Outline of Recent Trends

• Introduction to Obviousness
  – 35 U.S.C. § 103
  – *Graham v. John Deere Co.*
  – TSM
  – *KSR*

• Empirical Analysis
  – Federal Circuit Appeals
    • District Court
    • PTO

• Revival of Secondary Considerations
A patent is invalid as obvious "if the differences between the subject matter sought to be patented 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." 35 U.S.C. §103(a).
Framework for Obviousness

  - Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined.

*Secondary considerations* as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries may have relevancy.
Graham Factors

1) Scope and Content
2) Differences
3) Level and Skill
4) Secondary Considerations
Teaching, Suggestion, Motivation (TSM)

• Obviousness is a hindsight determination
  – TSM intended to reduce hindsight effect

• TSM required “clear and particular” or “express” teaching, suggestion, or motivation to combine reference to arrive at the claimed invention

• Pertains to the first three *Graham* factors
  – Secondary considerations truly secondary

- Rejected any rigid application of TSM
- Emphasized common sense
  - “If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability.”
- No clarification regarding the role of secondary considerations
Application of Obviousness Analysis

- **Federal Circuit:**
  - 1/2012 to 10/2013
  - 49 Precedential Decisions
  - From District Court: 36 (74%)
  - From USPTO: 13 (26%)

<table>
<thead>
<tr>
<th>Field</th>
<th>Number of Cases (DCT)</th>
<th>% of DCT Cases</th>
<th>Number of Cases (PTO)</th>
<th>% of PTO Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>ChemBio Pharm</td>
<td>17</td>
<td>46%</td>
<td>5</td>
<td>38%</td>
</tr>
<tr>
<td>Electrical / High-Tech</td>
<td>7</td>
<td>19%</td>
<td>4</td>
<td>31%</td>
</tr>
<tr>
<td>Mechanical</td>
<td>12</td>
<td>32%</td>
<td>4</td>
<td>31%</td>
</tr>
</tbody>
</table>
Fed. Cir. Obviousness Holdings

District Court Appeals

- Valid: 67%
- Invalid: 33%

PTO Appeals

- Valid: 25%
- Invalid: 75%
District Court Reversal at the Fed. Cir.

- DCT Affirmed: 59%
- DCT Reversed / Vacated / Remanded: 41%
Mechanical Patents Are the Most Obvious

Fed. Cir. Holdings from D.Ct. Data Set

- Mechanical: 47%
- ChemBioPharm: 38%
- Electrical/High-Tech: 15%
Value of Secondary Considerations

  - **Secondary considerations** as commercial success, long felt but unsolved needs, failure of others, etc., *might be utilized* to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or non-obviousness, these inquiries *may have relevancy*.

- **Post-KSR**
  - Initial Federal Circuit decisions were dismissive of secondary considerations
  - If prima facie obviousness established, then secondary considerations were insufficient
    - Usually relied on a lack of nexus
Revival of Secondary Considerations

- Secondary considerations can trump a prima facie case

  - Pipe handling system for offshore drilling
  - Reversed JMOL of obviousness despite earlier Fed. Cir. panel finding prior art established *prima facie* obviousness
  - District Court erred by discounting “compelling [objective] evidence of non-obviousness”
  - Fed. Cir. considered: commercial success; industry praise; unexpected results; copying; industry skepticism; licensing; long-felt need.
Revival of Secondary Considerations

- Secondary considerations “can protect against the prejudice of hindsight bias”
  - Improved power supplies for electronic devices
  - Court found that difference with the prior art (removal of EPROM memory) was *prima facie* obvious
  - But jury was presented with secondary consideration evidence
    - Long felt need – 11 years to solution
    - Unexpected benefits - prior art was more expensive
    - Commercial success due to patented features
  - Secondary considerations overcame prima facie case to support jury verdict that claims were not obvious
Revival of Secondary Considerations

• **Reversible error to decide obviousness without considering secondary considerations**

  - Cheese making vat with internally rotating panels
  - Affirmed SJ of validity
  - Obviousness arguments based on improper hindsight

  “Where a court holds a claim obvious without making findings of secondary considerations, the lack of specific consideration of secondary considerations *ordinarily requires a remand.*”
Revival of Secondary Considerations

- **Part of Prima Facie Case, i.e. Primary Considerations?**
  - Formulation having a certain pharmacokinetic profile
  - Appeal from bench trial holding obvious
  - The district court *erred*, however, by making its finding that the patents in suit were *obvious before it considered the objective considerations* and by shifting the burden of persuasion to Cephalon.
  - It was not until after the district court found the asserted claims obvious that it proceeded to analyze the objective considerations, or what it called the “secondary consideration.”
Revival of Secondary Considerations

• **Secondary Considerations are “Critical”**

• *Leo Pharm. Prods., Ltd. v. Rea* (August 12, 2013 Fed. Cir.)
  
  – Overcoming stability issues for a formulation of two known drugs
  
  – Appeal from obviousness holding during *inter partes* reexamination
  
  – “Whether before the Board or a court, this court has emphasized that consideration of the objective indicia is *part of* the whole obviousness analysis, not just an afterthought.”
  
  – “Objective indicia of non-obviousness play a critical role in the obviousness analysis.”
  
  – Fed. Cir. found unexpected results, commercial success, and long felt need
    
    • Even considered FDA approval
Revival of Secondary Considerations

• Secondary considerations failed to overcome “a strong case of obviousness”

• *WM. Wrigley Jr. Co. v. Cadbury Adams USA LLC* (June 22, 2012 Fed. Cir.)
  
  – Composition responsible for the cooling sensation in chewing gum
  
  – Appeal from MSJ of obviousness
  
  – Insufficient nexus with secondary considerations
    
    • Too many differences for unexpected results comparison
    
    • Commercial success came from marketing efforts
    
    • Failed to establish nexus between copying and claimed invention
Practical Implications

• **Client Practice/Opinion**
  - Secondary considerations must be evaluated with obviousness analysis
    - No longer combine references and dismiss secondary considerations
  - Secondary considerations should be more helpful during prosecution
    - But unlikely to change result at Federal Circuit

• **Litigation**
  - Secondary considerations deserve early role in strategy
    - Hire experts early, shape discovery, etc.
  - Build evidence demonstrating indicia of non-obviousness
  - Attack nexus in defense
Practical Implications (Cont.)

• Factual bases for secondary considerations overlap

  – The Fed. Cir. generally engages in holistic analysis on secondary considerations

• Commendations carry great weight

• Tout your patented features

• Market surveys for consumer demand

• Discriminatory licensing

  – Evidence of market premium attributed to patented feature