-Royce, PLC v. United Techs. Corp.

Why was the fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region, nonobvious?

1. There had been no suggestion in the prior art that changing the sweep angle as Rolls-Royce had done would have addressed the issue of endwall shock.
2. According to the Federal Circuit, changing the sweep angle “would not have presented itself as an option at all, let alone an option that would have been obvious to try.” Rolls-Royce, 603 F.3d at 1339.



C. Obvious To Try:

4.19. Rolls-Royce, PLC v. United Techs. Corp.

Teaching point: An obvious to try rationale may be proper when the possible options for solving a problem were known and finite. However, if the possible options were not either known or finite, then an obvious to try rationale cannot be used to support a conclusion of obviousness.



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Thank You

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