

Trends and Strategies for Obtaining Patents; Is the Patent Office Becoming the Rejection Office?

Presented by
Chris Lewis
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Patent Office = Rejection Office?

The Data

- Between 1961 and 1984
 - Patent applications varied between 70,000 to 100,000
 - Patents issued hovered around 50,000
- Between 1984 and 2005
 - Patents tripled to 150,000
 - Patent applications nearly quadrupled to 380,000
- The Board of Patent Appeals and Interferences
 - Affirmed between 35 and 50% before April, 2007;
Affirmed nearly 60% thereafter
 - Reversed between 35 and 55% before April, 2007;
Reversed between 25 and 25% thereafter

Correlation or Causation?

Why is this Happening?

Who's to Blame?

- Silly Patents - The Cat, the Cook, and the Lawyer
- Stifling Competition with Invalid Patents
- Need for Affordable Healthcare
- Blame it on the Press and Politicians
It all makes for a good story

Roadmap of Talk

- Basis of patentability
- Supreme Court weighs in
- Federal Circuit's flirtations
- The PTO tries to change the rules
- The "Rules" have changed, so how do we adapt?

Basis for Patentability

High Level Requirements

- Useful
- New
- Non-Obvious
- Adequately described/"enabled"

Find a Distinction in the Claim

- Claim:
A composition comprising a zeolite and a catalytic metal comprising platinum supported on the zeolite.
- Reference:
Discloses rhodium on zeolite
- New?
Yes, reference does not teach platinum

The Difference cannot be a Mere Obvious Modification

- Same facts as before
- A second reference teaches that platinum has improved activity over rhodium for the disclosed reaction
- Obvious?
At least "*prima facie*" obvious

The Examiner's Approach pre-KSR

The "Prima Facie" Obviousness Case

- References, as combined, disclose all of the claim limitations
- Teaching, suggestion, or motivation to combine the references
- Reasonable expectation of success that, upon combination, the invention would work

Holdings in *KSR v. Teleflex*

- Do not rigidly apply the “TSM” test
- Any need or problem can provide a reason for combining references in the field
- Not limited to be led to only those elements that solve the “primary purpose” of a patent
- Obvious to try might be enough
- Still important to find a “reason” for combining the references

Federal Circuit's Flirtations

Pfizer v. Apotex

- Patent: Besylate salt of amlodipine (blood pressure medication)
- Prior Art: Reference listing various amlodipine salts + Reference reciting benzene sulphonate (besylate) of other drugs
- Dist. Ct.: Not obvious; unexpected solubility, stability, processability

Stop the Press!

- Federal Circuit: Obvious
- Motivation to Combine:
 - Only 53 anions approved by FDA for pharmaceutical salts, but ...
 - Other besylate salt drugs also show improved stability, solubility, and pharmacokinetics
 - Routine to make and test
- Expectation of Success:
 - New salt derived from finite, known choices
 - No enhanced therapeutic efficacy or reduced toxicity
- No unexpected properties shown (same as other besylate salt drugs)

The PTO Tries to Change the Rules

GSK Sues the PTO and Wins

- Limits on the Number of Claims
- Limits on the Number of Continuations/RCEs
- Reporting Requirements and the “Presumption”

So, what do we do now?

Possible Arguments

- Still the best:
References as combined fail to disclose all of the claim limitations
- No reasonable expectation of success/unpredictability
- Secondary Considerations
- Others:
 - Non-analogous art
 - Modification to primary references changes its basis for operation

Arguments after KSR

No reasonable expectation of success

- Similar constituents do not work in similar environments
- Reference expressly discounts possibility the claimed invention would work
- Unpredictable technology area

Arguments after KSR

Unexpected Results

- Prove with evidence, not attorney argument
- Invention has new or unintended use or property (*e.g.*, treats other diseases, better bioavailability, low toxicity, etc.)
- Repeated failures or roadblocks during development
- Materials or methods to produce the invention not well developed or routine

Patent Trends and Conclusions

- Patents
 - Still have their place,
 - Are valued by industry and investors.
- But the trend is, patents
 - Will be harder to obtain,
 - Will be easier to attack,
 - Will have less of a “bang for the buck”
- Nonetheless, protect your worthy assets.

Is the PTO Becoming the R.O.?

THANK YOU!