

# **New Obviousness Guidelines from the USPTO and Their Impact on Prosecution**

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# Agenda

- Background on the 2010 Obviousness Guidelines
- Discussion of the 2010 Obviousness Guidelines
  - 1) Principles of Obviousness
  - 2) Impact of the *KSR* decision
  - 3) Obviousness examples from the Federal Circuit
  - 4) Cases related to consideration of evidence by USPTO
- Practical considerations on how to approach obviousness rejections
  - A novel approach to rebut a *prima facie* case of obviousness

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# 2010 USPTO Obviousness Guidelines

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- Effective September 1, 2010
- *Do not replace* the 2007 Guidelines published after KSR, but rather, supplement them
- Do not identify new obviousness rationales
- Do not represent new PTO policy

# 2010 USPTO Obviousness Guidelines

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- Do not constitute substantive rule making and hence do not have the force and effect of law.
- Thus, failure of the USPTO to follow the Guidelines is NOT appealable
- *Rejections* by Examiners are appealable
- Review 24 Federal Circuit cases decided after KSR

# Importance of 2010 Guidelines

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- Obviousness is the no. 1 cause of invalidity in litigated patents and the most common rejection by Examiners
- Provide examples of actual application of principles in KSR in which inventions were found obvious and examples of non-obvious inventions
- "No examiner may choose to disregard . . . [KSR] . . . or the associated examiner guidance materials" (PTO's slides summarizing Guidelines)

## Purpose of 2010 Guidelines

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- “The purpose of this 2010 KSR Guidelines Update is to remind Office personnel of the principles of obviousness explained by the Supreme Court in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S 398 (2007) (*KSR*), and to provide additional guidance in view of decisions by the United States Court of Appeals for the Federal Circuit (Federal Circuit) since *KSR*.”

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# 1) Principles of Obviousness

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- 2007 Obviousness guidelines remain valid
- Emphasize that the *Graham v John Deere* inquiries remain the starting point for obviousness analysis
- 2007 guidelines: every obviousness rejection requires to:
  - (a) Resolve the *Graham* inquiries;
  - (b) Articulate the appropriate findings of fact; and
  - (c) Explain how the rationale leads to a conclusion of obviousness.

# 1) Principles of Obviousness

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- *Graham v John Deere* inquiries
  - Determine the scope and content of the prior art
  - Identify the differences between the claimed invention and the prior art
  - Determine the level of ordinary skill in the art
  - Consider secondary indicia of nonobviousness (unexpected results, unmet long felt need, commercial success, etc)

# 1) Principles of Obviousness

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- “[I]t remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly. If a rejection has been made that omits one of the required factual findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection including all required factual findings”

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## 2) Impact of the *KSR* decision

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- *KSR* is a U.S. Supreme Court decision. Reaffirmed obviousness analysis under *Graham v John Deere*
- Teaching-Suggestion-Motivation (TSM) test no longer controls obviousness determinations
  - Examiner can use TSM test to find claim obvious, but
  - Applicants cannot use TSM test to argue nonobviousness
- Exemplified 7 rationales for obviousness, among them “obvious to try”

## 2) Impact of the *KSR* decision

- “[W]hen considering obviousness, Office personnel are cautioned against treating any line of reasoning as a *per se* rule . . . rather [each rationale] must be explained and shown to apply to the facts at hand.”
- “A similar caveat applies to any obviousness analysis. Simply stating the principle (e.g., “art recognized equivalent,” “structural similarity”) without providing an explanation of its applicability to the facts of the case at hand is generally not sufficient to establish a *prima facie* case of obviousness.”

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## 3) Examples from the Fed. Cir.

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- Guidelines discuss only 3 of the 7 rationales from *KSR*
  - Combining prior art elements
  - Substituting one known element for another, and
  - Obvious to try

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## 3.1 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.”

Case	Cite	Notes
<a href="#">In re Omeprazole Patent Litigation</a>	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.	No. 2009-1412— F.3d-- (Fed. Cir. July 22, 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.

## 3.1 Combining Prior Art Elements

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### **Examiners must articulate the following:**

- A finding that the prior art included each element claimed,
- Elements could have been combined
- Each element in the combination would have performed the same function as it did separately; and
- A finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable

## Example: In re Omeprazole Patent Litigation

- Invention (Prilosec®) :
  - A pharmaceutical formulation comprising two layers of enteric coatings over the active ingredient omeprazole
- Prior Art
  - Known coating materials used in invention
  - Known methods for applying coatings
  - A formulation of omeprazole comprising a *single-layer* coating
  - Known generally that a primary coating and a second coating could be used, but not specifically for omeprazole

# In re Omeprazole Patent Litigation

- Invention: nonobvious!
1. The patentee discovered that the single-coating prior art product was subject to degradation, and that the degradation could be reduced by adding a subcoating.
  2. Absent prior recognition of the problem, there would not have been a reason to add a subcoating. Even though the modification would have been technically feasible, it would have amounted to extra effort and expense for no apparent reason.

## In re Omeprazole Patent Litigation

- **Teaching point:** 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.

## 3.1 Combining Prior Art Elements

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### Considerations

- Did the examiner explain why it would have been obvious to one of ordinary skill in the art to combine the elements?
- Do the references disclose all claim elements?
- Could one of ordinary skill in the art have combined the elements as claimed?
- *Would* one of ordinary skill in the art have combined the elements as claimed?

## 3.1 Combining Prior Art Elements

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### Considerations (continued)

- After the combination, would each element have performed the same function as it did separately?
- Would one of ordinary skill in the art have recognized that the results of the combination are predictable?
- Are there secondary considerations or other arguments?

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## 3.2 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”

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.

## 3.2 Substituting One Known Element for Another

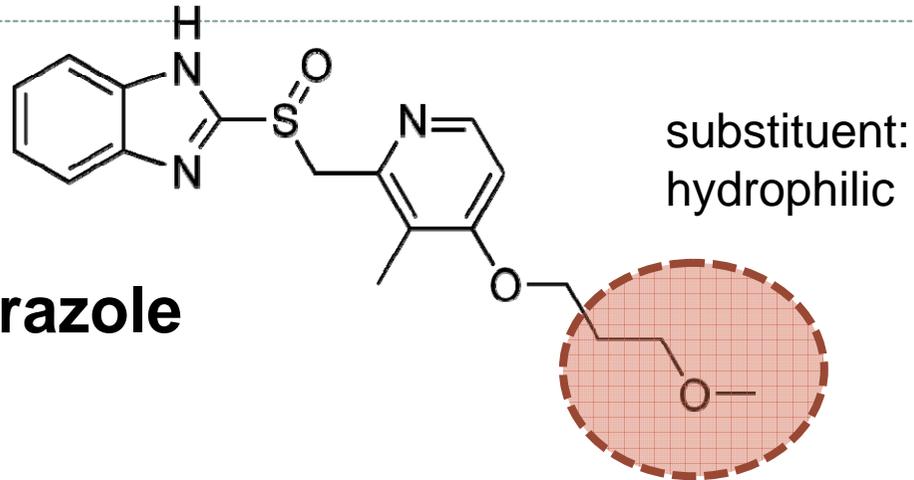
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### **Examiners must articulate the following:**

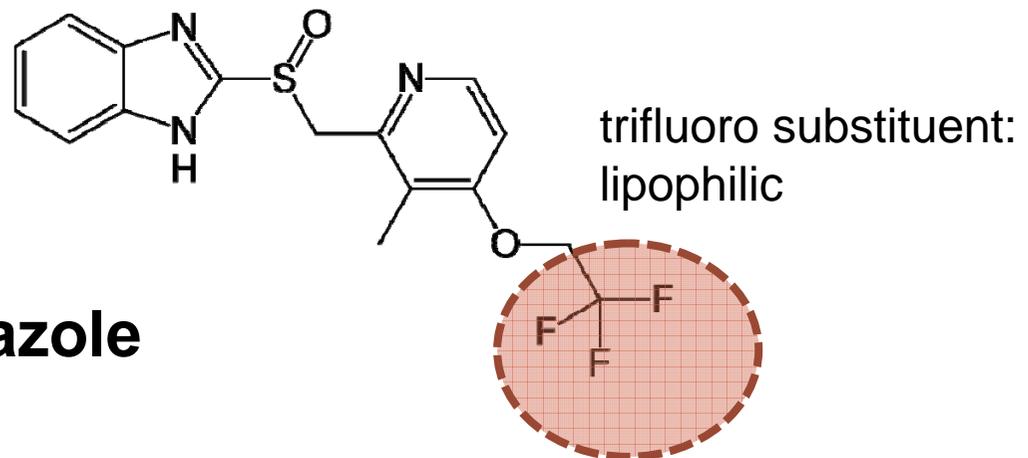
- A finding that the prior art contained a device (method, product, etc.) that differed from the invention by the substitution of some components (step, element, etc.) with other components;
- A finding that the substituted components and their functions were known in the art;
- A finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- Any other necessary findings to explain a conclusion of obviousness

# Example: *Eisai Co. Ltd. v. Dr. Reddy's Labs*

- Invention:



- Prior Art:



## Example: *Eisai Co. Ltd. v. Dr. Reddy's Labs*

### Prior Art:

- Lansoprazole was a compound with known superior biological activity to other compounds (ulcer treatment)
- Lansoprazole's desirable characteristics were due in part to the trifluoro substituent
- Federal Circuit considered Lansoprazole a reasonable starting point for further modification

## Example: *Eisai Co. Ltd. v. Dr. Reddy's Labs*

- Invention: nonobvious!
  1. There was no compelling reason to modify Lansoprazole.
  2. According to the Federal Circuit, the record “shows no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property.”

## Example: *Eisai Co. Ltd. v. Dr. Reddy's Labs*

- **Teaching point:** A claimed compound would not have been obvious where [a] there was no reason to modify the closest prior art lead compound to obtain the claimed compound and [b] 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.

## Example: *Eisai Co. Ltd. v. Dr. Reddy's Labs*

### Requirements for obviousness of chemical compounds

1. "post-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a *lead compound*."
2. Need to identify a reason one of ordinary skill in the art would have modified the lead compound in a particular manner to arrive at the claimed compound

## 3.2 Substituting One Known Element for Another

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### Considerations

- Did the examiner explain why it would have been obvious to one of ordinary skill in the art to substitute the elements?
- Could one of ordinary skill in the art have substituted the elements?
- *Would* one of ordinary skill in the art have substituted the elements?
  - Is there an argument that the result of the combination performs worse than the original prior art device, method, etc?

## 3.2 Substituting One Known Element for Another

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### Considerations (continued)

- Would the results of the substitution have been predictable?
- After the substitution, did the substituted element perform the same function as it did separately?
- Are there secondary considerations or other arguments?

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    - c) **Obvious to try**
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## 3.3 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.”

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.
<a href="#">Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.</a>	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.
<a href="#">Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.,</a>	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.
<a href="#">Sanofi-Synthelabo v. Apotex Inc.</a>	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, 1328-29 (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.

## 3.3 Obvious To Try

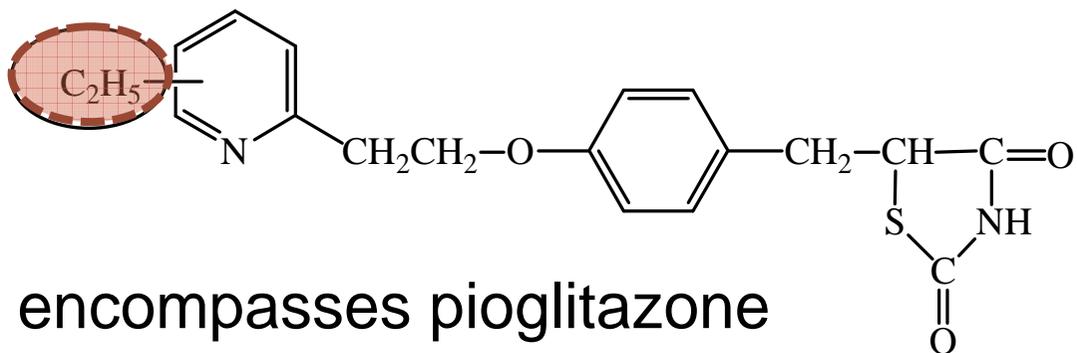
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### **Examiners must articulate the following:**

- A finding that there had been a recognized problem or need in the art including a design need or market pressure to solve a problem;
- A finding that there had been a finite number of identified predictable potential solutions;
- A finding that one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

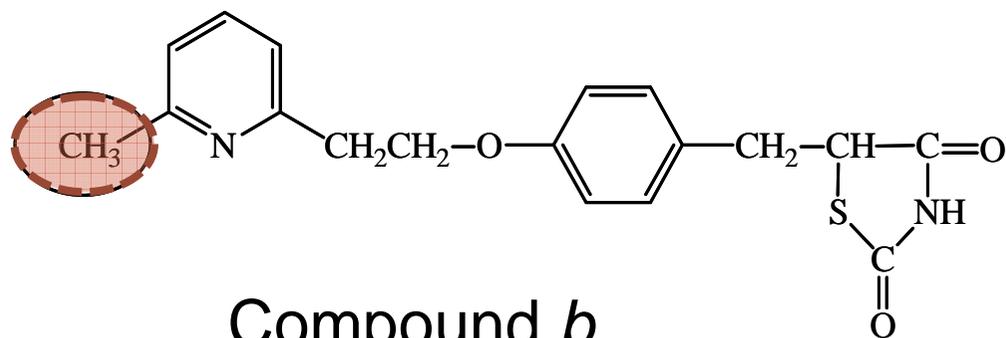
## Example: *Takeda v. Alphapharm*

- Invention:



General formula, encompasses pioglitazone (antidiabetic treatment)

- Prior Art:



Obvious to try?

Compound *b*

## Example: *Takeda v. Alphapharm*

### **Prior Art:**

- Compound *b* was one of fifty-four explicitly-disclosed compounds in a prior art patent ('200 patent)
- During prosecution of the '200 patent, the applicant submitted results for nine compounds, one of which was Compound *b*
- Compound *b* was specifically claimed in one of the dependent claims of the '200 patent
- During the prosecution of the '200 patent, the applicant stated that "the compounds in which these heterocyclic rings are substituted have become important, especially [Compound *b*]."

## Example: *Takeda v. Alphapharm*

### Prior Art:

- A prior art journal article ("the *Sodha II* reference") disclosed undesirable physiological effects of Compound *b*
- Undesirable side effects: "considerable increases in body weight and brown fat weight"
- The *Sodha II* reference identified **three** specific compounds among 101 disclosed compounds most favorable in terms of toxicity and biological activity (*Compound b was not among them*)

## Example: *Takeda v. Alphapharm*

- Invention: nonobvious!
  1. The prior art disclosed undesirable properties of compound b, which disqualify it as lead compound
  2. No finite number of predictable potential solutions to develop a new compound for treatment of diabetes
  3. No reasonable expectation of success in performing the necessary chemical modifications

## Example: *Takeda v. Alphapharm*

- **Teaching point:** A claimed compound would not have been obvious where [a] 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 [b] 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.

## Example: *Takeda v. Alphapharm*

- “*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.*”
- “[I]n cases involving new chemical compounds, *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 compound.”

## Example: *In re Kubin*

- **Invention:** isolated nucleic acid molecule
- Held obvious over the prior art.
- The polypeptide encoded by the claimed nucleic acid was known
- Limited number of methods available to make nucleic acid from polypeptides
- The skilled artisan would have had a reason to try to isolate the claimed nucleic acid
- There would have been a reasonable expectation of success based on the knowledge in the prior art

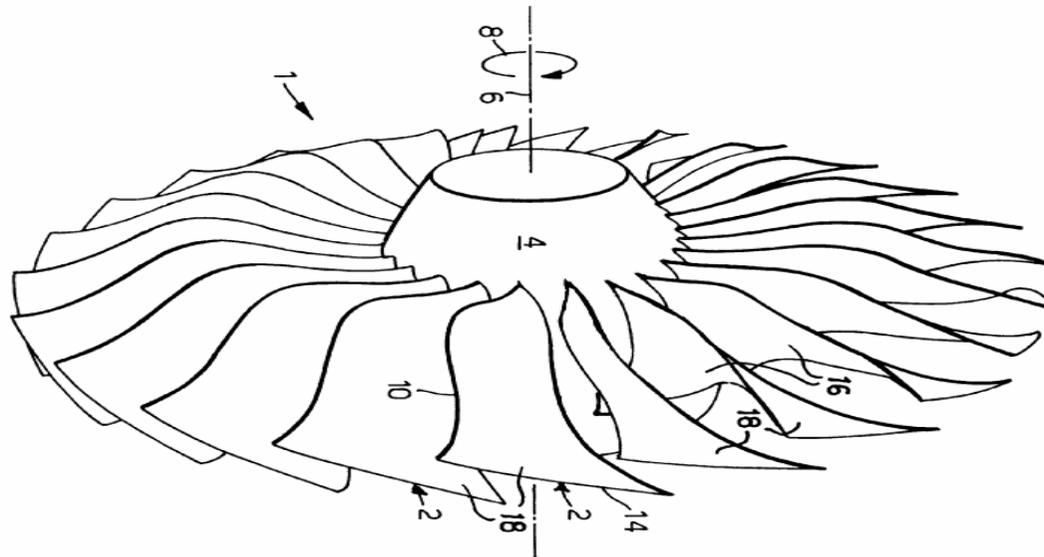
## Example: *In re Kubin*

Two situations where 'obvious to try' is improper:

- "(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."

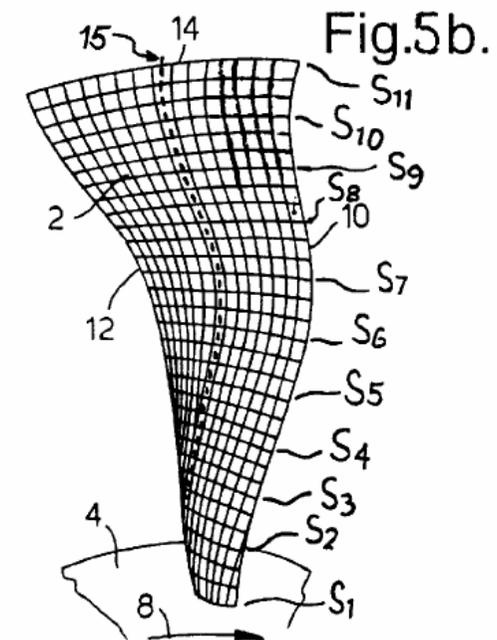
## Example: Rolls-Royce, PLC v. United Techs.

- **Rolls Royce disclosure (and count):** “a fan blade with a sweptforward inner region, a swept-rearward intermediate region, and forward-leaning outer region”



## Example: Rolls-Royce, PLC v. United Techs.

- **UTC disclosure:** a fan blade design in which the sweep angle in the outer region was not reversed
- Issue: is the Rolls Royce's fan blade obvious in light of UTC's disclosure?



Rolls Royce's fan blade

## Example: Rolls-Royce, PLC v. United Techs.

- “UTC argues that an ordinarily skilled artisan would have found it obvious to try to reverse the sweep angle from rearward to forward sweep in the outer region in order to intercept the endwall shock.”
- The Federal Circuit disagreed because “the record does not show that one of ordinary skill in the art would have any reason to try forward sweep in the outer region at all.”
- Thus, changing the sweep angle in the outer region “would not have presented itself as an option at all, let alone an option that would have been obvious to try.”

## Example: Rolls-Royce, PLC v. United Techs.

- "A particular course or selection is not obvious to try unless some design need or market pressure or other motivation would suggest to one of ordinary skill to pursue the claimed course or selection . . . *In other words, one of ordinary skill must have 'good reason to pursue the known options within his or her technical grasp.'*"

## 3.3 Obvious To Try

### Considerations

- Did the examiner explain why it would have been obvious for one of ordinary skill in the art to try the proposed modification?
  - Was there a finite number of possible predictable solutions?
- Could one of ordinary skill in the art have tried the proposed modification?
- *Would* one of ordinary skill in the art have tried the proposed modification?
  - Was there a good reason to pursue the proposed modification?
  - Avoid hindsight!

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## 3.4 Consideration of Evidence

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.

## 3.4 Consideration of Evidence

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- All evidence of nonobviousness presented in a timely manner should be considered by the examiner
- “Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record” (2010 Guidelines)
- “All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability”

## Example: *In re Sullivan*

- **Invention:** an antivenom composition comprising Fab antibody fragments (antigen-binding)
- **Prior Art:**
  - antivenom compositions comprising full length antibodies were known
  - methods of using Fabs from one snake for detecting venom of another snake were known
- **PTO argument:** It would have been obvious to use Fabs in antivenom compositions

## Example: *In re Sullivan*

- **Evidence:** 3 declarations showing unexpected results from the use of Fab fragments (minimized immune reactions) and reasons why POSITA expected antivenoms with Fab fragments to fail (Fab cleared from body faster than venom)
- Amended claims to recite: a composition “for treating a snakebite victim”
- BPAI (PTO Board): Evidence only addresses intended use of an obvious composition (merely reciting an intended use would not make patentable an otherwise obvious composition)

## Example: *In re Sullivan*

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Federal Circuit:

- Accepted a prima facie case had been made, but
- Faulted BPAI for not considering the 3 declarations, which showed:
  - (1) an unexpected property of the composition,
  - (2) teaching away in the art, and
  - (3) long felt but unmet need

## Example: *In re Sullivan*

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- **Teaching point:** All evidence, including evidence rebutting a *prima facie* case of obviousness, must be considered when properly presented.

## 3.4 Consideration of Evidence

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### *In re Sullivan*

- “Nonobviousness can be shown when a person of ordinary skill in the art **would not have reasonably predicted the claimed invention based on the prior art**, and the resulting invention would not have been expected. All evidence must be considered when properly presented.”

### 2010 Obviousness Guidelines

- “As reflected in the M.P.E.P., such evidence [rebuttal evidence] should not be considered simply for its “knockdown” value; rather, **all evidence must be reweighed to determine whether the claims are nonobvious.**”

# Agenda

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- Background on the 2010 Obviousness Guidelines
- Discussion of the 2010 Obviousness Guidelines
- Practical considerations on how to approach obviousness rejections
  - Requirements of an obviousness rejection (recap)
  - A novel approach to rebut a *prima facie* case of obviousness

# USPTO Obviousness Rejection

- Every obviousness rejection requires to:
  - (a) Resolve the *Graham* inquiries;
    - i. Determine the scope and content of the prior art
    - ii. Identify the differences between the claimed invention and the prior art
    - iii. Determine the level of ordinary skill in the art
    - iv. Consider secondary indicia of nonobviousness (unexpected results, unmet long felt need, commercial success, etc)
  - (b) Articulate the appropriate findings of fact; and
  - (c) Explain how the rationale leads to a conclusion of obviousness.

# USPTO Obviousness Rejection

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*Graham* inquiries:

- Are evaluated at the time the invention was made (Section 103)
- Thus, hindsight is impermissible, and
- Must not include knowledge of the claimed invention
- From the perspective of a person of ordinary skill in the art (POSITA)

# USPTO Obviousness Rejection

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## POSITA

- Hypothetical person presumed to be aware of all pertinent prior art in the area of the invention.
- Possesses ordinary creativity
- Exercises common sense when analyzing the available knowledge in the art

## ***Prima Facie* case of Obviousness**

- Each patent application is presumed valid when filed
- Examiner has burden of proving claims are not patentable
- “A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art” (*In re Rijckaert*)
- “If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned” (*Id*)

# Agenda

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- Background on the 2010 Obviousness Guidelines
- Discussion of the 2010 Obviousness Guidelines
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  - A novel approach to rebut a *prima facie* case of obviousness

# Background

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- Preliminary point: better to **rebut** *prima facie* case rather than to overcome it
- Typical rejection:
  - Examiner uses invention to search for closest prior art, then
  - Examiner develops arguments for why a POSITA would have modified closest prior art to arrive at invention
- Thus, **hindsight is inherent in a typical rejection!**
- Typical response from applicant:
  - If dates are correct, applicant “accepts” prior art as prior art
  - Applicant focuses on distinguishing invention from prior art

## A novel approach to rebut a *prima facie* case of obviousness

- Based on “lead compound” approach developed by Federal Circuit to determine patentability of new chemical compounds
- “Lead compound” approach
  - “[P]ost-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound.” (Eisai)
  - “[I]n cases involving new chemical compounds, 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 compound.” (Takeda)

## A novel approach to rebut a *prima facie* case of obviousness

- Eliminate hindsight
- Put yourself in the mind of POSITA at the time the invention was made
- Consider POSITA's options without knowledge of the invention
- Apply principles of "lead compound" approach and determine whether the prior art, even if it was published more than one year before filing of application, is the proper prior art to use in the rejection!

## Working example: *Takeda*

- As part of first *Graham* factor, analyze the scope and content of prior art (antidiabetic drugs, but consider all fields that could have suggested prior art selected by Examiner)
- Is there “a design need or market pressure to solve a problem” (*KSR*)? (yes, need more active compounds) If so, where does it point to? (improve existing known compounds)
- What options are available to innovate? (compound *b*, compounds from '200 patent, compounds in Sodha reference) Are there options that are more promising than others? (compounds from Sodha art.)

## Working example: *Takeda*

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- Thus, POSITA having no knowledge of claimed invention, and considering knowledge in the prior art at the time the invention was made, would have started the development of new antidiabetic drugs with the 3 compounds from the Sodha article
- Proper prior art for obviousness analysis: compounds from Sodha article!

# A novel approach to rebut a *prima facie* case of obviousness

## Considerations

- Not necessary to find best starting prior art, just a starting point that is better than the prior art cited by the Examiner
- Consider all possible solutions available in the prior art and their advantages and disadvantages
- Balance the advantages and disadvantages and determine whether some solutions are more promising than others
- *Any* information that would tilt the balance one way or another is useful

## A novel approach to rebut a *prima facie* case of obviousness

Does a particular starting point:

- display some kind of superior performance over other starting points?
- possess other desirable characteristics?
- lacks undesirable features or characteristics?
- allow easier development because there is more information available to POSITA about that option?
- have a higher, or lesser, degree of predictability or expectation of success than other starting points?

## A novel approach to rebut a *prima facie* case of obviousness

- Even if the prior art selected by Examiner could be considered suitable for the obviousness determination at hand, applicant can still employ traditional arguments:
  - Did examiner articulate the necessary factual findings?
  - Do references disclose all elements of claim?
  - Could a POSITA have combined the references?
  - Would a POSITA have combined the references?
  - Are the results of the combination predictable or expected?
  - Are there any secondary considerations? Etc.

# Shameless Plug: Article in print

- Lead Prior Art Methodology: Applying Lead Compound Case Law to Other Disciplines for Enhanced Objectivity
  - **Introduction**
  - **The Existing Obviousness Rubric** (Graham/KSR, *prima facie*, etc)
  - **Objective Indicia of Non-Obviousness** (unexpected results, commercial success, etc)
  - **Identification of the Proper Lead Prior Art**
  - **Method of Determining Obviousness Using Lead Prior Art Approach**

Email me at [carlos.tellez@finnegan.com](mailto:carlos.tellez@finnegan.com) if you would like copy when article publishes

# Thank you



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# Appendix to Slides

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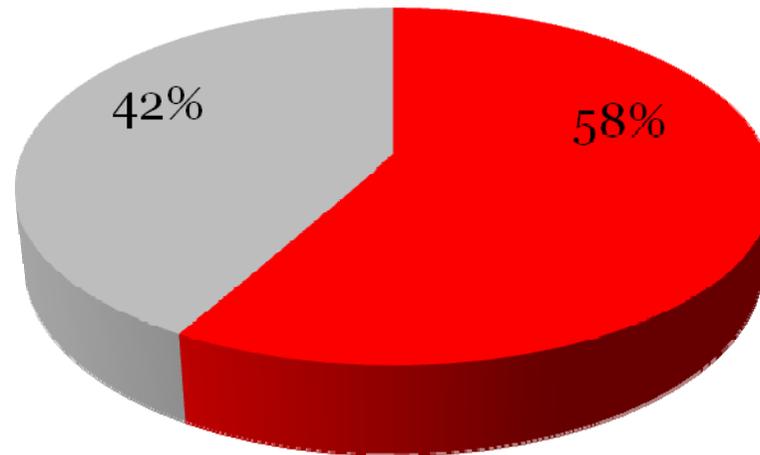
# FEDERAL CIRCUIT AFTER *KSR* - OVERVIEW

54 Federal Circuit obviousness decisions post-*KSR* (does not include “vacate and remand”):

30/52 (58%) held claims obvious

22/52 (42%) held claims non-obvious

■ Obvious      ■ Non-obvious



Current to Mar. 29, 2011.

Note: If exclude pharma and medical device cases, Federal Circuit is holding claims invalid for obvious 71% of the time (25/35). For pharma and medical device, the rate is the opposite 29% (5/17) obvious; nonobvious 71% (12/17).

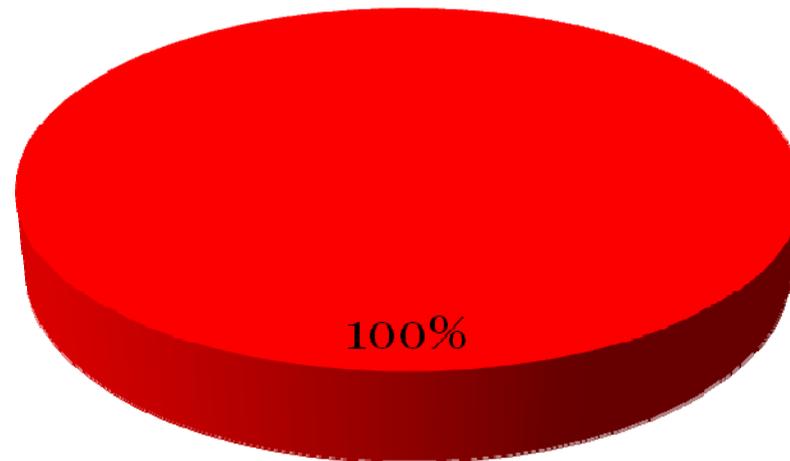
# CHEMICAL/MATERIAL SCIENCE CASES

Two Federal Circuit chemical/material science patent decisions:

2/2 (100%) held claims obvious

0/2 (0%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In both cases, the district court found the claims non-obvious (100% affirmance rate).

*Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009); *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334 (Fed. Cir. 2009).

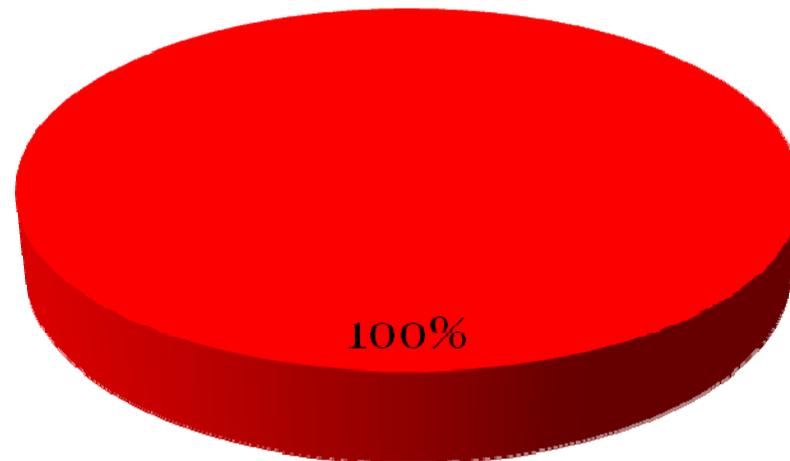
# BIOTECH SCIENCE CASES

Two Federal Circuit biotech patent decisions:

2/2 (100%) held claims obvious

0/2 (0%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In both cases, the district court found the claims obvious (100% affirmance rate).

*In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008); *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009)

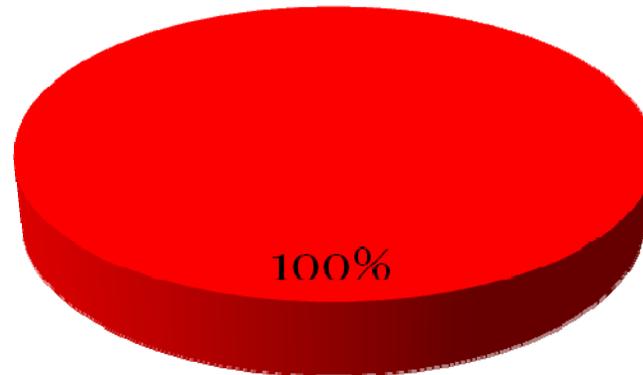
# BUSINESS METHOD SCIENCE CASES

Four Federal Circuit business method patent decisions:

4/4 (100%) held claims obvious

0/4 (0%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: Federal Circuit aff'd the district court's decision in 2/4 (50% affirmance rate).

*In re Trans Texas Holdings Corp.*, 498 F.3d 1290 (Fed. Cir. 2007); *Muniauction v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008); *Dow Jones & Co., Inc. v. Abtise Ltd.*, 606 F.3d 1338 (Fed. Cir. 2010); *Western Union Co. v. MoneyGram Payment Systems Inc.*, 626 F.3d 1361 (Fed. Cir. 2010).

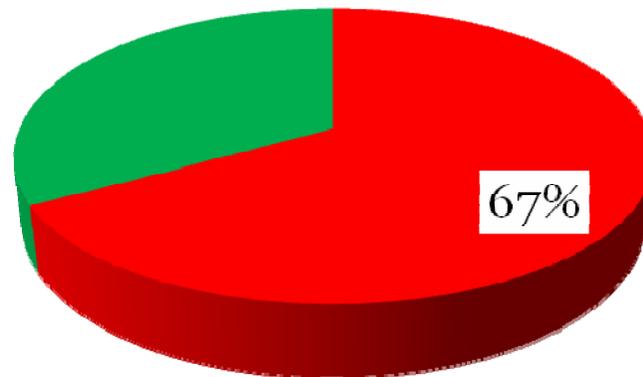
# ELECTRICAL CASES

Three Federal Circuit electrical science patent decisions:

2/3 (67%) held claims obvious

1/3 (33%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In two cases, the district court decision was affirmed; in one case (*Agrizap*), the district court found the claims non-obvious (67% affirmance rate). *Power-One, Inc. v. Artesyn Technologies, Inc.*, 599 F.3d 1343 (Fed. Cir. 2010); *Scanner Technologies Corp. v. ICOS Vision Systems Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008).

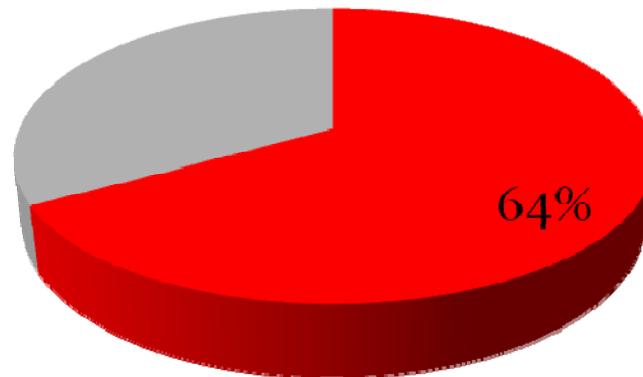
# MECHANICAL CASES

Fourteen Federal Circuit mechanical patent decisions:

9/14 (64%) held claims obvious

5/14 (36%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In 7/14 cases district court decision was affirmed; (50% affirmance rate).

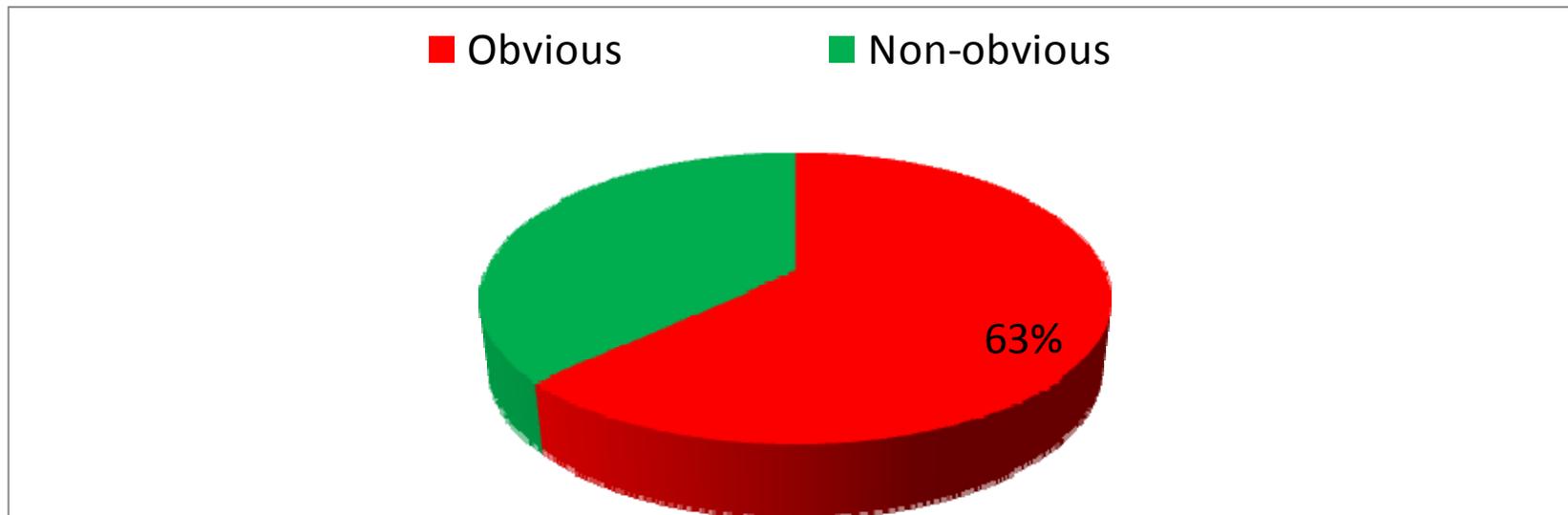
*Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371 (Fed. Cir. 2009), *reh'g denied* (Oct. 2, 2009); *Rothman v. Target Corp.*, 556 F.3d 1310 (Fed. Cir. 2009); *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010); *Ball Aerosol and Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984 (Fed. Cir. 2009); *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008); *Leapfrog Enterprises Inc. v. Fischer-Price Inc.*, 485 F.3d 1157 (Fed. Cir. 2008); *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310 (Fed. Cir. 2008); *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374 (Fed. Cir. 2007); *Honeywell Intern., Inc. v. U.S.*, 609 F.3d 1292 (Fed. Cir. 2010); *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010); *Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC*, 618 F.3d 1294 (Fed. Cir. 2010); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296 (Fed. Cir. 2010); *Tokai Corp. v. Easton Enterprises, Inc.*, --F.3d-- (Fed. Cir. Jan. 31, 2011); *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026 (Fed. Cir. 2011).

# COMPUTER HARDWARE/SOFTWARE CASES

Seven Federal Circuit computer hardware/software patent decisions:

5/8 (63%) held claims obvious

3/8 (37%) held claims non-obvious



Note: The Federal Circuit affirmed the district court decision in 8/8 cases (100% affirmance rate).

*In re Mettke*, 570 F.3d 1356 (Fed. Cir. 2009); *In re Translogic Technology, Inc.*, 504 F.3d 1249 (Fed. Cir. 2007); *Monolithic Power Systems, Inc. v. O2 Micro Intern. Ltd.*, 558 F.3d 1341 (Fed. Cir. 2009); *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325 (Fed. Cir. 2008); *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009); *Perfect Web Technologies, Inc. v. Infousa, Inc.*, 587 F.3d 1324 (Fed. Cir. 2009); *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011), reh'g denied (Mar 22, 2011).

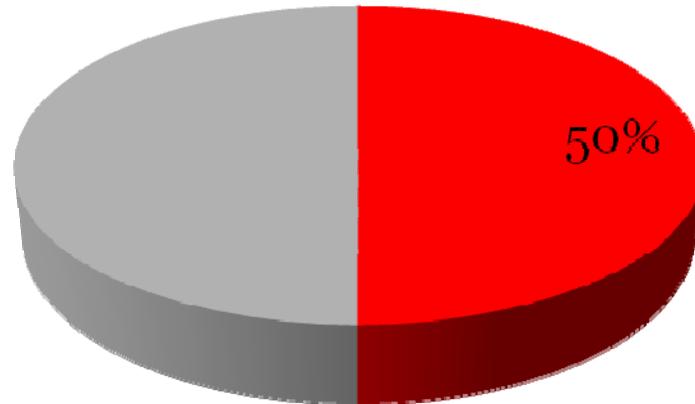
## OTHER CASES

Two Federal Circuit “other” patent decisions:

1/2 (50%) held claims obvious

1/2 (50%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In ½ cases, Federal Circuit affirmed district court decision (50% affirmance rate).

*Media Technologies Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334 (Fed. Cir. 2010); *Crocs, Inc. v. International Trade Com'n*, 598 F.3d 1294 (Fed. Cir. 2010).

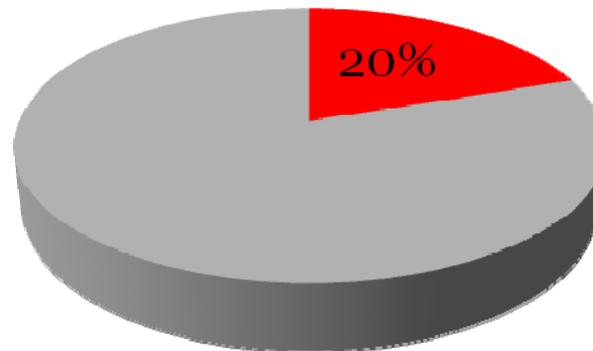
# MEDICAL DEVICE CASES

Five Federal Circuit medical device patent decisions:

1/5 (20%) held claims obvious

4/5 (80%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In the one case the Federal Circuit found obvious (*Fresenius*), the district court had found non-obviousness; in the one case the district court found obviousness, the Federal Circuit found the claims non-obvious (60% affirmance rate)

*Fresenius USA, Inc. v. Baxter Intern., Inc.*, 582 F.3d 1288 (Fed. Cir. 2009); *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*, 554 F.3d 1010 (Fed. Cir. 2009); *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010); *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305 (Fed. Cir. 2010);

*TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333 (Fed. Cir. 2010).

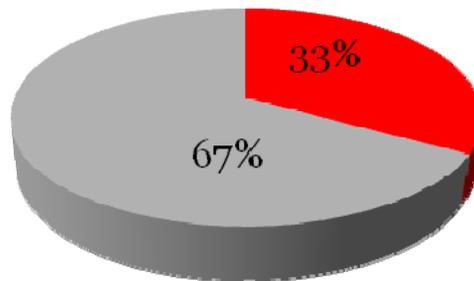
# PHARMACEUTICAL CASES

Twelve Federal Circuit pharmaceutical patent decisions:

4/12 (33%) held claims obvious

8/12(67%) held claims non-obvious

■ Obvious      ■ Non-obvious



Note: In 10 of the 12, the lower court was affirmed. In two (Aventis and PharmaStem), the Federal Circuit found obviousness, while the district courts held the claims non-obvious.

# PHARMACEUTICAL CASES

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- *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 575 F.3d 1341 (Fed. Cir. 2009); *Proctor & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008); *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008); *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007); *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007); *Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010); *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010); *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010)