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

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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 25 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”
Novelty

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
Non-Obviousness

**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
Obviousness

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
Pfizer v. Apotex

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!