

***KSR*: An Obvious Effect on Patent Validity?**

Stephen M. Hash
Vinson & Elkins L.L.P.
2801 Via Fortuna
Suite 100
Austin, Texas 78746
[*shash@velaw.com*](mailto:shash@velaw.com)

***KSR*: An Obvious Effect on Patent Validity?**

- ***KSR* Holding**
- **MPEP Obviousness Guidelines**
- **Empirical Studies of Post-*KSR* Cases**
- **Illustrative Cases**

Patentability Requirement

“A patent may not be obtained ... if the **difference** between the subject matter ... 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** to which said subject matter pertains.”

Patent Act of 1952, 35 U.S.C. § 103(a).

The *Graham* Factors

1. Scope and content of the prior art.
2. Differences between the prior art and the claims at issue.
3. The level of ordinary skill in the pertinent art.
4. Secondary considerations, including:
 - Commercial success;
 - Long-felt but unsolved need; and
 - Failure of others.

Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

Hindsight Bias

However, the *Graham* factors were criticized as being susceptible to **hindsight bias**.



Accordingly, the Federal Circuit used a simpler, bright-line test for the obviousness inquiry...

The “TSM” Test

“Obviousness can **only** be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some **teaching, suggestion or motivation** to do so....”

MPEP 2143.01

1. Show each claim element in the prior art.
2. Show specific teaching, motivation or suggestion to combine.
3. Show “reasonable expectation of success.”

KSR v. Teleflex – Supreme Court Decision ^{V&E}

Technology: Mechanical patent related to adjustable automobile pedals

Patent at Issue: Claimed an adjustable pedal assembly with an electronic sensor

Prior art: (1) adjustable pedal with a fixed pivot point
(2) accelerator with an electronic sensor

KSR v. Teleflex – Supreme Court Decision ^{V&E}

District Court: Summary judgment of obviousness

Federal Circuit: Reversed obviousness holding based on TSM test; reasoned that the prior art patents sought to solve different problems than the patent at issue, therefore no motivation to combine

Supreme Court: Unanimously reversed Federal Circuit's judgment

KSR v. Teleflex – Rejected Rigid Application of TSM Test V&E

- “The obviousness analysis **cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation**, or by overemphasis on the importance of published articles and the explicit content of issued patents.”
- Reaffirmed the “broad inquiry” set forth in *Graham*, allowing for a “flexible and expansive” approach to determining obviousness.
- “Rigid preventative rules that deny factfinders **recourse to common sense** . . . are neither necessary under our case law nor consistent with it.”

KSR v. Teleflex – Rejected Federal Circuit’s Motivation to Combine Standard

V&E

- Rejected Federal Circuit’s requirement that in order to find a motivation to combine prior art references, those references must address the “precise problem the patent was trying to solve.”
- Rather, an obviousness challenge is **not limited** to “the problem the patentee was trying to solve” or to “only those prior art elements designed to solve the same problem.”

KSR v. Teleflex – Reinstated “Obvious To Try” Analysis

V&E

- Rejected *In re Deuel* holding that “obvious to try” cannot constitute obviousness
- “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.”
- “**The combination of (1) familiar elements according to (2) known methods is likely to be obvious when it does no more than yield (3) predictable results.**”

KSR v. Teleflex – Obviousness Can Be Determined On Summary Judgment

V&E

- Corrected Federal Circuit’s misperception that expert affidavit addressing the question of obviousness precludes determination of the issue at summary judgment level.
- The *Graham* inquiry does not “exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness.”
- The ultimate judgment of obviousness is a legal determination.

2007 USPTO Obviousness Guidelines

- Prior art is not limited just to the references being applied, but **includes the understanding of one of ordinary skill** in the art.
- The prior art reference (or references when combined) **need not teach or suggest all the claim limitations** because the mere **existence of differences** between the prior art and an invention **does not establish the invention's nonobviousness.**
- In determining obviousness, neither the **particular motivation** to make the claimed invention nor the **problem the inventor is solving** controls.

72 Fed. Reg. 57528(October 10, 2007) (quoting *KSR*, 82 USPQ2d at 1396)

2007 USPTO Obviousness Guidelines

V&E

- Identified **rationales that support obviousness**
 - Prior art elements + **known methods** = **predictable results**
 - **Simple substitution** of known elements = **predictable results**
 - Known technique to **improve similar devices** in the same way
 - **Known technique** + **known device** = **predictable results**



2007 USPTO Obviousness Guidelines

V&E

- **Rationales** continued

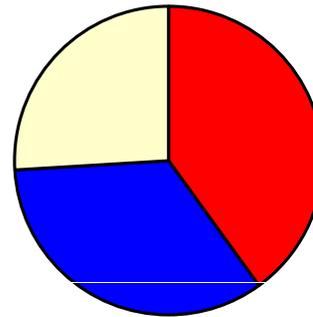


- **“Obvious to try”**/ finite number of **identified, predictable solutions** with reasonable expectation of success
 - **Predictable variations** prompted by **design incentives or market forces** (may be for use in same or different field)
 - **Teaching, suggestion, or motivation** in prior art
 - Note: if the **TSM test is negative**, the examiner must continue to **evaluate the other rationales**
- The USPTO must still review secondary considerations when argued

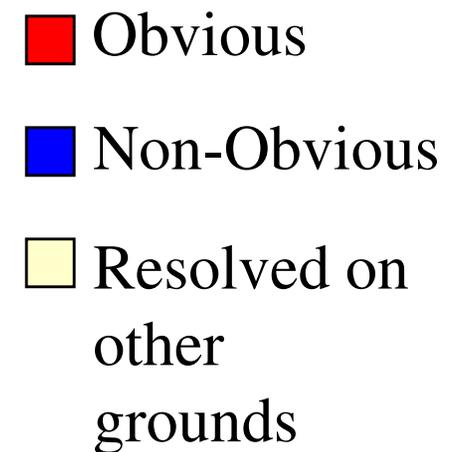
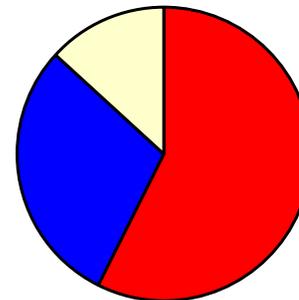
An Empirical Study of Effect of *KSR v. Teleflex* V&E (February 2009)—Federal Circuit Cases

- Pre-*KSR*
 - **40% Obvious**
 - 34.3% Non-Obvious
- Post-*KSR* (through 02/28/2009)
 - **57.4% Obvious**
 - 29.6% Non-Obvious

Pre-KSR



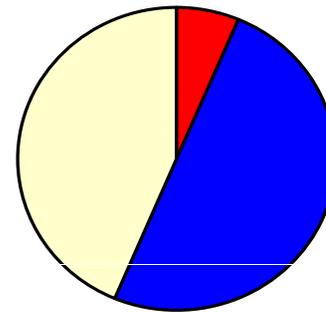
Post-KSR



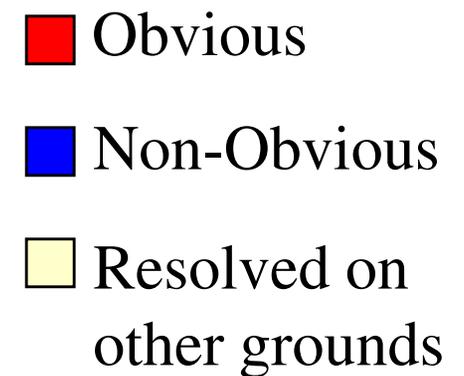
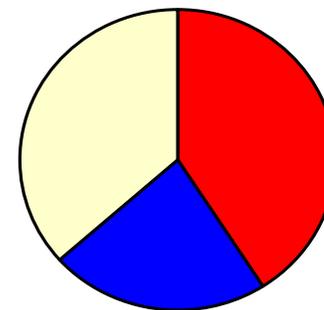
An Empirical Study of Effect of *KSR v. Teleflex* V&E (February 2009)—District Court Cases

- Pre-*KSR*
 - **6.3% Obvious**
 - 50% Non-Obvious
- Post-*KSR* (through 02/28/2009)
 - **40.8% Obvious**
 - 22.4% Non-Obvious
- Investigated courts:
 - N.D. of Cal., C.D. of Cal., N.D. of Ill., S.D. of NY

Pre-KSR



Post-KSR



Informal Survey of 41 Federal Circuit Opinions V&E Post-*KSR* (January 2010)

- As of January 2010, 41 published Federal Circuit decisions addressing obviousness
- Includes appeals from jury verdicts, bench trials, summary judgment determinations, and Board of Patent Appeals and Interferences decisions.
- Opinions analyzed according to technology: Mechanical, Computer/Electrical, Chemical/Material Science, Business Methods, Medical Device, Biotechnology, and Pharmaceutical

Michael J. Flibbert, Finnegan, Henderson, Farabow, Garrett & Dunner; *Obviousness in the Wake of KSR*, presented January 21, 2010

Informal Survey of 41 Federal Circuit Opinions Post-KSR (January 2010)

V&E

- Mechanical
 - 8 cases, 100% held claims obvious
- Computer/Electrical
 - 10 cases, 90% held claims obvious
- Chemical/Material Science
 - 2 cases, 100% held claims obvious
- Business Methods
 - 4 cases, 100% held claims obvious

Michael J. Flibbert, Finnegan, Henderson, Farabow, Garrett & Dunner; *Obviousness in the Wake of KSR*, presented January 21, 2010

Informal Survey of 41 Federal Circuit Opinions Post-KSR (January 2010)

V&E

- Medical Device
 - 3 cases, 67% held claims obvious
- Biotechnology
 - 4 cases, 100% held claims obvious
- Pharmaceutical
 - 10 cases, 40% held claims obvious

Michael J. Flibbert, Finnegan, Henderson, Farabow, Garrett & Dunner; *Obviousness in the Wake of KSR*, presented January 21, 2010

Illustrative Cases

- *Agrizap, Inc. v. Woodstream Corp.*
- *Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd.*
- *In re Kubin*
- *Depuy Spine v. Medtronic Sofamor Danek, Inc.*
- *Perfect Web, Inc. v. InfoUSA, Inc.*
- *Rolls-Royce, PLC v. United Techs. Corp.*

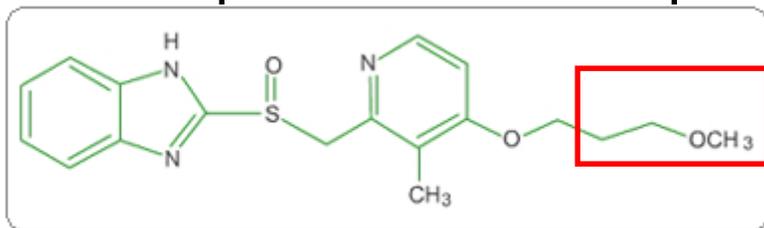
- **Invention:** A method/device for electrocuting pests
- **Prior Art:**
 - 1. Gopher Zapper: discloses all of the limitations of the asserted claims with one exception—it discloses a mechanical switch
 - 2. Dye Patent and Madsen Patent: disclose use of resistive electrical switches
- **Issue:** Obvious to substitute a resistive electrical switch for the mechanical switch?

- **Holding: Obvious** (reversed)
 - A textbook case
 - The asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results.
 - Dye Patent and Madsen Patent are directed to **solving the same problem** as the invention: **the malfunction of mechanical switches** in environments prone to dirt and dampness.
 - The secondary considerations cannot overcome such a strong prima facie case of obviousness.

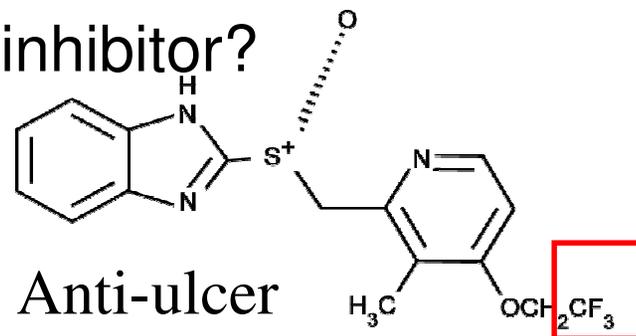
Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd.

V&E

- **Invention:** Gastric acid inhibitor (Rabeprazole: proton pump inhibitor)
- **Prior Art:**
 - 1. Anti-ulcer compound (very similar in structure)
 - 2. Acid inhibitor with same core structure as anti-ulcer compound
- **Issue:** Obvious to alter the structure of the anti-ulcer compound to develop the acid inhibitor?



Anti-acid



Anti-ulcer

Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd.

V&E

- **Holding: Not Obvious** (affirmed)
 - No Finite or Identifiable Solutions
 - No prior art reason to modify anti-ulcer (alleged lead compound) to obtain acid inhibitor
 - Nearly identical chemical structure= irrelevant
 - Unpredicted result: Anti-ulcer compound could be modified to obtain acid inhibitor



Eisai Co. Ltd. v. Dr. Reddy's Labs. Ltd., 533 F.3d 1353 (Fed. Cir. 08/16/2008)

- **Invention:** DNA polynucleotides encoding Natural Killer Cell Activation Inducing Ligand (“NAIL”)
- **Prior Art:**
 - 1. Patent '690: receptor protein p38 (same protein as NAIL), disclosed that DNA and protein sequences can be obtained by prior art 2.
 - 2. Laboratory Manual on Molecular Cloning
- **Issue:** Was the production of NAIL cDNA a product of ordinary skill and common sense?

- **Holding: Obvious** (affirmed)
 - Prior art disclosed conventional techniques to isolate nucleotide sequence
 - “One of ordinary skill in the art would have recognized the value of isolating NAIL cDNA”
 - “reasonable expectation of success”
 - Federal Circuit declined to “cabin *KSR* to the ‘predictable arts’” (applies to biotechnology too)

Depuy Spine v. Medtronic Sofamor Danek, Inc.

V&E

- **Invention:** polyaxial pedicle screws for spinal surgery
- **Prior Art:**
 - Puno: polyaxial pedicle screw assembly with “shock absorber” effect
 - Anderson: external fracture immobilization splint with a swivel clamp capable of polyaxial movement until secured by a compression member
- **Issue:** Obvious to combine screw assembly with compression member?



Depuy Spine v. Medtronic Sofamor Danek, Inc.

V&E



- **Holding: Not Obvious** (affirmed)
 - The combination of Puno and Anderson produced a “predictable result” of a rigidly-locked screw
 - However, Puno taught away from a rigid screw
 - Person of ordinary skill in the art would have been deterred from the combination
 - Addition of the Anderson compression member reduced Puno’s shock absorption
- ***First mechanical device case post-KSR holding not obvious***

Perfect Web Techs., Inc. v. InfoUSA, Inc.

V&E

- **Invention:** Methods of managing bulk e-mail distribution to groups of targeted consumers
- **Prior Art:**
 - Step (A) Identifying a group of target recipients
 - Step (B) Sending out emails to these recipients
 - Step (C) Calculating the number of successfully delivered emails.
- **Issue:** Obvious to iteratively repeat steps (A)–(C) until the number of recipients reaches a prescribed quantity?

Perfect Web Techs., Inc. v. InfoUSA, Inc.

V&E

- **Holding: Obvious** (affirmed)
 - Common Sense
 - merely the logical result of common sense application of the maxim “try, try again”
 - Obvious to Try
 - Sending messages to new addresses is more likely to produce successful deliveries
 - Predictable result that more emails reach more recipients
 - No Long-Felt Need
 - Perfect Web fails to show that over-sending constituted a long-felt need
 - Also fails to show its patent met any such “need”

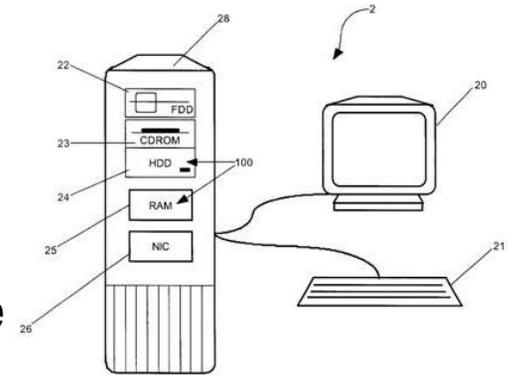
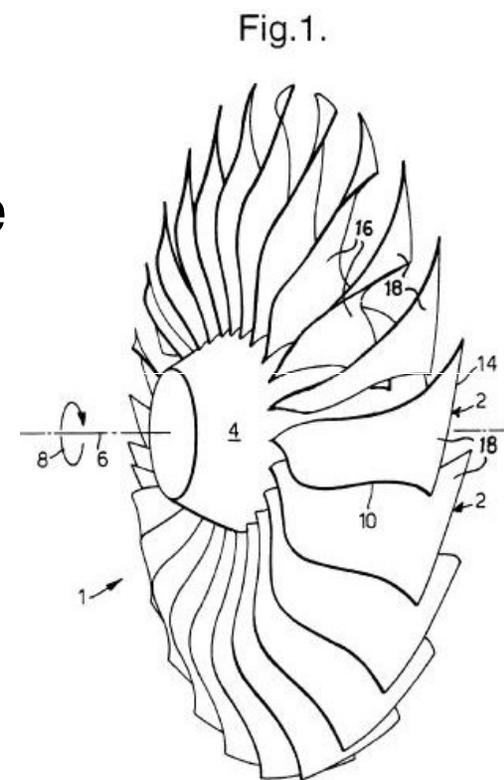


FIG. 2

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

- **Invention:** Swept fan blades used on turbofan jet engines, where the outer region defines a forward sweep angle
- **Prior Art:**
 - '931 Patent Application: The outer region defines a rearward sweep angle
- **Issue:** Obvious for a researcher to reverse the direction of the sweep angle?



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

V&E



- **Holding: Not Obvious** (affirmed)
 - No Suggestion or Motivation
 - The record before the invention showed that translation forward may create **an unusable fan blade**.
 - Not Obvious to Try
 - The broad selection of choices for further investigation included **any degree of sweep**.
 - Secondary Considerations
 - Long-felt need for quieter, more fuel efficient engines
 - An efficiency improvement of **1.8%** (0.5% considered to be a huge gain in the industry)
 - Nexus established between engine sales and the invention

Rolls-Royce, PLC v. United Techs. Corp., 603 F.3d 1325 (Fed. Cir. 05/05/2010)

Practice Tips: Patentee

- **Emphasize:**
- The **unpredictable nature** of your invention
 - **Specifics** about the method when combining prior art
 - Focus on differences in method, results, and/or problem solved
 - **Unexpected/unpredictable** results
 - **Infinite/unidentifiable** solutions
 - **Secondary considerations** and a proper nexus
- **Avoid:**
 - Broad disclosures that one could use **routine methods** to arrive at alternative embodiments

Practice Tips: Alleged Infringer

- **Emphasize:**
 - The **broader scope** of prior art
 - Include prior art in other fields or solving other problems
 - **design or market demand** that leads to a motivation to combine
 - **purpose of the invention** that leads to a motivation to combine
 - **USPTO reliance on a rigid TSM test** during prosecution
 - Consider re-examination
 - **Obvious to try** (expert witnesses)
 - **Finite, predictable** solutions
 - Predictable results/reasonable **expectation of success**

Questions?

Stephen M. Hash
Vinson & Elkins L.L.P.
2801 Via Fortuna
Suite 100
Austin, Texas 78746
shash@velaw.com