
KSR's Impact in the Courts

— Expect the Need to Show the Unexpected

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Presentation Overview

- How the Federal Circuit analyzed obviousness before *KSR*
- The guiding principles given in *KSR*
- How the courts are applying *KSR*'s principles
- Success-rate statistics for patentees and accused infringers under *KSR*

Landscape Before *KSR*

- *Graham* factors govern the § 103 analysis
 - scope and content of the prior art
 - differences between the prior art and the claims
 - level of ordinary skill
 - secondary considerations
- “Against this background, the obviousness or nonobviousness of the subject matter is determined.”
 - Amorphous standard with no real guidance

Federal Circuit's pre-*KSR* Gloss

- “Hindsight” improper
 - can’t use the patent as “a guide through the maze of prior art”
- Teaching, suggestion, or motivation in prior art to combine and/or modify references
 - “essential evidentiary component of an obviousness holding”
- Reasonable expectation of success
- Secondary considerations
 - “may often be the most probative and cogent evidence in the record”
- Rejected “obvious to try” and a “synergy” reqt.

Dissatisfaction with TSM

- Critics voice concern that TSM too rigid (Oct 2003 FTC Rpt.)
 - Difficult to find explicit disclosures in prior art to support motivation to combine
 - Leads to poor quality patents
 - Perception that TSM test creates a formidable, if not insurmountable, obstacle in litigation
- CAFC's response — TSM test not too rigid since the TSM may be implicit
 - *Ruiz v. A.B. Chance, Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004) (“express, written motivation to combine” not needed, nature of problem may provide an implicit TSM)
 - *In re Kahn*, 441 F.3d 977, 989-90 (Fed. Cir. 2006) (implicit motivation shown by inherent knowledge of skilled artisan identified on record)
- 2006 SCT grants cert. in *KSR*
 - 39 amicus briefs on the merits filed

CAFC's Expands "Implicit"

- *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1293-95 (Fed. Cir. 2006)
 - “We do not have a rigid test that requires an actual teaching to combine”
 - TSM may be implicit, only requires “*some* articulated reasoning with *some* rational underpinning”
 - Non-conclusory expert testimony that one of skill would have reasonable expectation of success sufficient to show motivation to combine
 - *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006)
 - TSM may be found from **market pressures** to produce something that is “stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient” than what already exists
 - “the proper question is whether the ordinary artisan possesses knowledge and skills rendering him **capable** of combining the prior art references”
 - Shift from *prior-art based* TSM to **technical capability** plus **market pressure** or any other rationale
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Principles from *KSR*

- General guidance
 - “Need for caution” where invention is a combination of elements found in the prior art
 - Rejects “rigid” approach to § 103 analysis; rather analysis should be “expansive and flexible”
 - Be aware of the “distortion caused by hindsight,” but fear of hindsight does not justify overly rigid rules
 - “A person of ordinary skill is also a person of ordinary creativity, not an automaton”

Principles from *KSR*

- Step 1 - Look for “*an apparent reason* to combine the known elements”
 - Reason can come from marketplace or design community demands
 - Reason may be implicit and based on “inferences and creative steps” that a PHOSITA would employ
 - Any known problem may provide the “apparent reason” even if inventor was working on a different problem
 - Analysis and proof of the “apparent reason” should be explicitly made on the record
 - TSM a “helpful insight” in the “apparent reason” analysis so long as it is not rigidly applied

Principles from *KSR*

- Step 2 - Obvious if “Predictable”
 - Combination likely obvious if “it does no more than **yield predictable results**” or “**implements a predictable variation**” of a known work
 - “A court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.”
 - When predictability is shown, a PHOSITA “will be able to fit the teachings of multiple patents together like pieces of a puzzle”
 - “Predictability” replaces *Graham*’s amorphous standard

Principles from *KSR*

- “Obvious to try” may show obviousness
 - “a finite number of identified, *predictable* solutions”
 - “a person of ordinary skill has *good reason* to pursue the known options”
- Summary Judgment can be proper
- Applying foregoing SCT reverses SJ denial
 - “A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.”

Contrasting Case Examples

- *Aventis Pharma*, 2007 WL 2593791 (Fed. Cir. 2007) — drug composition “substantially free of other isomers” obvious over 102(g) art of same drug with the other isomers because:
 - **Techniques** to isolate and purify the prior art drug composition to remove the other isomers were **known in the art** (i.e., capability)
 - Known in the art that a purer form of the drug product would likely produce greater therapeutic benefits (i.e., benefit to make the modification)
- *Forest Labs.*, 2007 WL 2482122 (Fed. Cir. 2007) — substantially pure form of a drug product *not* obvious in view of prior art reference theorizing the pure form of the drug product because:
 - **Not known** how to purify the drug product (reference was not enabling, others had tried and failed, and the technique needed to purify was a “new and unpredictable technique”)
- *PharmaStem*, 491 F.3d at 1363-64 — confirming what was theorized in the prior art obvious where inventors “merely used routine research methods to prove what was already believed to be the case”

Case Examples – Capability

- Low threshold to show apparent reason to combine where capability is present
 - *Leapfrog*, 480 F.3d at 1162 (“to gain the commonly understood benefits” of modern technology)
 - *Translogic*, 2007 WL 2965979, *9 (“value of using a known element”)
 - *Trans Texas*, 498 F.3d 1290, 2007 WL 237709, *8 (to employ well-known technology and achieve a predictable result)

“Obvious to Try” at the CAFC

- *KSR* – finite number of predictable possibilities + reason to try
- *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1365-67 (Fed. Cir.) (rev’g not obvious), *denying en banc reh’g*, 488 F.3d 1377 (Fed. Cir. 2007)
 - Using a different salt form in a pharmaceutical compound to achieve optimal manufacturing characteristics was “obvious to try” where
 - Prior art suggested using the particular salt form (FDA had approved its use)
 - There were *not* “numerous parameters” to try
 - There was a reasonable expectation of success

“Obvious to Try” at the CAFC

- *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359-60 (Fed. Cir. 2007) (aff’g not obvious)
 - replacing a methyl group with an ethyl group and putting the ethyl group in a different ring position was not “obvious to try” where
 - Prior art did not “identify predictable solutions”
 - Starting prior art composition was toxic and there was no reasonable expectation of success a non-toxic compound could be made from it
 - Prior art identified over 90 other non-toxic compounds that could have been used as a starting compound

“Obvious to Try” in the DCTs

- Number of possibilities key factor
 - Not obvious to try where there were thousands of possibilities
 - *Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353, 388, 391-92 (S.D.N.Y. June 19, 2007)
 - *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 532-34 (S.D.N.Y. May 31, 2007)
 - Obvious to try where there were only a few possibilities
 - *Novartis Pharm. Corp. v. Teva Pharm. USA, Inc.*, 2007 WL 2669338, *6-*8 (D.N.J. Sept. 6, 2007)
 - *Altana Phama AG v. Teva Pharm. USA, Inc.*, 2007 WL 2688917, *10 (D.N.J. Sept. 6, 2007)
 - *Ex parte Kubin*, 83 USPQ2d 1410, 1414 (Bd.Pat.App. & Interf. May 31, 2007) (*precedential*)

Secondary Considerations

- Must be given due consideration
 - *In re Sullivan*, 498 F.3d 1345, 2007 WL 2433841, *6
- No Federal Circuit cases yet where secondary considerations overcame an otherwise strong showing of obviousness
 - *PharmaStem*, 491 F.3d at 1365 (finding obvious despite peer-recognition)
 - *Leapfrog*, 485 F.3d at 1162 (obvious despite showing of commercial success, long-felt need and praise)
 - *Pfizer*, 480 F.3d at 1372 (unexpected results, if shown, would not trump the “clear case” of obviousness)

As Evidence to Rebut “Apparent Reason” or Predictability

- Secondary considerations used to show there was **no apparent reason** to combine or that combination was **not a predictable variation** of the prior art
 - *Forest Labs.*, 2007 WL 2482122, *2-*3,*6 (**failure of others** showed no reasonable expectation of success)
 - *Takeda*, 492 F.3d at 1357-63 (closest prior art was toxic, i.e., **taught away**)
 - *Eaton Corp.*, 2007 WL 2901692, *6 (E.D. Mich. Oct. 4, 2007) (*Eaton IV*) (patentee’s evidence of **long-felt need** compared to accused infringer’s “**common sense**” argument precluded SJ on apparent reason to combine)
 - *Eaton Corp.*, 2007 WL 2738811, *4 (E.D. Mich. Sept. 19, 2007) (*Eaton II*) (**conflicting teachings** in the prior art, i.e. “teaching away,” precluded SJ of invalidity)

Unofficial Judicial Statistics

- As of Oct. 15, 2007, approximately 51 reported post-*KSR* opinions substantively addressing obviousness (See Presenter for Case Appendix)
 - **17** favorable rulings for patentee
 - **34** favorable rulings for the challenger
- Board of Patent Appeals in the PTO issued 3 “Precedential” Opinions all affirming obviousness rejections.

CAFC Obviousness Statistics

- 16 CAFC cases substantively considering obviousness under *KSR*
- **4** had a ruling or instruction favorable to the patentee – (25%)
 - 3** – Affirming nonobviousness finding – (*Forest Labs, Takeda Chem., Verizon**)
 - 0** – Reversing or vacating obviousness finding
 - 1** – Reversing or vacating PTO rejection for obviousness – (*Sullivan*)

CAFC Obviousness Statistics

- **12** cases with a ruling or instruction favorable to the challenger – (75%)
 - 3** – Affirming obviousness – (*Leapfrog, Frazier, Syngenta*)
 - 5** – Reversing or vacating nonobviousness– (*PharmaStem, Aventis, OmegaFlex, Daiichi, Pfizer (en banc denial)*)
 - 4** – Affirming PTO rejection for obviousness – (*Trans Tech, Icon Health, Translogic, Comiskey**)

DCT Obviousness Statistics

- **35** DCT cases considering substantively an obviousness challenge
- **13** – DCT cases with a ruling favorable to the patentee – (37%)
 - 5** – Denying JMOL or motion for new trial to overturn verdict not invalid for obviousness – (*Lucent Tech.*, *Muniauction*, *Stryker Trauma*, *Sanofi-Synthelabo*, *Omeprazole Litig.*)

DCT Obviousness Statistics

- 1 – Granting JMOL overturning jury verdict for obviousness – (*Sundance*)
- 6 – Denying accused infringer SJ on obviousness – (*Eaton Corp. IV, Timeline, Eaton Corp. II, Boston Scientific, Baden Sports, Caponey*)
- 1 – Refusing to stay preliminary injunction – (*Abbott Labs*)

DCT Obviousness Statistics

- **22** – DCT cases with a ruling favorable to the accused infringer – (63%)
 - 4** – Verdict of invalidity for obviousness – (*Levenger*, *TradeCard*, *AdvanceMe*, *McNeil-PPC*)
 - 11** – Finding claim obvious on SJ or JMOL* – (*Sud-Chemie*, *PBI Performance*, *Craig*, *Asyst**, *Andersen Corp.*, *Friskit*, *Single Chip*, *Semiconductor Energy*, *Hamilton Prods.*, *Eaton I*, *Eaton III*)
 - 6** – Denying PI substantial question on obviousness – (*Altana Pharma*, *Novartis Pharm.*, *MMJK*, *Pass & Seymour*, *Andersen Mfg.*, *Titan Tire**)
 - 1** – Denying permanent injunction – (*MercExchange*)

By Technology

	Unfavorable to Patent	Favorable to Patent
Bio-Pharm/ Chemical	5 – CAFC 1 – bench trial 2 – PI denial Total = 8	3 – CAFC 2 – bench trial 1 – refusing to stay PI Total = 6
Electrical/ Computer	4 – CAFC ; 1 – bench trial 3 – granting SJ invalid 1 – JMOL invalid 1 – deny patentee JMOL 2 – PI denial 1 – Perm. Inj. Denial Total = 13	1 – CAFC (no analysis) 1 – denying accused infringer SJ 2 – denying infringer’s post trial motion Total = 4
Mechanical	3 – CAFC; 1 – bench trial 7 – granting SJ invalid 1 – PI denial Total = 12	5 – denying accused infringer SJ 1 – denying infringer JMOL 1 – granting patentee JMOL Total = 7

Observations for Challengers

- Obviousness is now a robust defense for accused infringers
- DCTs willing to grant SJ invalidating claims for obviousness (10 / 16 / 35)
- Obviousness defenses can defeat motions for Preliminary Injunctions
- Claims are more likely to be invalidated if they pertain to the predictable arts, i.e., electrical and mechanical
- Secondary considerations, while still relevant, appear to carry less weight

Observations for Patentees

- Understand that a flexible analysis now applies
- Make challengers prove the “apparent reason” to combine (See *Eaton IV*) and that the “reason” is not “*ex post* hindsight”
- Factors that may tend to negate an “apparent reason”
 - Too many possibilities to try
 - Physical impossibility to combine prior art (even by making modifications that would occur to a PHOSITA)
 - Prior art does not enable PHOSITA to make the combination
 - Others failed in trying to make the claimed invention
 - Conflicting teachings in the prior art
 - One of skill would be driven to try something else

Observations for Patentees

- To sustain patent when all elements in the prior art try to show claimed invention was *not* predictable
 - No reasonable expectation of success
 - Many of the factors for challenging the “apparent reason” to combine may also apply to challenging predictability
 - Too many possibilities to try
 - Physical impossibility to combine prior art
 - Prior art does not enable PHOSITA to make the combination
 - Failure of others
 - Conflicting teachings in the prior art
 - Secondary consideration of unexpected results and long felt need as evidence against predictability
- Base arguments on *claimed* elements
 - Unpredictability of unclaimed features irrelevant – *Icon Health*

Questions

Thank you! I hope you enjoyed the presentation.

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