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
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
  - Obvious to try where there were only a few possibilities
Secondary Considerations

• Must be given due consideration

• 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)
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 affirmg 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)*


  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

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<tr>
<th>Technology</th>
<th>Unfavorable to Patent</th>
<th>Favorable to Patent</th>
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| 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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