

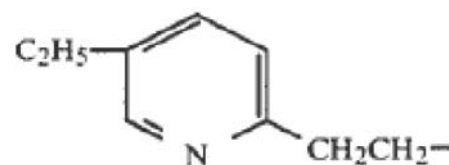
Preventing Obviousness Rejections post-KSR and its Progeny

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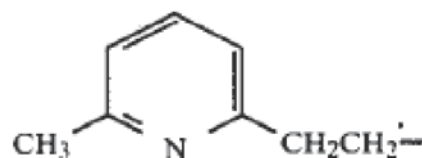
Federal Circuit's Application of *KSR*

▶ *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007)

– Pioglitazone (ACTOS)



– Prior art: “compound b”



– **Not obvious:** teaching away & unexpected properties (compound b was toxic, pioglitazone was not)

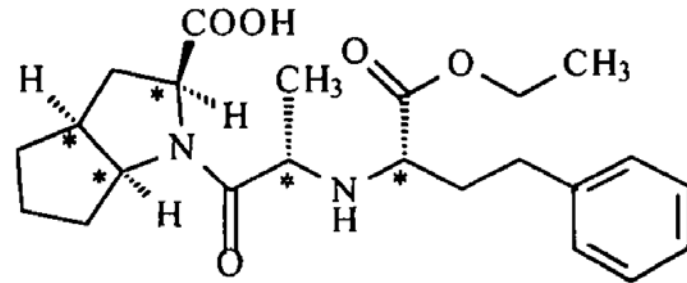
– Practice Tip: identify differences in structure and in properties, and why properties are unexpected

Federal Circuit's Application of *KSR*

▶ *Aventis Pharma Deutschland GmbH v. Lupin*, 499 F.3d 1293 (Fed. Cir. 2007)

– Ramipril (ALTACE):

▶ 5(S) enantiomer



– Prior art:

▶ same compound in racemic mixture (SSSSS and SSSSR)

▶ similar compound → SSS was 700-fold more potent than SSR

– **Obvious:** POSITA would know how to separate enantiomers and would expect benefit

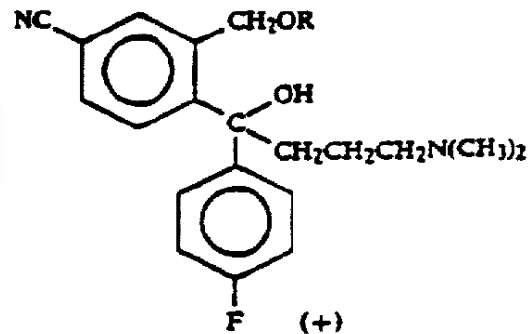
Federal Circuit's Application of *KSR*

- ▶ *Forest Labs. v. IVAX & Cipla*, 501 F.3d 1263 (Fed. Cir. 2007)

- escitalopram

- ▶ LEXAPRO

- ▶ S- or (+) -



- Not Obvious:

- ▶ difficulty of separating the enantiomers, and unexpected property: therapeutic benefit expected in R- citalopram rather than S- citalopram

- Practice Tip: identify reasons why separation of enantiomers was not routine and/or why properties of particular enantiomer were not expected

Federal Circuit's Application of *KSR*

- ▶ *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007)
 - Antibody fragment (Fab) that neutralizes rattlesnake venom
 - ▶ Prior art: whole Ab that neutralizes same venom, and Fab that detects different venom
 - ▶ *prima facie* obvious, with citation to *KSR*
 - Vacated & remanded because BPAI failed to consider rebuttal declaration evidence
 - ▶ Teaching away: only commercial products = whole IgG or F(ab)₂
 - ▶ Unexpected property or result: neutralizing toxicity while decreasing adverse immune reactions

Federal Circuit's Application of *KSR*

- ▶ *Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007)
 - Reading toy: pushing a letter in a word activates a switch and provides the sound of the letter within that word
 - Prior art: mechanical device with same goal; electronic device with similar operation; general knowledge
 - PTO Guidelines: “Applying modern electronics to older mechanical devices has been commonplace for years.”
- ▶ **Rebutting obviousness:**
 - “Leapfrog presents no evidence that the inclusion of a reader in this type of device was **uniquely challenging** or **difficult** for one of ordinary skill in the art.”

Guidelines Provided To The Examining Corps of the USPTO



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USPTO Guidelines

- ▶ Federal Register / Vol. 72, No. 195 / Oct. 10, 2007
 - Also found in MPEP (8th Ed., Rev. 6)
- ▶ *Graham* inquiries must be made
- ▶ Sets forth seven “**rationales**” that support a conclusion that the claim would have been obvious
- ▶ **Predictability** is overarching theme

USPTO Guidelines

► Notable facets of the Guidelines

- Examiners to act as **fact-finders**
- Must find particular facts to support the rationales
- Examiners may not have to find all claim elements in the prior art
- Emphasis on **predictability** or lack thereof
- Expects **evidence** in response to some rejections

Rationales A & B: Combining or Substitution

- ▶ (A) Combining prior art elements according to known methods to yield **predictable** results;
- ▶ (B) Simple substitution of one known element for another to obtain **predictable** results;
- ▶ *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988)
 - Claims to method of synthesizing a protein in a transformed bacteria
 - Obvious to replace one heterologous gene with another
 - Inventor's own prior art

Rationales C & D: Known Techniques

- ▶ (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- ▶ (D) Applying a known technique to a known device (method, or product) ready for improvement to yield **predictable** results;
 - “Base device” upon which claimed invention can be seen as “improvement”

Rationales C & D: Known Techniques

- ▶ Rationale used (and overcome) in *Sullivan* (Fab for rattlesnake venom)
- ▶ Emphasize unpredictability and unexpected results
 - Challenges & uncertainties even with “known” techniques
 - Step-by-step examples showing decision points & detours from known techniques

Rationale E: “Obvious to Try”

- ▶ (E) "Obvious to try" – choosing from a finite number of identified, **predictable** solutions, with a reasonable expectation of success;
- ▶ **Guidelines use pharma & biotech cases as examples**
 - Pfizer v. Apotex (salt form of active agent)
 - ALZA v. Mylan (controlled release formulation)
 - In re Kubin (nucleotide sequence encoding a known protein)

Rationale E: “Obvious to Try”

- ▶ *Pfizer v. Apotex*, 480 F.3d 1348 (Fed. Cir. 2007)
 - Claim to amlodipine besylate was obvious based on (1) amlodipine and (2) use of besylate anions
 - Finite no. of identified, predictable sol’ns: 53 anions
- ▶ **Salt forms no longer patentable?**
 - Look for therapeutic difference – would be truly unexpected
 - Identify any synergies, challenges in manufacture or screening, ingenuity in selection
 - Explain why the salt or its properties were not predictable

Rationale E: “Obvious to Try”

▶ *ALZA v. Mylan*, 464 F.3d 1286 (Fed. Cir. 2006)

- Reasonable expectation of successful development of sustained release oxybutynin

2. A sustained-release oxybutynin formulation for oral administration to a patient in need of treatment for urge incontinence comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that delivers from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.25 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating urge incontinence in the patient.

▶ **Controlled release formulations not patentable?**

- Is it more than a release rate of active agent?
- Is it more than combining known drug in known platform?

Rationale E: “Obvious to Try”

- ▶ ***Kubin***: Isolated nucleic acid was obvious from prior art disclosing encoded polypeptide
 - Problem was to isolate a specific nucleic acid
 - known methods of sequencing were used by the applicants
- ▶ **Nucleic acid sequences encoding known proteins no longer patentable?**
 - May depend on particular facts (e.g., mouse version of sequence, antibodies to human version of protein)
 - Emphasize challenges & obstacles in isolating sequence. Was it a technical achievement to obtain the sequence?
 - Claims to vectors, cell lines more important?

Rationales F & G

- ▶ (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on **design incentives** or other **market forces** if the variations would have been **predictable** to one of ordinary skill in the art;
 - *Leapfrog* used as example
- ▶ (G) 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.

Strategies For Prosecution



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Responding to Obviousness Rejections

▶ Responding to an Obviousness Rejection:

- Show that Office Action is incorrect about prior art or how it works
- Challenge the Examiner's **reason** for combining or modifying
- Point to prior art that **teaches away**
- No reasonable expectation of success

▶ Some traditional responses are still appropriate, but avoid TSM

Responding to Obviousness Rejections

▶ Responding to an Obviousness Rejection:

- Increased use of declaration & other evidence
 - ▶ Show why one skilled in the art would not find Examiner's reason reasonable
 - ▶ Show facts that contradict the rationale
 - ▶ Explain why there is unpredictability
 - ▶ Explain challenges, uncertainties & difficulties

▶ Some new approaches to obviousness rejections may be appropriate

Responding to Obviousness Rejections

► Challenge conclusory assertions in Office Actions

- Challenge the **fact findings** when wrong
- Guidelines frequently state: “**If any of these findings cannot be made, then this rationale cannot be used** to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.”
- More persuasive to challenge with **evidence**, not just argument

Respond by Showing Unpredictability

- ▶ **Unpredictability in context** of prior art
 - Not sufficient to say “chemistry is unpredictable”
 - Unpredictability is reduced as the field progresses

- ▶ **General unpredictability** may be insufficient
 - *Pfizer*: unpredictable as to results of forming besylate salt, but predictable that an improved salt could be found from finite number

Respond by Showing That Prior Art Teaches Away

- ▶ **“It is improper to combine references where the references **teach away** from their combination.”**
MPEP 2145
 - May be found in the teachings of the cited prior art
 - May be found in other references
 - Knowledge of one skilled in the art (may require a declaration)
- ▶ **Cite to evidence (references and/or declarations)**
- ▶ **Search for references that teach away?**

Respond by Showing That Prior Art Teaches Away

- ▶ **Teaching Away:** should criticize, discredit, or otherwise discourage
 - Inferiority may not rise to level of teaching away
- ▶ **Similar (not identical) compounds are discouraged**
 - *Takeda*: similar prior art compound was **toxic** and had **other adverse effects**
 - *Sullivan*: POSITA would not expect Fab fragments (in general) to be effective

More Frequent Use of Declarations

- ▶ **Unpredictable aspects and details of the art**
 - Inventor's earlier failures
- ▶ **Unexpected Results**
 - Explain results & why they were unexpected
- ▶ **Challenges, obstacles, difficulties**
- ▶ **Failure of proposed combination**
- ▶ **Secondary Considerations**
 - Failure of others (co-workers & competitors)
 - Long felt, but unresolved need
 - Commercial success

Pros & Cons of Arguing “Unexpected Results”

▶ Pros

- Evidence, not argument
- Quantitative
- Relies on inventor’s work
- Open to different types of results

▶ Cons

- Effort & expense
- Somewhat subjective
- Attack by infringer

Practical Consequences for New Applications



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Practical Implications of *KSR*

- ▶ Scope of “material” information under Rule 1.56 may be broader
- ▶ Defining the prior art search
- ▶ Determining the appropriate scope of the search

Drafting New Applications

- ▶ **Identify new structures, properties & functions**
 - Especially **therapeutic properties**, but others too
 - Ask whether properties & functions are **surprising or unexpected**
 - Identify departures from “conventional techniques”
- ▶ **Include more examples & data**
 - Avoid need to submit declaration later
 - Differences & unexpected results

Drafting New Applications

▶ **Specification**

- Background should not generalize or trivialize inventor's recognition of the problem
- ▶ May want to avoid the **problem-and-solution approach** favored in Europe
 - **Conflict:** The U.S. application may be more prone to rejection when it identifies a known problem and claims its solution

Drafting New Applications

► Specification

- Avoid use of prior art patents and publications to explain making or using the invention
- Identify **synergies** to illustrate the invention is not a mere “predictable result” or a “predictable function/property”
- Be wary of **inventor’s prior art** & its publication date

Drafting New Applications

▶ Claims

- More **independent** claims with different language
- Avoid claiming a list of stand-alone prior art elements (eg, formulations)
- **Commensurate** with the scope of discoveries & unexpected results
- **Combine** structure and property / function in claim
 - ▶ Salt: active agent, ion & physical properties?
 - ▶ Formulations: excipients & release rates?

Discussion Questions & Answers



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Thank you!

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