



Isn't This Obvious?

Kevin Meek
Presentation To Austin IPLA
October 20, 2009

Obviousness Standard

- **35 U.S.C. 103 Conditions for patentability; non-obvious subject matter**

(a) A patent may not be obtained . . . , *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. . . .*

***KSR v. Teleflex* - General Effects**

- **USPTO**

- New Examiner Guidelines have encouraged Examiners to rely on attempted reasoning more and prior art less
- Increased BPAI Appeals
 - 4,639 in 2007
 - 6,385 in 2008
 - Projected 15,500 in 2009

- **Courts**

- Increased number of claims found obvious
 - Up to 49% in 2008 from 39% in 2000-2004

***KSR v. Teleflex* - General Effects**

“I have noticed that more examiners are simply stating that something is obvious or well-known in the art without providing a supporting reference or taking ‘Official Notice.’ In particular, I have recently seen several single reference obviousness rejections. Back when I was an examiner, this type of rejection was strongly discouraged.”

Former Patent Examiner

***KSR* Introduces a Flexible Test**

- **Pre-*KSR***

- “Teaching-Suggestion-Motivation” (“TSM”) Test
- Review of secondary considerations mandatory
- “Obvious To Try” does not constitute obviousness

- **Post-*KSR***

- TSM test was overly rigid and formalistic
- “Obvious To Try” may constitute obviousness
- Use of creativity & common sense
- Non-analogous art ok for references
- Relative strength of secondary considerations

"Obvious To Try" in the Courts in General

- **Post-*KSR* Cases' Focus**
 - Predictability of Solutions – Finite/Identifiable number of solutions
 - Predictability of Result - Are there any unexpected “bonus” features?
 - Neither factor is entirely independent of the other

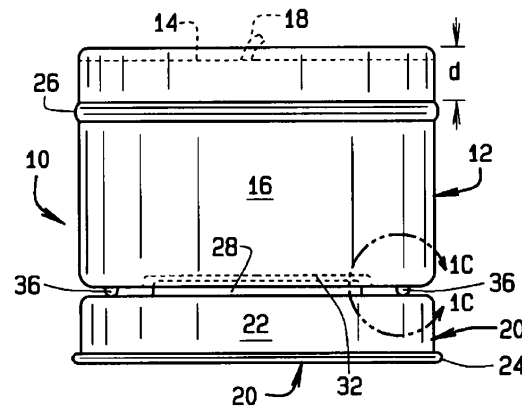
"Obvious To Try" in the Courts in General

- ***Ball Aerosol v. Limited Brands and Bath & Body Works*, 555 F.3d 984 (Fed. Cir. 2009)**
 - Problem
 - Tin candles scorching the surface they are placed on
 - Prior Art
 - Reference 1 - Placed feet at the bottom of the candle
 - Reference 2 - Cover doubled as a base
 - Alleged Invention
 - Placed feet at the bottom of the candle AND used a cover as a base
 - Issue
 - Was the feet/cover combination a variation that was obvious to try?

Downloaded from <http://ajph.org/> on November 10, 2015

"Obvious To Try" in the Courts in General

- ***Ball Aerosol* - Continued**
 - Holding – Obvious To Try
 - Finite/Identifiable Solutions – Feet and Cover
 - Predictable Result – No Scorching
 - The use of feet/cover combination to prevent scorching was "entirely predictable and grounded in common sense." *Ball*, 555 F.3d at 993.



"Obvious To Try" in the Courts in General

- ***In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009)**
 - Problem
 - Identifying the unknown DNA sequences of a known protein
 - Prior Art
 - Various methods to determine the DNA sequences of proteins
 - Alleged Invention
 - Specification stated that known methods could be used
 - Claimed a DNA sequence that was previously unknown
 - Issue
 - If it is obvious to try to obtain the claimed DNA sequences by known methods, are those sequences obvious?
 - The pre-*KSR* analysis was clear – The "knowledge of a protein does not give one a conception of a particular DNA encoding it." *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

"Obvious To Try" in the Courts in General

- ***In re Kubin* - Continued**

- Holding – Obvious

- Finite/Identifiable Solutions

- Known methods could be used to obtain the desired DNA sequence

- Predictable Result

- The known methods could obtain the previously unknown DNA sequence.
 - Even though the actual DNA sequence was unpredictable, the solution for identifying it was predictable.



"Obvious To Try" in the Courts in General

- ***In re Kubin* - Continued**

- “In light of the specific teachings . . . artisans in this field . . . had every motivation to seek and every reasonable expectation of success in achieving the sequence of the claimed invention.”

In re Kubin, 561 F.3d at 1361



"Obvious To Try" in the Courts in General

- ***Pfizer v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007)**
 - Problem
 - Improving the stability and handling of a hypertension drug (amlodipine)
 - Prior Art
 - 53 FDA approved anions used to improve stability and handling of drugs
 - Alleged Invention
 - Claimed a besylate salt created from combining amlodipine with one of the anions
 - Issue
 - Is the combination obvious since there are "only" 53 solutions to the problem?



"Obvious To Try" in the Courts in General

- *Pfizer* - Continued
 - Holding – Obvious
 - Finite/Identifiable Solutions
 - 53 anions available
 - Prior art narrowed it even more
 - Predictable Result
 - Amlodipine Besylate had improved stability and handling
 - Irrelevant that researchers could not have predicted which particular anion would create the best salt



"Obvious To Try" in the Courts in General

- **Pfizer - Continued**

- “Although we recognize some degree of unpredictability of salt formation, . . . the mere possibility that some salts may not form does not demand a conclusion that those that do are necessarily non-obvious.”

Pfizer, 480 F.3d at 1366



"Obvious To Try" in the Courts in General

- ***Sanofi v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008)**

- **Problem**

- Splitting an enantiomer attached to a drug to reduce the drug's toxicity while maintaining the drug's effectiveness

- **Prior Art Teachings**

- Reference 1 – Drug with a whole enantiomer
 - Chemists split whole enantiomers to determine if a split enantiomer would give a drug more favorable properties
 - Very rare to have an enantiomer that gives a drug all favorable properties without the drug having any significant toxicity
 - Enantiomers may be split using a technique developed by Louis Pasteur

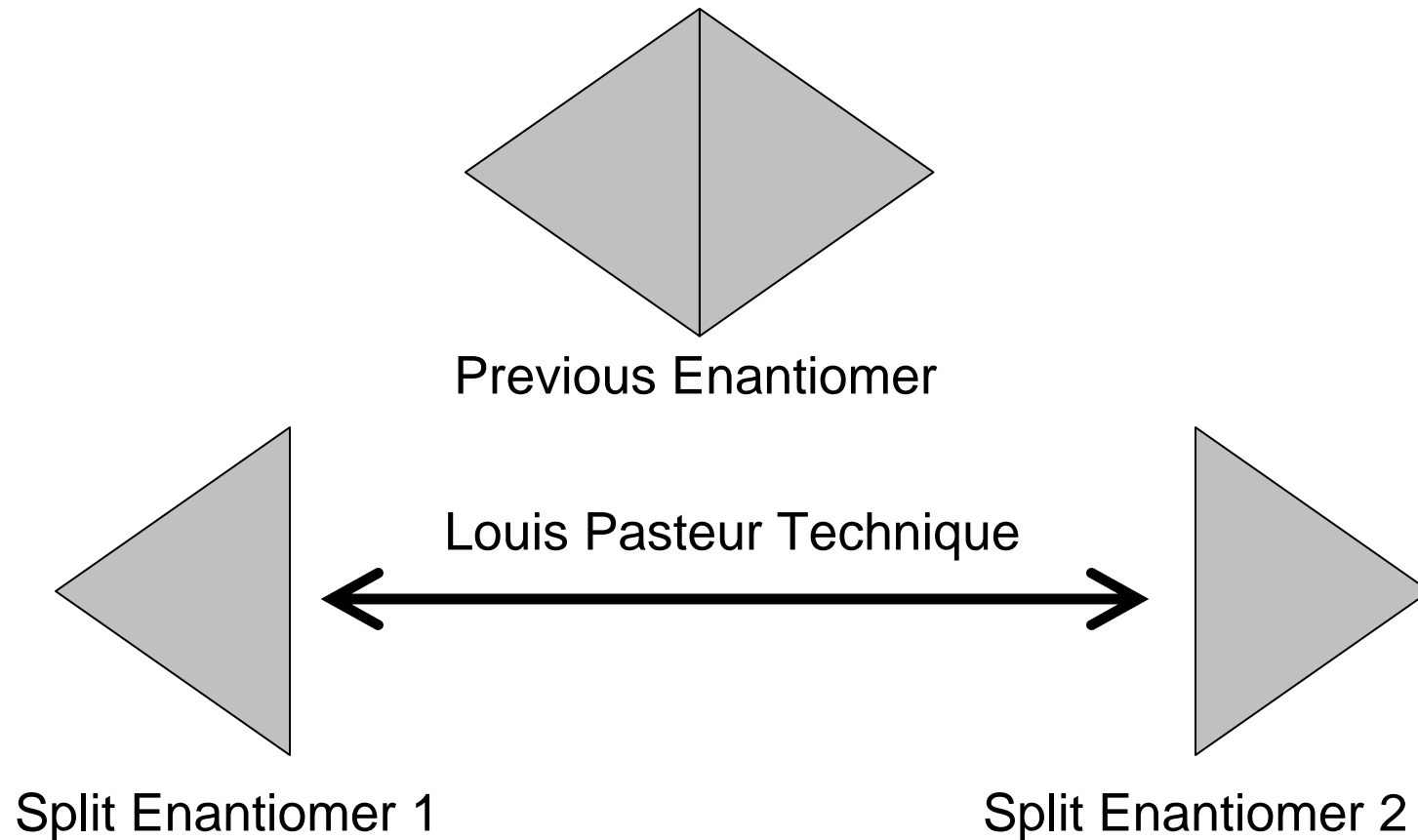
- **Alleged Invention**

- Claimed the same basic drug as Reference 1
 - Used a split enantiomer derived from the whole enantiomer
 - Split the enantiomer using the Pasteur technique
 - Drug had all the favorable properties without any toxicity issues

- **Issue**

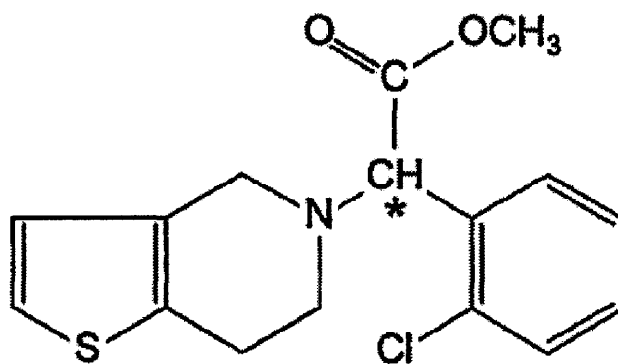
- Is the drug having the split enantiomer obvious?

"Obvious To Try" in the Courts in General



"Obvious To Try" in the Courts in General

- *Sanofi* - Continued
 - Holding – Not Obvious
 - No Finite Solutions
 - “Known” Pasteur technique required extensive experimentation to get the right recipe
 - Unpredictable Result
 - “Bonus” Feature – Drug with split enantiomer had all the beneficial properties with no significant toxicity problems

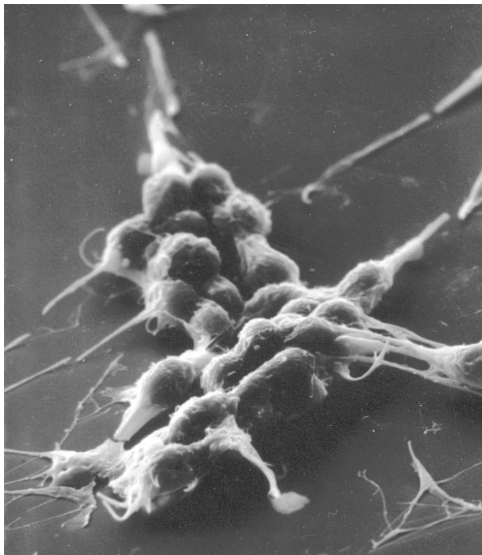


"Obvious To Try" in the Courts in General

- ***Sanofi* - Continued**

- “[A] person having ordinary skill would not have had the expectation that separating the enantiomers would be likely to produce an isomer having absolute stereoselectivity as to both the favorable antiplatelet activity and the unfavorable neurotoxicity.”

Sanofi, 550 F.3d at 1090

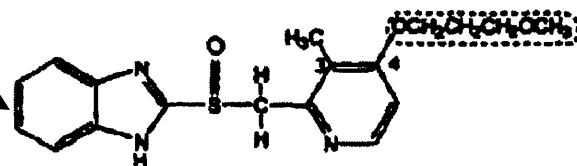


"Obvious To Try" in the Courts in General

- ***Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008)**
 - Problem
 - Developing a gastric acid inhibitor
 - Prior Art
 - Reference 1 - Anti-ulcer compound
 - Reference 2 - Acid inhibitor sharing the same core structure as the anti-ulcer compound
 - Alleged Invention
 - Claimed a new gastric acid inhibitor
 - Almost identical structure as the anti-ulcer compound
 - Issue
 - Was it obvious to begin with the anti-ulcer compound in developing an acid inhibitor?

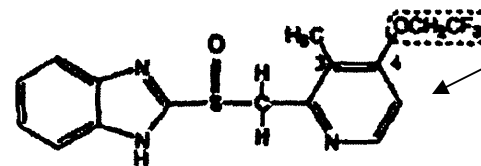
"Obvious To Try" in the Courts in General

New Acid Inhibitor



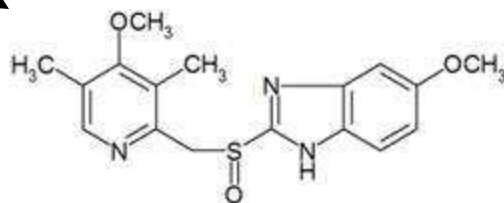
Rabeprazole

Anti-Ulcer Compound



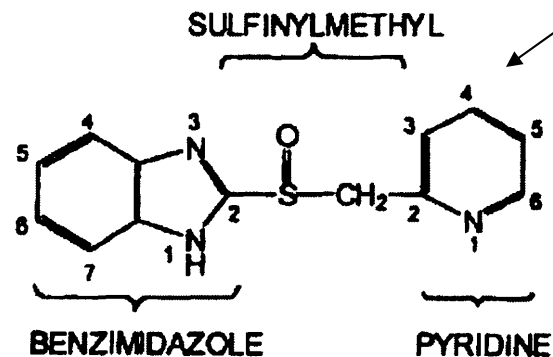
Lansoprazole

Old Acid Inhibitor



Omeprazole

Core Structure Shared by All 3



Brändström Core Structure

"Obvious To Try" in the Courts in General

- ***Eisai* - Continued**

- Holding – Not Obvious
 - No Finite/Identifiable Solutions
 - No prior art reason to modify an anti-ulcer drug to obtain an acid inhibitor
 - The almost identical chemical structure was irrelevant
 - Unpredictable Result
 - “Bonus” Feature – Anti-ulcer compound may be modified to obtain an acid inhibitor



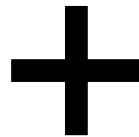
"Obvious To Try" in the Courts in General

- ***Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331 (Fed. Cir. 2009)**
 - Problem
 - Developing a golf ball that travels a long distance while maintaining playability
 - Prior Art
 - Reference 1 – 3 layer golf ball
 - Reference 2 – 2 layer golf ball
 - Polyurethane and ionomer blends used as cover materials
 - Discloses hardness limitations for the covers according to “Shore C” hardness
 - Alleged Invention
 - 3 layer golf ball
 - Polyurethane and ionomer blends used as cover materials
 - Discloses similar hardness limitations as Reference 2 for the covers, but according to “Shore D” hardness not “Shore C” hardness
 - Issue
 - Is the new, 3 layer golf ball an obvious variation?

"Obvious To Try" in the Courts in General



Polyurethane and
Ionomer Blend Covers
With Specific "Shore C"
Hardness



No Polyurethane &
Ionomer Blend Covers



Polyurethane and
Ionomer Blend Covers
With Specific "Shore D"
Hardness

Obvious To Try ?

"Obvious To Try" in the Courts in General

- **Callaway - Continued**

- Holding – Not Obvious

- No Finite/Identifiable Solutions

- Shore C hardness and Shore D hardness are difficult to compare

- Balls specifying Shore C shell hardness were 2 layer balls

- Shell hardness measurements can be affected by inner materials

- Unpredictable Result

- “Bonus” Feature – Alleged invention has the unexpected result of being a true dual personality ball

- Long distance AND no diminished playability



Avoiding The "Obvious To Try" Trap

- **Frame the Argument Regarding The Unpredictable Nature Of The Invention**
 - Make every effort to identify areas of unpredictability and highlight them.
 - Be very leery of attempting to broaden your disclosure by stating that "one of skill in the art could use routine methods to arrive at alternative embodiments."
 - In *Kubin*, the inclusion of such language undercut the fact that entirely new techniques were necessary to obtain the claimed nucleic acids
 - When combining well known arts, be as specific as possible about how the combinations are to be made.
 - *Sanofi* – Method of splitting particular enantiomer was very specific
 - *Callaway* – Golf ball had a specific "Shore D" hardness measurement

"Obvious To Try" in the USPTO

- **The USPTO issued more flexible Post-*KSR* Examination 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; The 'mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness.'"

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



"Obvious To Try" in the USPTO

- **Post-*KSR* Examination Guidelines continued**
 - The “obvious to try” guidelines are based on *Kubin* and other chemical or life sciences cases
 - Guidelines are sparse as to how particularly finite solutions must be identified and what establishes a reasonable expectation of success
 - Examiners are unsure what the guidelines mean
 - Examiner admitted that she did not understand how to apply the “obvious to try” guidelines

Non-Analogous Art

- **Non-Analogous Art Pre-*KSR***

- Rigid TSM analysis
 - Same Problem/Same Field



- **Non-Analogous Art Post-*KSR***

- Flexible Standard
 - Particular motivation and purpose does not control
 - Similar Problem/Similar Field



Non-Analogous Art

- ***Leapfrog Enterprises, Inc. v. Fisher Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007)**
 - Alleged Invention
 - Electronic reading device
 - Prior art
 - Mechanical reading device



Non-Analogous Art

- ***Leapfrog – Continued***

- Holding - Obvious

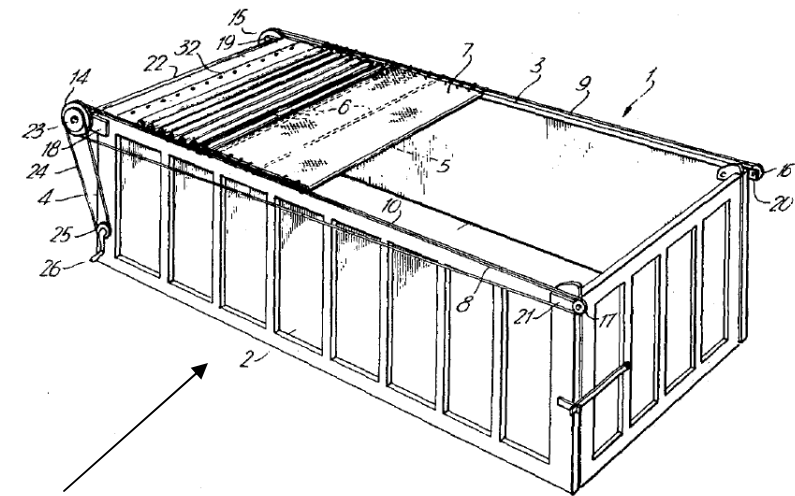
- Claims were held invalid as a mere application of electronics to an older mechanical system, which has become common now that processors are available and provide known benefits.
 - Reader added to device was also obvious because it was commonly added to toys



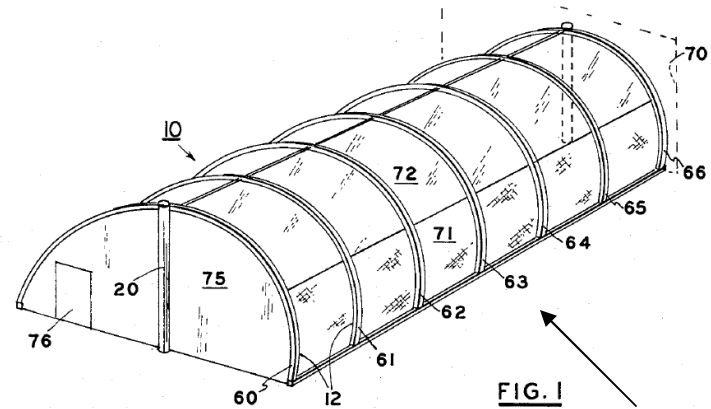
Non-Analogous Art

- **Sundance v. DeMonte Fabricating Ltd., 550 F.3d 1358 (Fed. Cir. 2008)**
 - Alleged Invention
 - Truck cover with removable sections
 - Prior Art
 - Reference 1 - Single piece truck cover
 - Reference 2 - Segmented pool cover with removable sections

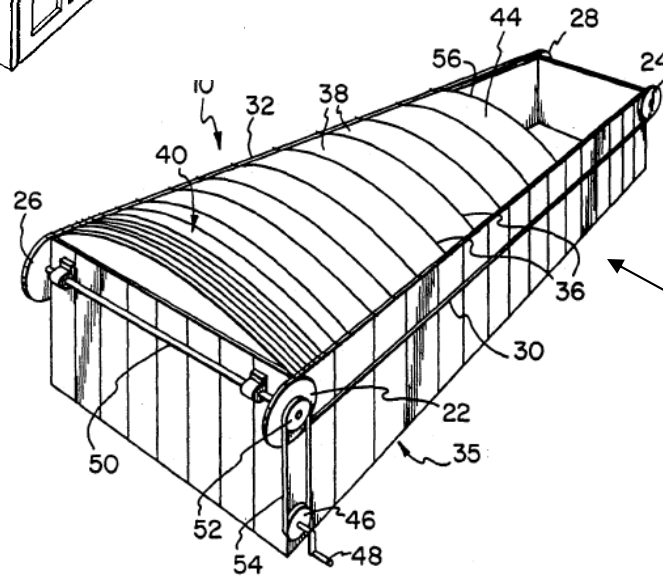
Non-Analogous Art



Single Piece Truck Cover



Segmented Pool Cover



Alleged Invention

Non-Analogous Art

- ***Sundance* - Continued**

- Holding – Obvious

- Mere application of the segmented cover technique to the one-piece truck cover
 - “Just as with the claim at issue in *KSR*, the segmented truck cover claimed in the ‘109 patent represents the ‘mere application of a known technique to a piece of prior art ready for the improvement.’ It would have been obvious to replace the one-piece cover in Cramaro with the segmented cover of Hall.”

Sundance, 550 F.3d at 1367 (quoting *KSR* 550 U.S. at 416)

Non-Analogous Art in the USPTO

- **USPTO Examination Guidelines also address non-analogous art situations**

“Known work in one field of endeavor may prompt variations of it for use in the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art.”

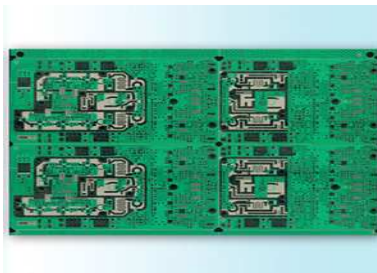
MPEP 2143



Non-Analogous Art in the USPTO

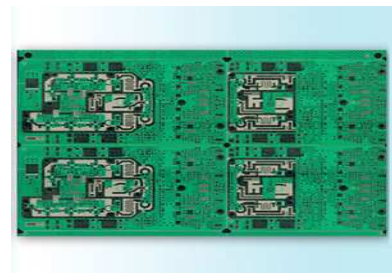
- “A person of ordinary skill is also a person of ordinary ***creativity***, not an automaton. . . . If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and ***common sense***.”

KSR, 550 U.S. at 421



Non-Analogous Art in the USPTO

- **Examiner rejected a patent application**
 - Reference A – circuit traces on a printed circuit board
 - Reference B – wireless microwave communication networks
 - Examiner asserted it was obvious to replace Reference A's circuit traces with Reference B's wireless capability
 - Pre-appeal panel re-opened for prosecution
 - Examiner no longer cites Reference A or Reference B
- **(Examiner) Creativity? – Yes**
- **(Examiner) Common Sense? - ???**



Secondary Considerations

- **Secondary Considerations Pre-KSR**
 - The traditional obviousness analysis requires the evaluation of objective indicia of non-obviousness.
 - Such objective indicia ("secondary considerations") include (but are not limited to):
 - Commercial success;
 - Long-felt but unresolved need;
 - Unexpected results;
 - Failure of others;
 - Skepticism of experts;
 - Teaching away by others; and
 - Praise and/or copying by others.
 - The role of secondary considerations is in part to guard against the use of impermissible hindsight.

Secondary Considerations



HINDSIGHT

Those really were the droids you were looking for.

Secondary Considerations

■ Secondary Considerations Post-*KSR*

- Evaluation of secondary considerations remains a mandatory aspect of any obviousness determination (*Sud Chemi v. Multisorb Tech*, 554 F.3d 1001, 1008 (Fed. Cir. 2009)).
- However, as *KSR* has increased the strength of *prima facie* obviousness (e.g., "obvious to try" and non-analogous art), secondary considerations need to be substantial.
 - "Secondary considerations of non-obviousness—considered here by the district court—simply cannot overcome this strong *prima facie* case of obviousness." *Sundance*, 550 F.3d at 1368.
 - "The minimal indications of commercial success argued by BASC do not outweigh the clear indication of obviousness apparent from the prior art." *Ball*, 555 F.3d at 994.

Secondary Considerations

- **Secondary Considerations Post-*KSR* - Continued**

- “Finally, we do not agree with Leapfrog that the court failed to give proper consideration to secondary considerations. The district court explicitly stated in its opinion that Leapfrog had provided substantial evidence of commercial success, praise, and long-felt need, but that, given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that claim 25 would have been obvious. We have no basis to disagree with the district court's conclusion.”

Leapfrog, 485 F.3d at 1162

- However, “unexpected results” carry significant weight in an “obvious to try” analysis.

Secondary Considerations in the USPTO

- The post-*KSR* Examination Guidelines indicate that Examiners must review secondary considerations when they are argued as a reason for non-obviousness.
 - Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." M.P.E.P. § 2145
- In general, the Examination Guidelines and Manual of Patent Examining Procedure do not provide substantial guidance for evaluating the persuasiveness of secondary considerations.
 - "The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966). " M.P.E.P. § 716.01(b)
- Secondary considerations are effectively introduced via evidence and declarations.
 - "Evidence traversing rejections, when timely presented, must be considered by the examiner whenever present." M.P.E.P. § 716.01

Other Post-*KSR* Obviousness Issues

- **Reexamination requests**
 - KSR provides valuable ammunition to requestor in suggesting a 103 rejection without a reference suggesting a combination or modification.
 - Federal Register, Vol. 72, No. 195, October 10, 2007 and M.P.E.P. 2143 provide example rationales that are sufficient to support an obviousness conclusion.
 - Opens up 103 art where not previously available.



Other Post-*KSR* Obviousness Issues

- **Reexamination requests continued – The MPEP 2143 list**
 - Combining prior art elements according to known methods to yield predictable results;
 - Simple substitution of one known element for another to obtain predictable results;
 - Use of known techniques to improve similar devices (methods, or products) in the same way;
 - Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
 - "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
 - Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and
 - Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference teachings to arrive at the claimed invention.

Other Post-*KSR* Obviousness Issues

- **Confusion in the District Courts**
 - Recent Case
 - Proposed jury instructions sought to teach the jury obviousness post-*KSR*
 - Obviousness consideration need not be limited by same problem, same elements, or the same field
 - Final Jury Instructions
 - Maintained the pre-*KSR* same problem/same field standard

Conclusions

- ***KSR* Has Set the Stage for More Restrictive Obviousness Analysis During Prosecution & Litigation.**
 - Applicants who frame their inventions correctly will be in a better position to fend off such attacks.
 - Applicants who focus on secondary considerations and establish the proper nexus will be in a better position to fend off such attacks.

