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# **Obviousness Post-KSR**

## **An Unpredictable Season?**



# Cases Post-KSR

- **Takeda Chemical Industries v. Alphapharm Pty, Ltd., 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007)**
- **Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 83 USPQ2d 1289 (Fed. Cir. 2007)**



# Cases Post-KSR

- **Forest Laboratories v. Ivax Pharmaceuticals, 501 F.3d 1263, 84 USPQ2d 1099 (Fed. Cir. 2007)**
- **Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 84 USPQ2d 1285 (Fed. Cir. 2007)**
- **Aventis v. Lupin, 499 F.3d 1293, 84 USPQ2d 1197 (Fed. Cir. 2007)**



# Cases Post-KSR

- **McNeil-PPC, Inc. v Perrigo Company, 443 F. Supp. 2d 492 (S.D. N.Y. June 5, 2007), aff'd by Fed. Cir. in April 2008 without published decision**
- **In re Omeprazole Patent Litigation, 490 F. Supp. 2d 381 (S.D. N.Y. June 1, 2007), aff'd by Fed. Cir. in June 2008 in a non-precedential decision**



# Cases Post-KSR

- **Ortho-McNeil v. Mylan, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008)**
- **Eisai v. Dr. Reddy's, 533 F.3d 1353, 87 USPQ2d 1452 (Fed. Cir. 2008)**



# Cases Post-KSR

- **Sanofi-Synthelabo v. Apotex, 550 F.3d 1075, 89 USPQ2d 1370 (Fed. Cir. 2008)**
- **Boston Scientific Scimed v. Cordis, 554 F.3d 982, 89 USPQ2d 1704 (Fed. Cir. 2009)**
- **In re Kubin, 561 F.3d 1351, 90 USPQ2d 1417 (Fed. Cir. 2009)**



# Cases Post-KSR

- **Procter & Gamble v. Teva, 566 F.3d 989, 90 USPQ2d 1947 (Fed. Cir. 2009)**
- **Bayer Schering v. Barr, 575 F.3d 1341, 91 USPQ2d 1569 (Fed. Cir. 2009)**



# Takeda v. Alphapharm

- **Court's Rationale**
  - **No "finite number of identifiable, predictable solutions"**
  - **Prior art provided "broad selection of compounds"**
  - **Closest prior art compound exhibited negative properties**
- **Holding**
  - **Patent valid –nonobvious**





# Pharmastem v. Viacell

## □ Court's rationale

- Could not reconcile expert testimony with statements in the specification
- Did not agree with expert that terminology was "flawed"
- Prior art references to "stem cells" were consistent with Applicants' statements in the specification
- Citing KSR, determined that invention was confirmation of what was already believed to be true

## □ Holding

- Patent invalid - composition obvious



# Forest v. Ivax

## □ Court's Rationale

↪ Evidence of failure of others to separate the enantiomers permitted conclusion that prior art reference was not enabling with regard to the suggestion to isolate the (S) enantiomer

## □ Holding

□ Patent valid – compound unobvious



# Daiichi Sankyo v. Apotex

- **Court's Rationale**
  - **District Court erred in the determination of the level of skill**
  - **By finding the level of skill in the prior art to be too high, prior art teaching was dismissed by the District Court**
- **Holding**
  - **Patent invalid – method obvious**



# Aventis v. Lupin

## □ Court's Rationale

↪ **Obviousness flowed from recognition of the properties of similar prior art compounds combined with recognition of the presence of the claimed isomer in the prior art mixture**

## □ Holding

↪ **Patent invalid – compound obvious**



# McNeil v. Perrigo

- **Court's Rationale**
  - ❑ **The combination of coated famotidine and the antacids provided no more than predictable results, citing KSR**
  - ❑ **Costs alone are not indicative of non-obviousness**
  
- **Holding**
  - ❑ **Patent invalid – formulation obvious**



# In re Omeprazole

- **Court's Rationale**
  - ❑ **References taught away from subcoated formulation**
  - ❑ **Expert testimony of "multitude of possible paths and dead-ends" in formulation attempts**
  
- **Holding**
  - ❑ **Patent valid – formulation unobvious**



# Score at Half-Time

- **Non-Obvious: 3**
- **Obvious: 4**



# Ortho-McNeil v. Mylan

## □ Claim

□ Topirimate (Topomax®)

## □ Prior Art

□ **Materials produced during discovery indicating inventor interest in preparing FBPase inhibitors as useful in controlling blood glucose levels in diabetic patients**





# Ortho-McNeil v. Mylan

## □ Court's Rationale

- a person of ordinary skill would have to
  - start with 2,3:4,5 di-isopropylidene fructose (DPF)
  - have some reason to select the exact route that produced topiramate as an intermediate
  - stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (diabetes)

## □ Holding

- Patent valid – compound unobvious



# Esai v. Dr. Reddy's

## □ Claim

□ **Rabeprazole and its salts (Aciphex<sup>®</sup>)**

## □ Prior Art

□ **Lansoprazole**

□ **Omeprazole**

□ **Review article of class of compounds of which all three compounds are a member having anti-ulcerative activity**



# Esai v. Dr. Reddy's

## □ Court Rationale

□ No reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave an advantageous property

## □ Holding

□ Patent valid – compound nonobvious



# Sanofi-Sythelabo v. Apotex

- **Claim**
  - **Hydrogen sulfate of the D isomer of clopidogrel substantially separated from the L isomer (Plavix®)**
  
- **Prior Art**
  - **Patent to the racemate**



# Sanofi-Sythelabo v. Apotex

## □ Court Rationale

□ A person of ordinary skill would not have had the expectation that separating the enantiomers would be likely to produce an isomer having absolute stereoselectivity as to the favorable antiplatelet activity and lacking the unfavorable neurotoxicity

## □ Holding

□ Patent valid – compound nonobvious



# Boston Scientific v. Cordis

## □ Claim

- **An implantable metallic medical device covered with a coating for release of at least one biologically active material which coating comprises an undercoat incorporating the biological material and a topcoat which provides long term non-thrombogenicity wherein the topcoat is substantially free of an elutable material**



# Boston Scientific v. Cordis

## □ **Prior Art**

- **Patent disclosed two separate embodiments in the same figure, each with different combinations of elements all present together in the claimed stent**



# Boston Scientific v. Cordis

- **Court's Rationale**
  - **Even though identified as separate embodiments, the immediate juxtaposition of the two embodiments would have suggested a third embodiment with all the elements**
  
- **Holding**
  - **Patent invalid – device obvious**





# In re Kubin

## □ Claim

- **An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22 – 221 of SEQ ID NO:2, wherein the polypeptide binds CD48**



# In re Kubin

## □ **Prior Art**

- **Reference disclosed p38 protein (same protein as NAIL) and methods of isolation by using mAbs as well as methods of obtaining the polynucleotide sequence but does not disclose the sequence of p38**
- **Reference disclosed the nucleic acid sequence of the highly conserved murine version of p38 and identified a human homologue**



# In re Kubin

- **Court's Rationale**
  - ❑ **Appellants used conventional techniques to isolate a gene sequence for NAIL**
  - ❑ **Claim required only finding a gene sequence within the genus claimed**
  
- **Holding**
  - ❑ **BPAI affirmed – compound obvious**



# Procter & Gamble v. Teva

## □ Claim

□ **Risedronate (Actonel®)**

## □ Prior Art

□ **Prior patent to P&G identifies 36 polyphosonates as treatment candidates, and 8 preferred compounds including 2-pyr EHDP**



# Procter & Gamble v. Teva

- **Court's Rationale**
  - ❑ **No direction to identify closest structure as lead compound**
  - ❑ **Unpredictability of bisphosphonate characteristics**
  - ❑ **Secondary indicia outweighed any assertion of obviousness**
  
- **Holding**
  - ❑ **Patent valid – compound non-obvious**



# Bayer Schering v. Barr

## □ Claim

□ **Oral contraceptive containing micronized drospirenone (Yasmin®)**

## □ Prior Art

□ **Drospirenone was known as a poorly water-soluble, acid-sensitive compound with contraceptive effects**

□ **Micronization improves the solubility of poorly water soluble drugs**



# Bayer Schering v. Barr

## □ Court's Rationale

- The prior art would have funneled the formulator toward two options (enteric coating and micronization) who would not have been required to try all possibilities in a field unreduced by the prior art
- The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill

## □ Holding

- Patent invalid – formulation obvious



# Final Score

- **Non-Obvious: 7**
- **Obvious: 7**





# Highlights and Guidance

- **When inconsistencies occur between the specification and other evidence, the specification may be considered to be more probative**
- **Arguments that the prior art is above the level of ordinary skill may not be persuasive**
- **Scope of claim impacts a finding of obviousness**



# Highlights and Guidance

- **Context of disclosures in a prior art document may suggest an obvious embodiment**
- **Recognition that stereoisomers may exhibit different properties may not be sufficient evidence of obviousness if prior art does not teach which results may ensue or how to separate any given enantiomer**



# Highlights and Guidance

- **Structural relationships often provide the requisite motivation to modify known compounds to obtain new compounds**
- **An obviousness rationale based on structural similarity may depend on a preliminary finding that one of ordinary skill in the art would have selected the prior art compound as a lead compound**



# Highlights and Guidance

## □ Obvious To Try

- **An invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art (Bayer v. Barr at 1347)**
  
- **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,” an invention would not have been obvious. (Bayer v. Barr at 1347)**



# Highlights and Guidance

## □ Obvious To Try

- **An invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution (Bayer v. Barr at 1347)**
  
- **A finding of obviousness would not obtain where "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" (Bayer v. Barr at 1347)**



# Thank You!

- **jean.witz@uspto.gov**
- **571-272-0927**