Developments in Non-Obviousness

Duke Patent Law Institute
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Presented by
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AIA AMENDS 35 U.S.C. §103:
CHANGE EFFECTIVE MARCH 16, 2013

- **OLD**: A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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.

- **NEW**: A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.
<table>
<thead>
<tr>
<th>PRE-AIA §103</th>
<th>NEW §103</th>
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<tr>
<td>• Applicable to claims with effective filing dates before March 16, 2013.</td>
<td>• Applicable to claims with effective filing dates on or after March 16, 2013, including JMM claims.</td>
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<td>• Pre-AIA §102 definitions of prior art.</td>
<td>• New §102 definitions of prior art.</td>
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GRAHAM V. JOHN DEERE


“[if] the difference between the subject matter sought to be patented and the prior art… would have been obvious at the time to a person skilled in the art, then the subject matter cannot be patented.”

Satisfying §103 is legal question with factual underpinnings:

- the scope and content of the prior art;
- differences between the prior art and the claims at issue; and
- the level of ordinary skill in the pertinent art.

And “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., … may have relevancy.”
EVALUATION OF OBVIOUSNESS

- Use of known elements for known function to yield expected results.
  - Look for evidence of unexpected benefit or result (e.g., synergism).

- Finite v. very large number of possibilities.

- Look for teachings away or disincentive to make a modification to arrive at claimed invention, particularly in mechanical and electrical (so-called predictable arts).

- Obviousness requires motivation, rationale for change and reasonable expectation of success.
USPTO GUIDELINES: COMBINING PRIOR ART ELEMENTS

- Post-KSR cases have held such combinations to be nonobvious “when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings.”

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<tr>
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<tr>
<td>In re Omeprazole Patent Litigation</td>
<td>536 F.3d 1361 (Fed. Cir. 2008)</td>
<td>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.</td>
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<tr>
<td>Crocs Inc. v. International Trade Commission</td>
<td>598 F.3d 1294 (Fed. Cir. 2010)</td>
<td>“[M]erely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness.”</td>
</tr>
<tr>
<td>Sundance Inc. v. DeMonte Fabricating Ltd.</td>
<td>550 F.3d 1356 (Fed. Cir. 2008)</td>
<td>A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination and the combination yields more than predictable results.</td>
</tr>
<tr>
<td>Ecolab Inc. v. FMC Corp.</td>
<td>569 F.3d 1335 (Fed. Cir. 2009)</td>
<td>A combination of known elements would have been prima facie obvious if an ordinarily skilled artisan would have recognized an apparent reason to combine those elements and would have known how to do so.</td>
</tr>
<tr>
<td>Wyers v. Master Lock Co.</td>
<td>No. 2009-1412—F.3d-- (Fed. Cir. July 22, 2010)</td>
<td>The scope of analogous art is to be construed broadly and includes references that are reasonably pertinent to the problem that the inventor was trying to solve. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.</td>
</tr>
<tr>
<td>DePuy Spine Inc. v. Medtronic Sofamor Danek Inc.</td>
<td>567 F.3d 1314 (Fed. Cir. 2009)</td>
<td>Predictability as discussed in KSR encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose. An inference that a claimed combination would not have been obvious is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.</td>
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USPTO GUIDELINES: SUBSTITUTING ONE KNOWN ELEMENT FOR ANOTHER

- “applies when the claimed invention can be viewed as resulting from substituting a known element for an element of a prior art invention”

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<td>In re ICON Health &amp; Fitness Inc.</td>
<td>496 F.3d 1374 (Fed. Cir. 2007)</td>
<td>When determining whether a reference in a different field of endeavor may be used to support a case of obviousness (i.e., is analogous), it is necessary to consider the problem to be solved.</td>
</tr>
<tr>
<td>Agrizap v. Woodstream</td>
<td>520 F.3d 1337 (Fed. Cir. 2008)</td>
<td>Analogous art is not limited to references in the field of endeavor of the invention, but also includes references that would have been recognized by those of ordinary skill in the art as useful for applicant’s purpose.</td>
</tr>
<tr>
<td>Muniauction Inc. v. Thomson Corp.</td>
<td>532 F.3d 1318 (Fed. Cir. 2008)</td>
<td>Because Internet and Web browser technologies had become commonplace for communicating and displaying information, it would have been obvious to adapt existing processes to incorporate them for those functions.</td>
</tr>
<tr>
<td>Aventis Pharma Deutschland v. Lupin Ltd.</td>
<td>499 F.3d 1293 (Fed. Cir. 2007)</td>
<td>A chemical compound would have been obvious over a mixture containing that compound as well as other compounds where it was known or the skilled artisan had reason to believe that some desirable property of the mixture was derived in whole or in part from the claimed compound, and separating the claimed compound from the mixture was routine in the art.</td>
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<td>Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.</td>
<td>533 F.3d 1353 (Fed. Cir. 2008)</td>
<td>A claimed compound would not have been obvious where there was no reason to modify the closest prior art lead compound to obtain the claimed compound and the prior art taught that modifying the lead compound would destroy its advantageous property. Any known compound may serve as a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.</td>
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<tr>
<td>Procter &amp; Gamble Co. v. Teva Pharmaceuticals USA Inc.</td>
<td>566 F.3d 989 (Fed. Cir. 2009)</td>
<td>It is not necessary to select a single compound as a “lead compound” in order to support an obviousness rejection. However, where there was reason to select and modify the lead compound to obtain the claimed compound, but no reasonable expectation of success, the claimed compound would not have been obvious.</td>
</tr>
<tr>
<td>Altana Pharma AG v. Teva Pharmaceuticals USA Inc.</td>
<td>566 F.3d 999 (Fed. Cir. 2009)</td>
<td>Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify a prior art lead compound in a particular way to produce the claimed compound. It is not necessary for the reasoning to be explicitly found in the prior art of record, nor is it necessary for the prior art to point to only a single lead compound.</td>
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USPTO GUIDELINES: OBVIOUS TO TRY

- Applies when "there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success."

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<td>In re Kubin</td>
<td>561 F.3d 1351 (Fed. Cir. 2009)</td>
<td>A claimed polynucleotide would have been obvious over the known protein that it encodes where the skilled artisan would have had a reasonable expectation of success in deriving the claimed polynucleotide using standard biochemical techniques, and the skilled artisan would have had a reason to try to isolate the claimed polynucleotide. KSR applies to all technologies, rather than just the “predictable” arts.</td>
</tr>
<tr>
<td>Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.</td>
<td>492 F.3d 1350 (Fed. Cir. 2007)</td>
<td>A claimed compound would not have been obvious where it was not obvious to try to obtain it from a broad range of compounds, any one of which could have been selected as the lead compound for further investigation, and the prior art taught away from using a particular lead compound, and there was no predictability or reasonable expectation of success in making the particular modifications necessary to transform the lead compound into the claimed compound.</td>
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<tr>
<td>Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.</td>
<td>520 F.3d 1358 (Fed. Cir. 2008)</td>
<td>Where the claimed anti-convulsant drug had been discovered somewhat serendipitously in the course of research aimed at finding a new anti-diabetic drug, it would not have been obvious to try to obtain a claimed compound where the prior art did not present a finite and easily traversed number of potential starting compounds, and there was no apparent reason for selecting a particular starting compound from among a number of unpredictable alternatives.</td>
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<tr>
<td>Bayer Schering Pharma A.G. v. Barr Laboratories Inc.</td>
<td>575 F.3d 1341 (Fed. Cir. 2009)</td>
<td>A claimed compound would have been obvious where it was obvious to try to obtain it from a finite and easily traversed number of options that was narrowed down from a larger set of possibilities by the prior art, and the outcome of obtaining the claimed compound was reasonably predictable.</td>
</tr>
<tr>
<td>Sanofi-Synthelabo v. Apotex Inc.</td>
<td>550 F.3d 1075 (Fed. Cir. 2008)</td>
<td>A claimed isolated stereoisomer would not have been obvious where the claimed stereoisomer exhibits unexpectedly strong therapeutic advantages over the prior art racemic mixture without the correspondingly expected toxicity, and the resulting properties of the enantiomers separated from the racemic mixture were unpredictable.</td>
</tr>
<tr>
<td>Rolls-Royce PLC v. United Technologies Corp.</td>
<td>603 F.3d 1325 (Fed. Cir. 2010)</td>
<td>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.</td>
</tr>
<tr>
<td>Perfect Web Technologies Inc. v. InfoUSA Inc.</td>
<td>587 F.3d 1324, 1328-29 (Fed. Cir. 2009)</td>
<td>Where there were a finite number of identified, predictable solutions and there is no evidence of unexpected results, an obvious to try inquiry may properly lead to a legal conclusion of obviousness. Common sense may be used to support a legal conclusion of obviousness so long as it is explained with sufficient reasoning.</td>
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**USPTO GUIDELINES: CONSIDERATION OF EVIDENCE**

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<td>PharmaStem Therapeutics Inc. v.</td>
<td>491 F.3d 1342 (Fed. Cir. 2007)</td>
<td>Even though all evidence must be considered in an obviousness analysis, evidence of nonobviousness may be outweighed by contradictory evidence in the record or by what is in the specification. Although a reasonable expectation of success is needed to support a case of obviousness, absolute predictability is not required.</td>
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<tr>
<td>Viacell Inc.</td>
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<td>In re Sullivan</td>
<td>498 F.3d 1345 (Fed. Cir. 2007)</td>
<td>All evidence, including evidence rebutting a prima facie case of obviousness, must be considered when properly presented.</td>
</tr>
<tr>
<td>Hearing Components Inc. v. Shure</td>
<td>600 F.3d 1357 (Fed. Cir. 2010)</td>
<td>Evidence that has been properly presented in a timely manner must be considered on the record. Evidence of commercial success is pertinent where a nexus between the success of the product and the claimed invention has been demonstrated.</td>
</tr>
<tr>
<td>Inc. v. Shure Inc.</td>
<td></td>
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<tr>
<td>Asyst Technologies Inc. v. Emtrak</td>
<td>544 F.3d 1310 (Fed. Cir. 2008)</td>
<td>Evidence of secondary considerations of obviousness such as commercial success and long-felt need may be insufficient to overcome a prima facie case of obviousness if the prima facie case is strong. An argument for nonobviousness based on commercial success or long-felt need is undermined when there is a failure to link the commercial success or long-felt need to a claimed feature that distinguishes over the prior art.</td>
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</table>
THE USPTO IS NOT LAS VEGAS!

You can improve your odds!!

FINNEGAN
HOW?

- Study the post-KSR “lead compound” cases from the Federal Circuit, and use the rationale to argue against obviousness arguments from the US PTO (or opposing parties in litigation!) in all technologies.
Example: the US PTO examines the claims, then, by hindsight, picks the closest prior art. The examiner states that a prima facie case of obviousness has been made, and you now have to show unexpected results to overcome the rejection.

What do you do?

Use the Federal Circuit “no lead compound” case law, no matter what technology!
“LEAD COMPOUND” CASE LAW

- The “lead compound” cases have strong origins in drug patent litigations involving patent claims covering active ingredients of drug products approved by US FDA.

- Why do those cases have to be limited to drug active ingredient claims?
Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075 (Fed. Cir. 2008)

Was clopidogrel bisulfate (brand name Plavix®) obvious in view of its known racemate (mixture of the approved clopidogrel and its mirror image)?

- District court bench trial: patent valid and enforceable.
  - “the wide range of possible outcomes and the relative unlikelihood that the resulting compound would exhibit the maximal increase in anti-platelet aggregation activity and the absence of neurotoxicity makes clopidogrel bisulfate non-obvious.”

  - Unexpected and unpredictable properties of clopidogrel.

“LEAD COMPOUND” CASE LAW
LESSONS FROM SANOFI

- **Multiple choices faced inventors** (80 acids as candidates for forming salts with basic drug compounds)

- **Unpredictable result when combining elements** (whether a pharmaceutically suitable crystalline salt will form from a particular acid-base combination is unpredictable)

- **Properties do not teach process** (“recognition that stereoisomers may exhibit different properties does not teach which results may ensue or how to separate any given enantiomers.”)
POST-KSR CASES:
PRIOR ART DID NOT INDICATE LEAD COMPOUND

• Show situation was not one with “a finite number of identified, predictable solutions”
  
  • See Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007), cert. denied, 128 S.Ct. 1739 (March 31, 2008)

• Show that nothing in prior art would “have led a person of ordinary skill in the art to identify [X] as the lead” prior art or motivated such person to make the specific modifications to X to make invention.

  • See Procter & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989 (Fed. Cir. 2009)
    • Unpredictable nature; unique nature; no reasonable expectation [at time of the invention] of success.

  • See Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd., 619 F.3d 1346 (Fed. Cir. 2010), cert. denied, 131 S.Ct. 1678 (U.S. 2011)
KSR FRAMEWORK TO ANALYZE PRIOR ART

- Are there starting reference points “in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions”

- Does “the record up to the time of invention . . . give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed [invention]”

- Would one of ordinary skill in the art have a reason to narrow the prior art universe to a ‘finite number of identified, predictable solutions’”?

POST-KSR LIMITED CHOICE CASES ->
INVENTION HELD OBVIOUS

• One of 18 compounds in the prior art

  • Altana Pharma v. Teva, 566 F.3d 999 (Fed. Cir. 2009), but note: Altana suggests that the prior art must point to only a single lead compound for further development but that would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in KSR.

  • Note, however, Daiichi: “While the lead compound analysis must, in keeping with KSR, not rigidly focus on the selection of a single, best lead compound, see Altana Pharma, 566 F.3d at 1008, the analysis still requires the challenger to demonstrate by clear and convincing evidence that one of ordinary skill in the art would have had a reason to select a proposed lead compound or compounds over other compounds in the prior art.”
POST-KSR LIMITED CHOICE CASES -> INVENTION HELD OBVIOUS

• POSITA faced choice between limited options
  • Bayer Schering Pharma AG v. Barr Laboratories, Inc., 575 F.3d 1341 (Fed. Cir. 2009), cert. denied, 130 S.Ct. 2404 (U.S. 2010)
  • “motivation to modify a prior art reference to arrive at the claimed invention need not be the same motivation that the patentee had”
    • Alcon Research, Ltd. v. Apotex, 687 F.3d 1362 (Fed. Cir. 2012)
  • motivation to develop product, reasonable expectation of success
    • Allergan v. Sandoz, --F.3d__ (Fed. Cir. May 1, 2013)
  • “express motivation to combine those disclosures in the prior art.”
    • Bayer Healthcare Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc., --F.3d__ (Fed. Cir. April 16, 2013)
NO PRIMA FACIE CASE BECAUSE NO REASON TO MODIFY PRIOR ART STARTING POINT

- Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc., 655 F.3d 1291 (Fed. Cir. 2011)
  - DC: dismissed GI’s action for no “interference in fact.”
  - FC: Affirmed.

- No p.f. obviousness for the claimed proteins because of the failure of the challenger to “identif[y] some reason that would have prompted a researcher to modify the prior art compounds in a particular manner to arrive at the claimed compounds.”.
  - “. . . every property of a claimed compound need not be fully recognized as of the filing date.”

- Relied upon Takeda (Fed. Cir. 2007) and Dillon (Fed. Cir. 1990)(en banc).
DEVIATIONS FROM “COMMONSENSICAL PATH” SUGGEST NONOVBVIOUSNESS


  – Federal Circuit affirmed nonobviousness

  “when design need and market pressure may dictate a commonsensical path using a finite number of identified predictable solutions to one of ordinary skill, deviations from that path are likely products of innovation.”
PRE-AIA: “AT THE TIME OF THE INVENTION” CANNOT PICK LEAD COMPOUND IN HINDSIGHT

- Federal Circuit: “is the possession of promising useful properties…that motivates [an inventor] …. Yet the attribution of [art as lead prior art] after the fact must avoid hindsight bias; it must look at the state of the art at the time the invention was made to find a motivation to select and then modify [the lead prior art] to arrive at the claimed invention.” (Daiichi)
HINDSIGHT REASONING IMPERMISSIBLE


– Two-part inquiry

1. Would one of ordinary skill have selected the asserted prior art as the best candidate(s), or most promising starting point(s), for further development efforts?

2. Would the prior art have supplied one of ordinary skill in the art with a reason or motivation to modify the lead prior art to make the claimed invention with a reasonable expectation of success?

– Not simply obvious to try. See In re Brimonidine Patent Litigation, 643 F.3d 1366 (Fed. Cir. 2011), cert. denied (March 26, 2012)

— “Kubin stated that KSR ‘resurrects’ the Federal Circuit’s own wisdom in O’Farrell, in which ‘to differentiate between proper and improper applications of ‘obvious to try,’ ’ the Federal Circuit ‘outlined two classes of situations where ‘obvious to try’ is erroneously equated with obviousness under §103.’ In re Kubin, 561 F.3d 1351, 1359 (Fed. Cir. 2009). These two classes of situations are:
KSR USPTO GUIDELINES (con’t)

- (1) When what would have been ‘obvious to try’ would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; and

- (2) when what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. Id. (citing O’Farrell, 853 F.2d at 903).”
USPTO AFTER KSR

- Ex Parte SUBRAMANYAM (BPAI March 29, 2010)
  - Rejected claim: toothpaste with antibacterial effective amount of compound I.
  - Would an ordinary artisan have chosen tetrahydrohonokiol out of all of the polyols found in the plant extracts disclosed by the prior art?
  - Board: Reversed rejection.
    - “structural similarity, alone, however, is insufficient to establish a prima facie case of obviousness, as there must be some reason that would have led the ordinary artisan to the compound required by the claims. The Examiner, however, has not provided any evidence or any reason as to why the ordinary artisan would have picked tetrahydrohonokiol out of all of the polyols found in the plant extracts disclosed by Ning as a lead compound.”
USE RATIONALE

- Is there a reasoned identification of a lead candidate in the prior art? Or might multiple candidates be possible?
  - Must be more than an unsupported assertion.

- Any reason a skilled artisan would have considered modification of the prior art and expected the invention as an identifiable, predictable solution?
Example: the US PTO examines the claims, then, by hindsight, picks the closest prior art. The examiner states that a prima facie case of obviousness has been made, and you now have to show unexpected results to overcome the rejection.
USE YOUR AMMUNITION!

- Conclusion: It is unacceptable for USPTO to pick closest prior art in hindsight.

- Use “no lead compound” rationale to attack rejection.

- No acceptable reasoning for picking applied prior art out of “scope and content of the prior art.” Graham v. John Deere.

- Not “lead prior art.”

- Therefore, extrapolate to all technologies.
POST-KSR “LEAD PRIOR ART”

• For further discussion of the “lead prior art” analysis in obviousness determinations, see articles by Carlos M. Tellez, David J. Martens, Carla Mouta, Stacy D. Lewis, and Thomas L. Irving:


WHICH CHART DO YOU PREFER?

All other Technologies

- 25, 69% (Non-obvious)
- 11, 31% (Obvious)

Pharma/Med Device/Biotech

- 20, 69% (Non-obvious)
- 9, 31% (Obvious)

TAKE-AWAY POINTS

- The Federal Circuit has broadly applied KSR
- **KSR** most significantly impacts factually similar cases
  - Inventions combining known elements yielding predictable results.
  - Finite number of identified, predictable solutions (obvious to try).
- Obviousness may be avoided when
  - Prior art missing one or more claim elements
  - High level of unpredictability
  - Prior art teaches away
  - Prior art is vague or suggests many possible choices with little guidance toward the claimed invention
  - Unexpected results
SIGNIFICANT CHANGE IN PERSON OF ORDINARY SKILL IN THE ART

- Pre-KSR, not creative
  - “is presumed to be aware of all the pertinent prior art” in an obviousness analysis. … “is also presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which.” Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

- Post-KSR, creative
  - “The person of ordinary skill in the art has creativity, and uses common sense, and therefore the legal standard of obviousness should not diminish these attributes. A demonstration of an express teaching, suggestion or motivation is not required to show obviousness…. A person of ordinary skill is also a person of ordinary creativity, not an automaton.” USSC, KSR.
ARGUING NO PRIMA FACIE CASE OF OBVIOUSNESS

- No reasonable expectation of success.
- Argue lack of predictability (i.e. invention not “predictable”).
- Teaching away
- Prior art (particularly file history) may support lack of predictability argument(s) and teaching away arguments.
- Consider level of ordinary skill in art evidence; what was the direction of the art as a whole? Remember duty of candor.
- Consider arguing missing claim limitations.
ARGUING NO PRIMA FACIE CASE OF OBVIOUSNESS (con’t)

- If non-obviousness works for genus, works for dependent claims directed to subgenus and species.

- See, MPEP 2142-2144.04

- Advocate no need to show surprising or unexpected properties because properties are irrelevant if no prima facie case of obviousness established.

- And make sure that allowance is based on post-KSR.
Consider submitting comparative data—i.e. determine closest prior art, and compare against it.

But better yet: defeat prima face case by showing unpredictability

Property or result not “predictable.”

Unpredictability commensurate in scope.

- Consider interview with examiner to agree on testing compounds.

Commercial success: commensurate in scope and nexus with the claimed invention: harder for genus.
REBUTTING PRIMA FACIE CASE OF OBVIOUSNESS

- Watch out for duty of candor (Rule 56); Danger: inconsistent, non-disclosed data.

- Watch out for effect on enablement, even if not legally correct.
  - Consider claiming species in a continuation.
  - If species not claimed, consider narrowing reissue.

- If can’t rescue genus, try techniques for subgenus/species.
  - Commercial success may be easier, particularly for species.
  - Nexus: was success because of marketing?
- Post-KSR Prosecution: Still best to destroy, rather than rebut, a prima facie case of obviousness.

- Attacking premise of rejection rather than amending claim important in view of prosecution history estoppel and litigation implications.
POST-KSR STRATEGIES: APPLICATION DRAFTING

“Don’t give away the farm!” Consider this from KSR:

“One of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.”

Don’t give away “starting point” prior art from which one could argue a POSITA may identify a problem and pursue potential solutions.

Avoid “problems” in the Background

− KSR allows a connection between the stated “problem” and a skilled person motivated by that problem to find an “obvious to try” solution

Note: Applicant may have discovered a “problem” that differs from any problems suggested by the prior art.
POST-KSR STRATEGIES:
PROSECUTION

- Hold the Examiner to requirements:
  - “There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

- Argue against combination:
  - Not combinable by known methods
  - Elements in combination do not perform the function that each performs separately (not predictable)
POST-KSR STRATEGIES: PROSECUTION

- Unpredictability can be important: show that invention was not predictable.
  - Show no reasonable expectation of success.
  - Show there was not a “finite number of identified, predictable solutions.”
  - Show unexpected results
  - Other objective indicia of nonobviousnes?

- Show teaching away, particularly in so-called predictable results.

- Showing lack of predictability or expectation of success may require submitting data and/or declarations earlier in prosecution; evidence to destroy, not rebut, the prima facie case.

- Interview Examiner!
POST-KSR STRATEGIES FOR PRE-KSR PATENTS

- Chance that important pre-KSR patents will be attacked.

- Review those patents **BEFORE** litigation/listing and consider options:
  - Everything look good?
    - Support for “no finite number of predictable solutions with anticipated success”?
  - File petition for reexamination? reissue? continuation?
  - Effective filing date before or after March 16, 2013?
ANALOGOUS ART

- In re Klein, 647 F.3d 1343 (Fed. Cir. 2011)
  - Board: Upheld rejection of claims as obvious.
  - FC: Reversed.

  - “A reference qualifies as prior art for an obviousness determination under §103 only when it is analogous to the claimed invention.”
    - Test from Clay: same field of endeavor or “reasonably pertinent.”

  - Correctly identified problem the inventor faced, but invalidating references were directed to different problem; no finding of fact as to why a POSITA would look to those references to solve the problem faced by the inventor.
TEMPERATURE AND CONCENTRATION LIMITATIONS

- Used to be that overlap with a prior art range triggered prima facie case of obviousness, and burden shifted to applicant (Iron Grip Barbell Co., Inc. v. York Barbell Co., Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004)).

- Now, however, there is no automatic presumption, at least in litigation, and a claimed point in a prior art range is just one factor for the court to consider in its obviousness determination.

REBUTTAL EVIDENCE

- Unexpected results
  - Must compare to closest prior art.
  - Must compare to closest example within closest prior art.
  - Showing must be commensurate in scope with the claims.

- Objective indicia of unobviousness/secondary considerations
  - commercial success
  - long-felt need
  - failure by others
  - copying
  - teaching away
  - initial disbelief and subsequent acclaim by experts
Thank you.

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