

Obviousness Standard for Patents

Approaches to Withstand USPTO Obviousness Rejections and Attacks on Patent Validity

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Today's faculty features:

Paul Davis, Partner, **Goodwin Procter**, Menlo Park, Calif.

Scott J. Szala, Partner, **Winston & Strawn**, Chicago

Thomas L. Irving, Partner, **Finnegan Henderson Farabow Garrett & Dunner**, Washington, D.C.

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***THE FEDERAL
CIRCUIT'S EVOLVING
OBVIOUSNESS
ANALYSIS***

Paul Davis

Partner

PDavis@goodwinprocter.com

650.752.3106 (Menlo Park)

858.202.2700 (San Diego)

THE FEDERAL CIRCUIT'S EVOLVING OBVIOUSNESS ANALYSIS

- The Federal Circuit continues to take some of the bite out of the Supreme Court's KSR decision (*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)) that broadened the basis for determining that patent claims are obvious by, among other things, avoiding overly rigorous application of the TSM (teaching, suggestion, motivation) test.

NEED A TITLE

Unigene Labs. and Upsher-Smith Labs. v. Apotex (Fed. Cir. August 25, 2011)

- The Federal Circuit continued to develop law on obviousness in view of KSR.
- In the chemical arts, the court tends to apply a modified TSM analysis.
- The Federal Circuit held that use of 20 mM citric acid as an absorption-enhancing agent and surfactant in a nasal spray composition was not obvious.

NEED A TITLE

- The Federal Circuit acknowledged that *KSR* broadly held that the motivation to combine references.
 1. The court uses a “reference composition” for the first time in looking at obviousness of a formulation.
- The court broadens its use in the chemical and medical fields.
 2. The purpose of citric acid is not identified in the claim, although it was defined during prosecution as being significant.
- This opinion can serve as a reminder that reciting the purpose or advantage is not required in the claim.
 3. In its prior art analysis, the court takes a hard look for a suggestion, motivation or teaching to combine references.
- The court recognized that the desire to create a formulation that is bioequivalent to an existing formulation provides motivation to develop new formulations.

Motivation to Combine

Wyers v. Master Lock Co., 616 F.3d 1231 (Fed. Cir. 2010)

- In *Wyers* the Federal Circuit found that even in the absence of expert testimony, judges can make a common sense determination to combine the prior art to find patent claims obvious and thus invalid.
- On February 22, 2011, the Supreme Court declined to grant *Wyers*' petition for a writ of *certiorari*.
- The Federal Circuit reversed, holding that it was a matter of common sense to combine the prior art under *KSR* as a matter of law.

Motivation to Combine (cont)

- The Federal Circuit addressed three primary issues:
 1. Whether the prior art references were within the same field of endeavor;
 2. Whether there was a motivation to combine the prior art references, and
 3. Whether secondary considerations existed and were significant.
- Judge Linn concurred, and wrote separately.

Motivation to Combine (cont)

- In *Tokai Corp. v. Easton Enterprises, Inc.*,—F.3d—, 2011 WL 308370 (Fed. Cir. 2011)
- In *Tokai* the Federal Circuit again affirmed a grant of summary judgment in the trial court which found the patents-in-suit to be invalid as obvious.
- Tokai's March 3, 2011 petition for panel rehearing and rehearing *en banc* is currently pending as of this writing.
- Tokai's patents related to safety utility lighters with extended lighting rods, used for barbecue grills, for example.
- The district court declined to consider Tokai's expert declarations granted Easton's motion for summary judgment and concluded that the patents were invalid as obvious, based on the *Graham* factors because Tokai failed to submit written reports during discovery, thereby failing to give Easton an opportunity to depose the experts.

The Federal Circuit's Decision

- The panel issued a split decision affirming the court below.
- Judge Lourie stated that courts “may find a motivation to combine prior art references in the nature of the problem to be solved.”
- The Court relied on Tokai’s admission “the components required to assemble the claimed inventions are “simple mechanical parts that are well known in the art.””
- Judge Newman, disagreeing with the majority that the invention was the result of combining previously existing inventions, described Tokai’s utility rod lighter as “ingenious,” “having a novel safety mechanism that achieves a new level of child-safety over the prior art.”

Impact of Wyers and Tokai

- These decisions support a summary judgment strategy for invalidity claims in three ways:
 1. By making it easier to find a motivation to combine;
 2. By not requiring expert testimony to establish a motivation to combine and,
 3. In cases where a strong *prima facie* case of obviousness is established, by making it difficult for secondary considerations to save the patents.
- *Wyers* provides federal judges with some confidence to invalidate patents using common sense as the motivation to combine prior art references.
- *Tokai* makes it more challenging for a simple mechanical patent to withstand an obviousness challenge.
- In *Tokai*, the Federal Circuit may have been influenced by the simplicity of the invention.

Impact of Wyers and Tokai (cont)

- *In re Klein* reversed the Patent Office's rejection of a hummingbird nectar mixer based on non-analogous art.
- The Court found that the five references were inappropriately used by the Patent Office because they were not analogous art and therefore not prior art under [§103](#).
- The Court noted that “[a] reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention.”
- There are two separate tests for determining what defines the scope of analogous art:
 - “Whether the art is from the same field of endeavor, regardless of the problem addressed” and;
 - “If the reference is not within the field of the inventor’s endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.”
- The Court reversed the Patent Office’s finding of obviousness and remanded for further consideration.

NEED A TITLE

Western Union Co. v. MoneyGram Payment Systems, Inc., Nos. 10-1080, -1210 (Fed. Cir. Dec. 7, 2010)

- The Federal Circuit reversed the jury's determination that the patents-in-suit were not invalid for obviousness.
- At trial, a jury determined that MoneyGram's original and redesigned systems infringed Western Union's money transfer patents.
- On appeal, the Federal Circuit first considered the district court's denial of MoneyGram's renewed motion for JMOL.
- The Federal Circuit turned next to the merits of MoneyGram's obviousness argument.
- The Court agreed with MoneyGram that the money transfer patents are obvious.

NEED A TITLE (cont)

- The Federal Circuit concluded that, based on this evidence, no reasonable jury should have found that MoneyGram failed to present sufficient evidence to demonstrate that electronic transaction devices were commonplace in the art at the time of the invention.
- The Court specifically concluded that it would not have been difficult at the time of the invention for a person of ordinary skill in the art to integrate an electronic transaction device that was available from Western Union itself into a well-known money transfer system that was also owned by Western Union.
- The Court then addressed whether the use of a code as part of a formless money transfer was obvious.
- Finally, the Court concluded that the district court erred in its heavy reliance on secondary considerations in denying MoneyGram's JMOL of obviousness.
- The Federal Circuit reminded that the patentee must establish a nexus between evidence of commercial success and the patented invention.



Applying the USPTO Examination Guidelines in Patent Prosecutions *Post-KSR*

Scott Szala
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5875
sszala@winston.com

KSR Int'l Inc. v. Teleflex, Inc., 550 U.S. 398 (2007)

- Pre-*KSR*, the courts considered the teaching, suggestion, and motivation ("TSM") test in determining "obviousness." 35 U.S.C §103.
- In *KSR*, the Supreme Court rejected an obviousness analysis that was limited to using the TSM test in an "overly rigid and formalistic way."
- *KSR* reaffirmed the use of the *Graham v. John Deere Co.*, 383 U.S. 1 (1966) factors to determine obviousness, including: (1) the scope and content of prior art; (2) the differences between the claimed invention and prior art; and (3) the level of ordinary skill in the art.
- Post-*KSR*, the courts consider obviousness based upon the predictability of the invention and whether a person of ordinary skill in the art ("POSITA") would reasonably expect to arrive successfully at the claimed invention based upon the teachings of the prior art references.

Sources of Information Regarding "Obviousness"

- 35 U.S.C. 103
- www.uspto.gov
- Manual of Patent Examining Procedures (MPEP) (8th ed. 2001, revised July 2010), 2141
- 72 Fed. Reg. 57526 (10/10/07)
- 75 Fed. Reg. 53643 (9/1/10)
- 324 OG (11/6/07)
- 1358 OG (9/28/10)
- Karen Canaan, Canaan Law, P.C., Menlo Park, CA (1/12/11 Strafford Seminar)

Post-*KSR* Examination

- *Post-KSR Changes To USPTO Obviousness Examinations*
 - The TSM standard no longer controls.
 - Examination of prior art searches is not limited to the problem sought to be solved by the invention.
 - The USPTO performs obviousness examinations under its seven (7) post-*KSR* promulgated guidelines (Guidelines A to G).
 - Common sense and creativity will be considered.
 - "Teaching away" from the invention will be considered.
 - Unexpected results and extraordinary skill will be considered.
 - Non-analogous art in other fields will be considered.
 - "Obvious-to-try" is now a valid ground for a rejection.

PTO OFFICE ACTION

- When considering the first *Graham* factor -- determining the scope and content of prior art -- the PTO reviews the specifications and claims and understands what the applicant actually invented. The content of prior art is determined at the time of the invention was made to avoid hindsight. Analogous prior art from a different field will be considered.
- As to the second *Graham* factor, the PTO ascertains the difference between the claimed invention and the prior art. The claimed invention is generally to be viewed as a whole, but can be distilled down to the "gist" or "thrust" to avoid the general rule. Prior art must be considered in its entirety, including that which "teaches away."
- When considering the third factor -- resolving the level of ordinary skill in the art -- the PTO considers: the types of problems encountered in the art; prior art solutions to those problems; the rapidity in which the invention was made; the sophistication of the technology; and the educational level of active workers in the field. Ascertaining the level of ordinary skill is necessary to maintain objectivity.

Examination Guideline A (2007): "Combinations"

- Obviousness can be found by combining prior art elements according to known methods to yield predictable results:
 - If the *Graham* factors so indicate;
 - If all prior art of claimed elements, not in combination, must be collectively considered;
 - If a POSITA would have combined the claimed elements under the known methods and, if in combination, each element would have performed the same function as if performed separately; and
 - If a POSITA would have recognized the combination results as predictable is considered.
- Under the first guideline factor, the reasons why the POSITA would combine the elements in the way that the claimed new invention does should be explicitly stated. If the prior art "teaches away" from a combination, then nonobviousness is found.

Examination Guideline B: "Substitution"

- Simple substitution of one known element for another to obtain predictable results can render a patent obvious:
 - If the prior art contained a device (method, product, etc.), which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;
 - If the substituted components and their functions were known in the art;
 - It POSITA could have substituted one known element for another and the results of the substitution would have been predictable; and
 - If the *Graham* factors so indicate.
- The second examination guideline considers whether an element from a secondary reference is substituted into the teaching from the primary reference to determine obviousness, even where no suggestion in the latter exists.
- An obviousness finding only requires a reasonable expectation of successful, not an absolute predictability of success.

Examination Guideline C: "Similar Device Improvement"

- Use of a known technique to improve similar devices (methods or products) in the same way can result in obviousness.
 - If the prior art contained a "base" device (method or product) upon which the claimed invention can be seen as an "improvement;"
 - If the prior art contained a "comparable" device (method, or product that is not the same as the base device) that was improved in the same way as the claimed invention;
 - If the POSITA could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and
 - If the *Graham* factors so indicate.
- The third examination guideline whether the improvement relating to the invention is within the skill level of the POSITA. If the application of the technique is beyond the skill level of the POSITA, then the technique is not obvious.

Examination Guideline D: "Improvements"

- Applying a known technique to a known device (method or product) ready for improvement to yield predictable results will result in an obviousness finding:
 - If the *Graham* factors are met;
 - If the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement";
 - If the prior art contained a "known technique" that is applicable to the base device (method or product);
 - If a POSITA would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and
 - If any other relevant factors so indicate.
- The fourth examination guideline considers that if a particular recognized technique is recognized as part of the ordinary capabilities of a POSITA, obviousness can be found.

Examination Guideline E: "Obvious to Try"

- Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success will be deemed obvious:
 - If the *Graham factors are met*;
 - If at the time of the invention, a recognized problem or need in the art existed, which may have included a design need or market pressure to solve a problem;
 - If a finite number of identified, predictable potential solutions to the recognized need or problem existed;
 - If a POSITA could have pursued the known potential solutions with a reasonable expectation of success; and
 - If any other relevant factors so indicate.
- The fifth "obvious to try" examination guideline addresses whether a POSITA would have pursued the known options within his technical grasp. If this leads to anticipated success, then it is likely the product was not of innovation, but of ordinary skill and common sense. Thus, a combination that was "obvious to try" can be deemed obvious.
- The unpredictability of a procedure may be obviated when only a "finite" number of solutions to solve a problem exist and the testing of the solutions is within the skill level of a POSITA.

Examination Guideline F: "Analogous Fields"

- 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 a POSITA:
 - If the *Graham* factors are met;
 - If the scope and content of the prior art, whether in the same field of endeavor as that of the applicant's invention or a different field of endeavor, included a similar or analogous device (method or product);
 - If design incentives or market forces existed that would have prompted adaptation of the known device (method, or product);
 - If the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the art;
 - If a POSITA, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and
 - If any other relevant factors so indicate.
- The sixth examination guideline considers whether a POSITA would vary the prior art in a predictable manner to result in the claimed invention.

Examination Guideline G: "TSM"

- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention can result in an obviousness finding:
 - If the *Graham* factors are met;
 - If some TSM existed, either in the references themselves or in the knowledge generally available to a POSITA, to modify the references or to combine reference teachings;
 - If a reasonable expectation of success existed; and
 - If other relevant factors so indicate.
- The seventh examination guideline considers the use of the TSM test in obviousness determinations, and stresses that TSM must be flexible and that no explicit suggestion to combine is necessary.

Office Action Rejection And The Applicant's Reply and Rebuttal Evidence.

- If the PTO establishes the *Graham* factors and makes a *prima facie* case of obviousness, the burden then shifts to the applicant: (1) to show the PTO erred; or (2) to provide other evidence to show that the claimed subject matter is nonobvious. Mere arguments or conclusory statements will not meet the applicant's burden of proof. The applicant has a right to reply and to submit rebuttal evidence.
- Although the Guidelines are not dispositive, they carry substantial weight and the applicant should carefully review whether the Examiner properly applied the law and/or the appropriate Examination Guideline to the facts. The PTO is supposed to give a "reasoned explanation for every obviousness rejection."
- A proper response should address erroneous statements and citations and additional legal authorities, where appropriate, should be cited (e.g., evidence or case law addressing non-known problems, teaching away, unexpected results, hindsight reconstruction). Other responses included: a POSITA would not have combined the claimed elements by known methods; the combined elements do not perform the function that each element performs separately, and the results of the claimed combination were unexpected.

Unknown Problem – Examination Guideline A (2010)

- **In re Omeprazole Patent Litigation, 536 F.3d 1361 (Fed. Cir. 2008) (Example 4.1).**
- Although a general method could have been applied to make the claimed product known and was within the skill level of the POSITA, the claim was held to be nonobvious when the problem which had a suggested use of the method had been previously unknown.
- The applicant applied an enteric coating to the drug omeprazol to avoid having the bill disintegrate before reaching the intended site.
- Although the enteric coatings were known, the coating under prior art was interfering with the action of the drug.
- Federal Circuit affirmed the district court finding that the patent was nonobvious because the problem that the invention addressed was not previously known so there was no reason for a POSITA to add the enteric layer.

"Teaching Away"

Examination Guideline A

- **Crocs, Inc. v. U.S. International Trade Commission, 598 F.3d 1294 (Fed. Cir. 2010) (Example 4.2)**
- A claimed combination of prior art elements was nonobvious since the prior art teaches away from the claimed combination and the combination yielded no more than predictable results.
- The case involved Crocs footwear and its one-piece foam base for the top part of the shoe and a strap to provide Achilles' support on the lower portion of the shoe.
- The Federal Circuit reversed the finding of the International Trade Commission and held that the prior art taught against using foam as a material for the heel strap, so the results were not predictable, and thus, nonobvious.

Teaching Away 1 – Examination Guideline B

- **Eisai Co. Ltd. v. Dr. Reddy's Labs (Fed. Cir. 2008) (Example 4.11).**
- A claimed compound was nonobvious where no reason existed to modify the closest prior art lead compound to obtain the claimed compound and prior art taught that modifying it would destroy its advantageous property.
- Rabeprazole, a proton pump inhibitor for treating stomach ulcers and related disorders, was the product at issue.
- The Federal Circuit affirmed the district court grant of summary judgment that despite structural similarities of certain products, no reason existed for a POSITA to modify the lead compound.

Teaching Away 2 – Examination Guideline A

- **Example 4.6. DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314 (Fed. Cir. 2009) (Example 4.6).**
- Predictability as discussed in KSR encompasses the expectation the 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.
- The invention was a screw used in spinal surgeries that included a compression member for pressing a screw head against a receiver member.
- The Federal Circuit that prior art (Puno) taught away from the combination because a rigid screw increases the likelihood that the screw will fail within the human body rendering the device inoperative. Secondary considerations relating to the failure of others and copying also supported the finding that the combination was not obvious.

Ordinary, not Extraordinary Skill – Examination Guideline C

- Factors pertinent to the level of skill element of the *Graham* obviousness analysis include (1) educational level of the inventor, (2) type of problems encountered in the art, (3) prior art solutions to those problems, (4) rapidity with which innovations are made, (5) sophistication of the technology, and (6) education level of workers active in the field. *Environmental Design, Ltd. v. Union Oil Co. of Calif.* , 713 F.2d 693 (Fed. Cir. 1983).
- A person of ordinary skill in the art is "one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate ... " *Standard Oil Co. v. American Cyanamid Co.* , 774 F.2d 448 (Fed. Cir. 1985).
- "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. 398,421 (2007).

Common Knowledge Assertions – Examination Guideline D

- Where an Examiner chooses to take notice of facts beyond the record for the *prima facie* case, those facts must be "capable of such instant and unquestionable demonstration as to defy dispute." *In re Alhert*, 424 F.2d 1088, 1091 (CCPA 1970). It is not appropriate for an Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well-known are not capable of *instant and unquestionable demonstration as being well-known*. *Id.* Assertions of technical facts in esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *Id.*;

Not Obvious to Try 1 – Exam Guideline E

- **Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007) (Example 4.15).**
- A claimed compound was nonobvious because 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 because the prior art taught away from using a particular lead compound, since no predictability or reasonable expectation of success existed to make the particular modifications necessary to transform the lead compound into the claimed compound.
- The invention was Pioglitazone, a drug used in treatment of Type 2 diabetes.
- The Federal Circuit affirmed the district court's finding that no reason existed to select a specific compound as the lead compound from the scores of compounds identified in the prior patent art, especially since the prior art taught disadvantages and it was not obvious to try.

Not Obvious to Try 2 – Examination Guideline E

- **Rolls-Royce, PLC v. United Technologies Corp., 603 F.3d 1325 (Fed. Cir. 2010) (Example 4.19).**
- An obvious to try rationale is 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.
- The invention was a fan blade for jet engines that was modified.
- The Federal Circuit affirmed the district court and found the fan blade not obvious to try because the possible options for solving a problem must have been "known and finite." In this case, there was no suggestion in the prior art that changing the sweep angle would have addressed the issue of fan blade modification.

TSM: No Reasonable Expectation of Success – Examination Guideline G

- The rationale to support a conclusion that a claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." USPTO Examination Guidelines, 72 Fed. Reg. 195 (2007).
- "While absolute certainty is not necessary to establish a reasonable expectation of success . . . , there can be little better evidence negating an expectation of success than actual reports of failure." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339 (Fed. Cir. 2003).

Hindsight Reconstruction 1 – All Examination Guidelines

- An obviousness analysis that relies upon the applicant's disclosure rather than the prior art reference is improper as being based upon an impermissible hindsight reconstruction. *In re Deuel*, 51 F.3d 1551, 1558 (Fed. Cir. 1995).
- A single line in a prior art reference should not be taken out of context and relied upon with the benefit of hindsight. *Bausch & Lomb, Inc. v. Barnes-Hine/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986).
- Using the inventor's success as evidence that one of ordinary skill in the art would have reasonably expected success represents an impermissible use of hindsight. *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320 (Fed. Cir. 2000).
- The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

Hindsight Reconstruction 2 – All Exam Guidelines

- One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). (Exam Guidelines A).
- It is impermissible to engage in a hindsight reconstruction of the claimed invention by using the applicant's structure as a template and selecting elements from references to fill in the gaps. *In re Gorman*, 933 F.2d 892 (Fed. Cir. 1991). (Exam Guideline B).
- The combination of elements from nonanalogous sources, in a manner that reconstructs the applicants invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). (Exam Guideline F).
- A retrospective view of inherency is not a substitute for some teaching or suggestion that supports the selection and use of the various elements in the particular claimed combination. *In re Newell*, 891 F.2d 899 (Fed. Cir. 1989). (Exam Guideline G).
- Both the suggestion and the reasonable expectation of success “must be founded in the prior art, not in the applicant's disclosure.” *In re Vaeck*, 947 F.2d 488, 473 (Fed. Cir. 1991). (Exam Guideline G).

Closing Comments

- Although the Examination Guidelines regarding obviousness are not dispositive, they carry significant weight, and as such, the Office Action must be carefully reviewed to determine whether the guidelines were followed.
- Since an Office Action rejecting an application on obviousness grounds should be based on objective facts and legal analysis, if it is not, a valid basis for overturning the decision is possible.
- If the Office Action relies upon purported common knowledge or judicial notice, the PTO should be asked for the specifics underlying those conclusions or statements.
- An applicant's response and submission of rebuttal materials to an application rejected on obviousness grounds should be detailed and the appropriate Examination Guidelines and case law should be cited.
- Various responses exist including, for example, that the problem was not known, the prior art teaches away from the invention, and a POSITA would have no reasonable expectation of creating the invention from the prior art.
- "Protecting the record" in the Office Action is thus essential to reversing a finding of obviousness.

Obviousness Standard for Patents and USPTO Guidelines: Strategies to Withstand Obviousness Rejections and Attacks on Validity



**TOM IRVING
STACY LEWIS**

FINNEGAN

JANUARY 31, 2012

Select America Invents Act Effective Dates

Effective Date	AIA Provisions			
Sept. 16, 2011 (Date of enactment)	Best mode (Sec. 15) ("proceedings commenced on or after" September 16, 2011. "proceedings" = ?	Defense of Prior Commercial Use (Sec. 5) Prioritized Exam: Sept 26, 2011	Standard for inter partes reexam changes from SNQP to "reasonable likelihood" of prevailing	Marking (Sec. 16)
				Venue (Sec. 9)
Sept. 16, 2012 (1 year from date of enactment)	General catch-all ("unless otherwise provided" SEC. 35)	Inventor's oath, changes to 112 (joint inventor) (Sec. 4)	Technical amendments, includes changes to reissue statute (Sec. 20)	Business method patents (Sec. 18)
	Post-Grant Review and IPR (Sec. 6)(gradual implementation over 4 years).	Supplemental examination (Sec. 12)(applies to patents filed before, on, or after effective date)	Patent Trial and Appeal Board (Sec. 7), except jurisdiction over appeals of reexam decisions to CAFC take effect upon enactment	
March 16, 2013 (18 months from date of enactment)	First-inventor-to-file, new 102, amended 103, repeal of 104, derivation (Sec. 3)			

Obviousness (35 U.S.C. § 103)

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- New § 103:

- 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. Patentability shall not be negated by the manner in which the invention was made. **[see 125 STAT. 287]**

- ***Big change!! Old law was “at the time the invention was made”***

New Definition of Prior Art Under the AIA

44



- A public disclosure ANYWHERE in the world before the effective filing date of the claimed invention; **OR**



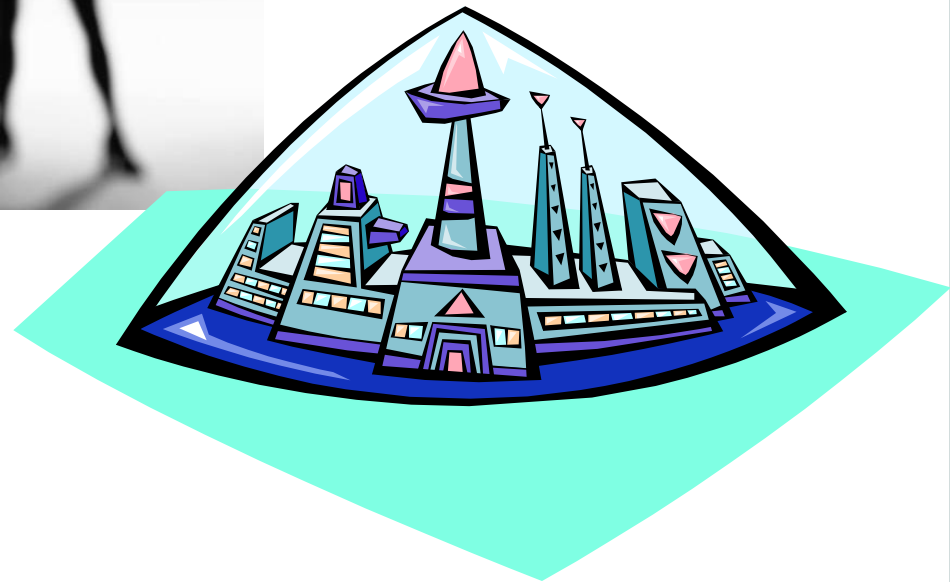
- Patent filing disclosures (in the U.S. or PCT designating the U.S.) that later become public, that name another inventor, and were effectively filed before the effective filing date of the claimed invention.

35 U.S.C. 102(a) (1) and (a)(2)[125 STAT. 285-286]

Patent Practitioners Need To Know BOTH OLD AND NEW LAW Until At Least March 15, 2034*

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** with patent term extension, to March 15, 2039!*



The US PTO Is Not Las Vegas!

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You can improve your odds!!

How?

47

- 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.



Let's Have A Look

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- 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

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- The “lead compound” cases have strong origins in drug patent litigations involving patent claims covering active ingredients of drug products approved by US FDA.
- Let us examine those cases.
- Why do those cases have to be limited to drug active ingredient claims?

Unexpected and Unpredictable -> Nonobvious

- Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075 (Fed. Cir. 2008), cert. denied, 130 S.Ct. 493 (U.S. 2009)
 - 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.”
 - Federal Circuit: Affirmed.
 - ✦ Unexpected and unpredictable properties of clopidogrel.

Unexpected and Unpredictable -> Nonobvious

- Sanofi (con't)
 - **Multiple choices faced inventors** (80 acids as candidates for forming salts with basic drug compounds) Mechanical? Electrical?
 - **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

• Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007), cert. denied, 128 S.Ct. 1739 (March 31, 2008)

- Prior art: A patent describing genus of millions of compounds
- Situation was not one with “a finite number of identified, predictable solutions”
- “Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation.”
- Basis for obviousness, prior art “compound b”, was not suggested to be best, and in fact, exhibited negative properties that would have directed one skilled in the art away from that compound.

Mechanical? Electrical?

Post-KSR Cases: Prior Art Did Not Indicate Lead Compound

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- Procter & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989 (Fed. Cir. 2009)
 - Claim: risedronate (osteoporosis drug Actonel®).
 - P&G's expired patent listed 36 polyphosphonate molecules as osteoporosis treatment candidates and 8 preferred compounds for intermittent dosing, including X (positional isomer of claimed risedronate).
 - District court: No evidence that the expired patent would “have led a person of ordinary skill in the art to identify [X] as the lead compound.”
 - ✦ Skilled artisan would not have been motivated to make the specific molecular modifications to X to make risedronate.

What Did P&G Show?

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- P&G (con't)
 - **Unpredictable nature** (“extremely unpredictable nature of bisphosphonates at the time of the invention”; “properties of bisphosphonates could not be anticipated based on their structure.”)
 - **Unique nature** (“every compound, while remaining a bisphosphonate, exhibits its own physical-chemical, biological and therapeutic characteristics, so that each bisphosphonate has to be considered on its own. To infer from one compound the effects in another is dangerous and can be misleading.”)
 - **No reasonable expectation [at time of the invention]** that risedronate would be a successful compound.
 - Unexpected results of risedronate's potency and toxicity and secondary considerations of non-obviousness.

Post-KSR Cases: Prior Art Did Not Indicate Lead Compound

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- P&G (con't)
 - Federal Circuit: Affirmed nonobviousness.
 - ✦ T-S-M test still useful if not rigidly applied.
 - ✦ “under KSR, ‘it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.’ Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1357 (Fed. Cir. 2007).”

Post-KSR Cases: Prior Art Did Not Indicate Lead Compound

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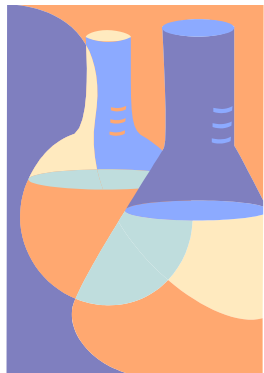
- P&G (con't)

- Federal Circuit: (con't)

- ✦ “An obviousness argument based on structural similarity between claimed and prior art compounds ‘clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [the prior art compound] as a lead compound.’”
- ✦ Teva argued prior art patent identified X as the most promising compound; District court disagreed; Federal Circuit declined to address, but said:
 - “even if [X] was a lead compound, the evidence does not establish that it would have been obvious to a person of ordinary skill at the time of the invention to modify [X] to create risedronate.”

Post-KSR Cases: Prior Art Did Not Indicate Lead Compound

- Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd., 619 F.3d 1346 (Fed. Cir. 2010), cert. denied, 131 S.Ct. 1678 (U.S. 2011)
- Federal Circuit: Affirmed nonobviousness.



- “We agree with Daiichi that the district court did not err in holding that Mylan failed to establish a *prima facie* case of obviousness. Specifically, we agree that Mylan failed to show that one of ordinary skill in the art would have been motivated to select the '902 ARBs as lead compounds or, even if they had, that the skilled artisan would have been motivated to modify the '902 compounds to synthesize olmesartan medoxomil, the claimed invention.”

Post-KSR Cases: Prior Art Did Not Indicate Lead Compound

- Daiichi (con't)
 - Federal Circuit: prior art suggested lead compound other than structurally closest compound.
 - “many of the latter ARBs demonstrated greater potency and all had been more thoroughly studied than the [claimed] ARBs.”
 - support from Takeda (“one of skill in the art would not have chosen the structurally closest prior art compound, compound b, as the lead compound in light of other compounds with more favorable characteristics.”)
 - “it is the possession of promising useful properties in a lead compound that motivates a chemist to make structurally similar compounds. Yet the attribution of a compound as a lead compound 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 a lead compound to arrive at the claimed invention.”

Must Prove Reason To Select Lead Compound

- Daiichi (con't)

- Federal Circuit:

- "Potent and promising activity in the prior art trumps mere structural relationships."

- "While the lead compound analysis must, in keeping with KSR, not rigidly focus on the selection of a single, best lead compound, ...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. "



Note: Mylan's petition for cert asked: "Whether, contrary to this Court's decision in KSR International Co. v. Teleflex Inc., 550 U.S. 398 (2007), the Federal Circuit has erred in applying a "lead compound test" as the exclusive standard for determining whether a patent claim directed to a new chemical compound is "obvious" and therefore invalid under 35 U.S.C. 103(a)." Supreme Court denied certiorari.

KSR Framework To Analyze Prior Art

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- Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir.), reh'g denied (2008)
 - Eisai patent claims rabeprazole and its salts, sold as ACIPHEX[®]
 - DC: Patents valid, enforceable, and infringed.

KSR Framework To Analyze Prior Art

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- Eisai (con't)

- Federal Circuit: Affirmed.

- ✦ KSR framework:

- 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 compound”?
 - “reasons for narrowing the prior art universe to a ‘finite number of identified, predictable solutions’”
- “this ‘easily traversed, small and finite number of alternatives . . . might support an inference of obviousness.’”

No Lead Compound

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- Eisai (con't)

- Federal Circuit (con't):

- ✦ “In other words, post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound.”
- ✦ Teva cannot create a genuine issue of material fact on obviousness through the unsupported assertion that compounds other than lansoprazole might have served as lead compounds.
- ✦ “The record contains no reasons a skilled artisan would have considered modification of lansoprazole ... as an identifiable, predictable solution.”

Post-KSR Cases: Inventors Faced Multiple Choices



• Ortho-McNeil Pharms. Inc. v. Mylan Labs., Inc., 520 F.3d 1358 (Fed. Cir. 2008)

- Patent claims the anticonvulsive drug topiramate nonobvious.
- Federal Circuit:

• “even if an ordinarily skilled artisan sought an FBPase inhibitor, that person would not have chosen topiramate. Moreover this invention, ... does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness.”

• Record shows that a person of ordinary skill would not even be likely to start with the compound that the inventor did.

• “the ordinarily skilled artisan would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate. Even beyond that, the ordinary artisan in this field would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes).”

See also, Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341 (Fed. Cir. 2008), *reh’g denied* (2009) and *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008), *cert. denied*, 129 S.Ct. 1593 (U.S. 2009)

Hindsight Reasoning "Always Inappropriate"



• Ortho-McNeil (con't)

• Federal Circuit:

- "In sum, this clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness."

- "Mylan's expert... simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious. Of course, this reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it " would have been obvious at the time the invention was made." 35 U.S.C. 103(a) (emphasis added). In retrospect, Dr. Maryanoff's pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of invention, the inventor's insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted." (emphasis added)

Post-KSR Cases: Obviousness Found

- Altana Pharma v. Teva, 566 F.3d 999 (Fed. Cir. 2009)

- Affirm denial of preliminary injunction.
- Claimed compound pantoprazole, the active ingredient in Altana's antiulcer drug Protonix[®].
- Prior art disclosed 18 compounds, including that compound 12 was one of the more potent.
- Pantoprazole exhibits structure very similar to one of the 18.
- Defendants argued that prior art compound 12 was the lead compound and pieced together a scientific story to modify that compound to achieve pantoprazole.
- FC: Obvious. One of skill in the art would have selected compound 12 as a lead compound for modification.

• *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*.

• See also Bayer Schering Pharma AG v. Barr Laboratories, Inc., 575 F.3d 1341 (Fed. Cir. 2009), cert. denied, 130 S.Ct. 2404 (U.S. 2010), for a "limited choice" case.

Altana Did Not Undermine Lead Prior Analysis

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- Daiichi (2010)
 - “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.”

No Prima Facie Case Because No Reason To Modify Prior Art Starting Point

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- 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).
 - ✦ Judge Dyk, dissenting: “unexpected properties must either be set forth in the specification or contemporaneously known to the inventors”

“Commonsensical Path” From “Lead Prior Art”

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- Unigene Laboratories, Inc. v. Apotex, Inc., 655 F.3d 1352 (Fed. Cir. Aug. 25, 2011), petition for cert. filed (Jan 13, 2012)
 - Claim: A liquid pharmaceutical composition for nasal administration comprising about 2,200 MRC units of salmon calcitonin, about 20 mM citric acid, about 0.2% phenylethyl alcohol, about 0.5% benzyl alcohol, and about 0.1% polyoxyethylene(2) sorbitan monooleate.
 - District Court granted summary judgment of nonobviousness.
 - ✦ “[N]o prior art teaches using 20 mM citric acid to achieve ‘both shelf stability and enhanced bioavailability’ in a nasal salmon calcitonin formulation.”
 - ✦ “[I]t would not have been obvious to a person of ordinary skill in the art to modify Miacalcin® to reach the formulation of claim 19.
 - Federal Circuit affirmed.
 - ✦ “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.”

Post-KSR “Lead Prior Art”

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- Unigene (con’t)

- Federal Circuit affirmed.

- ✦ “Thus, the ‘about 20.0 mM citric acid’ limitation alone supports the district court’s grant of summary judgment of nonobviousness. When used as an absorption enhancer in the ‘116 patent, citric acid was one of over fifty options. ... Further, when the prior art used citric acid at about 20 mM, as in the ‘315 patent, it was used only as a buffer. There is no genuine dispute of material fact that a person of ordinary skill attempting to make a liquid composition to deliver salmon calcitonin into a human body through nasal administration, **would not have considered** using about 20 mM citric acid ..., because the formulation would not be expected to perform properly to meet the specificity of a pharmaceutical use. Thus, even accepting that there was a design need and market pressure to develop a pharmaceutical formulation that is bioequivalent to Miacalcin®, there is no evidence in the record that claim 19 would be an obvious solution to those motivations.”

Not Obvious To Try

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- In re Brimonidine Patent Litigation, 643 F.3d 1366 (Fed. Cir. 2011)
 - Apotex argued that it was obvious to try to reduce the brimonidine concentration in the original Alphagan[®]
 - FC: “Apotex’s ‘obvious to try’ arguments, based on KSR, are unavailing in light of the district court’s factual findings. The district court found that the solutions that Allergan identified and eventually claimed would not have been an ‘anticipated success.’ See *Rolls–Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010). The court found that one of ordinary skill would not have been expected to disregard those roadblocks. Because the court’s findings are well supported, we do not agree with Apotex that the trial court’s conclusion as to the ‘obvious to try’ issue must be overturned.”

U.S. PTO AFTER KSR

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- Ex Parte SUBRAMANYAM (BPAI March 29, 2010)
 - Rejected claim: toothpaste with antibacterial effective amount of compound I.
 - Issue: 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.
 - ✦ For prima facie case, “not only must the structural similarity exist, but the prior art must also provide reason or motivation to make the claimed compound.”

U.S. PTO AFTER KSR



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- SUBRAMANYAM (con't)

- Board: Reversed.

- ✦ Claimed compound is structurally similar to a polyol disclosed by Ning, which is one polyol among many other polyols disclosed by Ning to be found in the plant extracts taught by that reference.
- ✦ “Such 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.”
- ✦ “We conclude that the Examiner has not established a prima facie case that the ordinary artisan would have chosen tetrahydrohonokiol out of all of the polyols found in the plant extracts disclosed by Ning as a lead compound to arrive at the claimed compositing requiring an antibacterial effective amount of a compound of structure (I).”

KSR in USPTO Guidelines

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- *Example 4.14* from the September 1 2010 Guidelines: *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009):
 - “*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.’ *Kubin*, 561 F.3d at 1359. These two classes of situations are:
 - ✦ (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).” 75 Fed. Reg. 53643, 53653 (Sept. 1, 2010).

Use Rationale

74

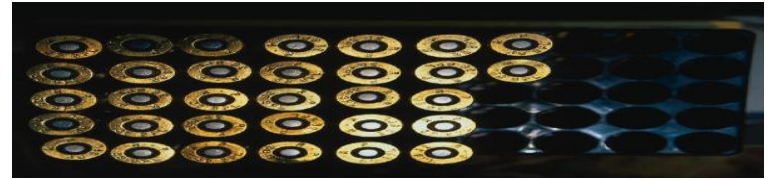
- Is there a reasoned identification of a lead candidate in the prior art? Or might multiple candidates be possible?
 - Must be more than an unsupported assertion.
- Any reason a skilled artisan would have considered modification of the prior art and expected the invention as an identifiable, predictable solution?

Think Back to The Example...

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- 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!



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- 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, “no lead” formulation, device, circuit

Post-KSR Suggestions

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- Patentees may wish to review pre-KSR patents BEFORE litigation and/or licensing arises and consider their options such as filing a reissue application or, if available, a continuation application, or a request for reexamination.
- Rolling effective date provisions of the AIA may impact what options are available.
- Patentees may also find it beneficial to compile evidence of unpredictability well before litigation is an issue.

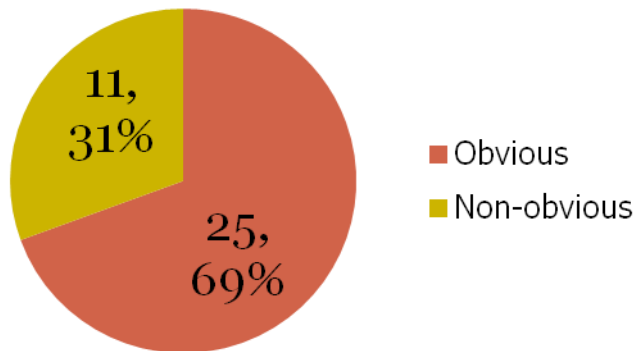
- Use the post-KSR pharma/med device rationales to
 - establish non-obviousness at the USPTO and
 - establish “no demonstration of obviousness” in litigation.



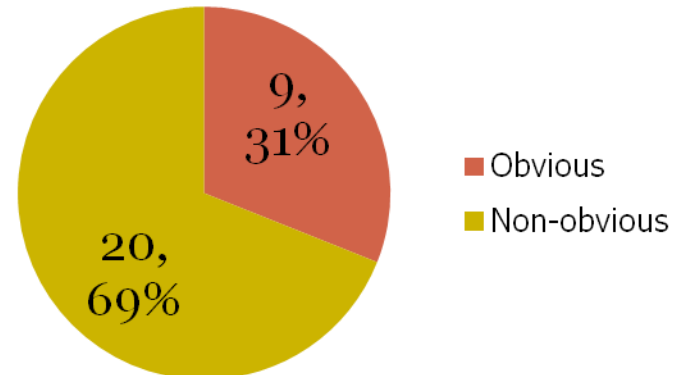
Which Chart Do You Prefer?

79

All other Technologies



Pharma/Med Device/Biotech



Court of Appeals for the Federal Circuit post-KSR published decisions. Current to Jan. 26, 2012.

Take-Away Points

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- 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

What KSR Did Not Change

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- Graham remains the basic test for obviousness.
- Reasonable expectation of success still required for obviousness.
- Teaching away by the prior art may support a finding of non-obviousness.
- Objective evidence of non-obviousness such as unexpected results, failures of others, long-felt but unmet need, or commercial success may be important although may not overcome a strong prima facie case of obviousness.
- Hindsight analysis is improper.

Thank you.

Tom Irving
tom.irving@finnegan.com
202.408.4082

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, “*A Hindsight-Averse Application Of Lead Compound Case Law*,” Law360.com, Aug. 24, 2011) and *Lead Prior Art Methodology: Applying Lead Compound Case Law to Other Disciplines for Enhanced Objectivity*,” published in the Fall 2011 Santa Clara Computer & High Technology Law Journal. A copy of the article is available at: <http://www.chtlj.org/volumes/v27#v027.i3.Finnegan.pdf>

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Appendix to Slides

Tom Irving
tom.irving@finnegan.com
202.408.4082

USPTO Guidelines: Combining Prior Art Elements

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- 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.”

Case	Cite	Notes
In re Omeprazole Patent Litigation	536 F.3d 1361 (Fed. Cir. 2008)	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.
Crocs Inc. v. International Trade Commission	598 F.3d 1294 (Fed. Cir. 2010)	“[M]erely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness.”
Sundance Inc. v. DeMonte Fabricating Ltd.	550 F.3d 1356 (Fed. Cir. 2008)	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.
Ecolab Inc. v. FMC Corp.	569 F.3d 1335 (Fed Cir. 2009)	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.
Wyers v. Master Lock Co.	616 F.3d 1231 (Fed. Cir. 2010)	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.
DePuy Spine Inc. v. Medtronic Sofamor Danek Inc.	567 F.3d 1314 (Fed. Cir. 2009)	Predictability as discussed in <i>KSR</i> 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.

USPTO Guidelines: Substituting One Known Element for Another

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

Case	Cite	Notes
In re ICON Health & Fitness Inc.	496 F.3d 1374 (Fed. Cir. 2007)	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.
Agrizap v. Woodstream	520 F.3d 1337 (Fed. Cir. 2008)	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.
Muniauction Inc. v. Thomson Corp.	532 F.3d 1318 (Fed. Cir. 2008)	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.
Aventis Pharma Deutschland v. Lupin Ltd.	499 F.3d 1293 (Fed. Cir. 2007)	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.
Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.	533 F.3d 1353 (Fed. Cir. 2008)	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.
Procter & Gamble Co. v. Teva Pharmaceuticals USA Inc.	566 F.3d 989 (Fed. Cir. 2009)	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.
Altana Pharma AG v. Teva Pharmaceuticals USA Inc.	566 F.3d 999 (Fed. Cir. 2009)	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.

USPTO Guidelines: Obvious To Try

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- 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.”

Case	Cite	Notes
In re Kubin	561 F.3d 1351 (Fed. Cir. 2009)	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.
Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.	492 F.3d 1350 (Fed. Cir. 2007)	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.
Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.,	520 F.3d 1358 (Fed. Cir. 2008)	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.
Bayer Schering Pharma A.G. v. Barr Laboratories Inc.	575 F.3d 1341 (Fed. Cir. 2009)	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.
Sanofi-Synthelabo v. Apotex Inc.	550 F.3d 1075 (Fed. Cir. 2008)	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.
Rolls-Royce PLC v. United Technologies Corp.	603 F.3d 1325 (Fed. Cir. 2010)	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.
Perfect Web Technologies Inc. v. InfoUSA Inc.	587 F.3d 1324, (Fed. Cir. 2009)	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.

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Case	Cite	Notes
PharmaStem Therapeutics Inc. v. Viacell Inc.	491 F.3d 1342 (Fed. Cir. 2007)	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.
In re Sullivan	498 F.3d 1345 (Fed. Cir. 2007)	All evidence, including evidence rebutting a prima facie case of obviousness, must be considered when properly presented.
Hearing Components Inc. v. Shure Inc.	600 F.3d 1357 (Fed. Cir. 2010)	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.
Asyst Technologies Inc. v. Emtrak Inc.	544 F.3d 1310 (Fed. Cir. 2008)	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.