

# AVOIDING LANDMINES IN U.S. BIOMED PATENT PROCUREMENT

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# Avoiding Landmines in U.S. BioMed Patent Procurement

- Strategic Thinking – Procurement and Enforcement
- Provide an Adequate Written Description
- Post-Filing Date Evidence
- Non-obviousness – Key Tips After the Supreme Court’s *KSR* Decision
- Avoid Inequitable Conduct
- Proper Use of Provisional Applications



# Strategic Thinking

- A smart patent procurement strategy increases the value of the intellectual property
  - Licensing
  - Sale
  - Enforcement

# Avoiding Landmines in U.S. Biomed Patent Procurement



- Statutory Requirements for Patenting
  - Utility
  - Novelty
  - Non-obviousness
  - Enablement
  - Written Description
  - Best Mode
  - Clear Claims

# Provide an Adequate Written Description



- Literal support for words of the claim is not enough
- Possession of the invention is required
- Not just a requirement for Biomed inventions

# Provide an Adequate Written Description



- *UC Regents v. Eli Lilly*
- Claim to genus of vertebrate DNA encoding insulin but only possessed rat DNA
- Held: generic claim failed to satisfy possession requirement even though human DNA could be readily obtained from rat DNA



# Post-Filing Date Evidence

- May confirm specific statements in the specification with post-filing date evidence if questioned by examiner
- *In re Brana* – may use post-filing date evidence to support statements of how to use the invention
- Should still include as much data as possible
- Many countries do not permit use of post-filing date evidence



# Post-Filing Date Evidence


- May NOT rescue nebulous statements of utility with post-filing date evidence
- *In re Fisher* – DNA sequences alleged to have general uses in carrying out research into the function of genes
- Held: no specific credible utility was described in the specification as filed





# Post-Filing Date Evidence

- Do NOT use post-filing date evidence that suggests inventive skill needed
- *Enzo v. Calgene* – used post-filing date journal articles to confirm that antisense method worked in other species
- Held: cited journal articles were prestigious peer-reviewed publications, suggesting inventive effort was needed to reduce to practice in other species



# Non-obviousness – Key Tips After the Supreme Court’s *KSR* Decision

- Avoid characterizing the invention in the “Background” section of the patent application or by describing objects or problems overcome by the invention
- When appropriate provide fact-based expert opinion to support “unexpected results,” “unpredictability,” or “level of ordinary skill and common sense”
  - *In re Harris* and the substantial evidence rule
  - *Pfizer, Inc. v. Apotex, Inc.* – a disturbing court decision



# Avoid Inequitable Conduct

- The peril of misrepresenting what is included
  - Present tense - prophetic
  - Past tense - working examples in the specification
  - *Hoffman-La Roche v. Pro Omega* – example contained some description in past tense and results stated in present tense
    - Held: could be sufficient to constitute inequitable conduct potentially rendering entire patent unenforceable



# Avoid Inequitable Conduct

- Expert Opinions – even more important post-*KSR* but a significant landmine for an allegation of inequitable conduct
  - Disclose relationship of expert, if any, to company
  - Disclose data adverse to patent strategy to Patent Office

# Proper Use of Provisional Applications



- Not examined
- Priority document
  - Within one-year of filing provisional must file regular U.S. utility patent application, PCT patent application and non-PCT country patent applications if intend to claim priority
- Provisional application filing does not start 20-year patent term
- Can file numerous provisional patent applications during year after first provisional filed and claim priority to all of them

# Proper Use of Provisional Applications



- Does your provisional application satisfy the statutory requirements for patenting?
  - *New Railhead v. Vermeer*
    - Spring 96 - Sale of new Drill Bit
    - Feb. 97 - Provisional Application filed with a general description of the drill bit and its use
    - Spring 97 - CRITICAL DATE
    - Nov. 97 - Utility Application filed claiming priority to the provisional application with specific claims

# Proper Use of Provisional Applications

- Held: Specific Claims Invalid – insufficient written disclosure in the provisional application
- **WARNING – A GENERAL DESCRIPTION IN A PROVISIONAL APPLICATION MAY NOT SUPPORT SPECIFIC CLAIMS IN A LATER FILED NON-PROVISIONAL PATENT!**

# Timeline 1



## Timeline 1a

Provisional Application 1	July 1, 2007
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008

## Timeline 1b

Provisional Application 1	July 1, 2007
Provisional Application 2	December 1, 2007
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008

## Timeline 1c

Provisional Application 1	July 1, 2007
Provisional Application 2	December 1, 2007
Provisional Application 3	March 1, 2008
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008



# Timeline 2



## Timeline 2a

CPA	July 1, 2007
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008

## Timeline 2b

CPA	July 1, 2007
<b>KPA</b>	<b>March 1, 2008</b>
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008

## Timeline 2c

CPA	July 1, 2007
RPA	December 1, 2007
<b>KPA</b>	<b>March 1, 2008</b>
U.S. Regular Application PCT Application Non-PCT Member Country Applications	July 1, 2008



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