

# Prophecies, Predictions and Patents: How Much Data Is Required to Obtain a Patent in the United States

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## Scenario: File or Wait?

- Do you have enough data to file an application?
- Do you file an application now or do you conduct further experiments?
- Do you file a provisional application or a nonprovisional application?

# Requirements For a U.S. Patent

- 35 U.S.C. § 101 (utility)
- 35 U.S.C. § 102 (novel)
- 35 U.S.C. § 103 (nonobvious)
- 35 U.S.C. § 112, first paragraph
  - Written description
  - Enablement
  - Best Mode
- 35 U.S.C. § 112, second paragraph (definiteness, clarity)

# Utility

- Rejections based on lack of enablement more common than lack of utility
- “Specific and substantial utility that is credible”
- Example: Higher standard for methods for curing diseases and methods for preventing diseases
- *In vivo* or *in vitro* data, or similarity to prior art compounds
- Later evidence permitted (e.g., by expert declaration)

## Written Description

- Can claim only aspects for which the inventor demonstrated “possession”
- Requires a “structure, formula, chemical name, or physical properties” or “whatever characteristics sufficiently distinguish it” – Not just function
- Example 17 of USPTO written description guidelines (based on *Univ. of Rochester v. G.D. Searle*): insufficient written description
  - A method for selectively inhibiting POPKIN-2 activity in a patient, comprising administering a compound that selectively inhibits activity of the POPKIN-2 enzyme

# Enablement

- No “undue experimentation” (*Wands* factors)
  - e.g., unpredictability of the art, relative skill of those in the art, presence/absence of working examples
- Expert declaration permitted to rebut prima facie nonenablement
- Working examples are not required (but highly recommended)
  - Prophetic examples are helpful, but carry less weight
  - Working examples especially important in unpredictable arts
- Some inoperable embodiments may be permissible
  - But the application must provide guidance in determining operable/inoperable embodiments without undue experimentation
  - Example: A method of treating Disease X with a compound selected from the group consisting of . . . .

## Enablement (con'd)

- Scope of enablement
  - The claim scope must bear a “reasonable correlation” to the disclosure
  - Example: A formulation for treating Disease X comprising 10-20% of component 1, 10-40% of component 2 and 40-70% component 3
    - If the specification only provides one example (e.g., 15% component 1, 25% component 2 and 60% component 3), then may not be enabled for full scope
    - But enablement may be adequate if:
      - The specification provides multiple examples; or
      - The claim scope is narrowed; or
      - The art is relatively predictable

## Tips For Establishing Enablement

- Draft claims for provisional to evaluate scope
- Use claims of varying scope
- Test representative species, e.g., moieties, solvents, pH, ranges
- Provide as many working examples as possible
- Supplement working examples with prophetic examples when necessary

## Best Mode

- Subjective determination by the inventors of what the best mode is
- Not a problem if you disclose everything
- Does not include production details or commercial details
- Only critical features of the claimed invention
  - Claim:  $A + B \rightarrow C$
  - If one skilled in the art can make or purchase A, then no duty to disclose preferred method of making A
  - If not, then some method of making A is required

# Novelty and Nonobviousness

- Conduct a literature search or patentability search
- Novelty
  - Be familiar with the prior art
  - Draft claims as soon as possible and in view of the prior art
- Obviousness
  - Side-by-side comparisons with closest prior art
  - Use unexpected results to rebut prima facie obviousness
    - Still effective in view of the *KSR* case
    - For some jurisdictions, unexpected results must be presented in the specification as filed

# Filing Objectives and Strategies

- Objective: Obtain the earliest possible filing date
  - Avoid prior art
  - Block competitors
  - Senior party in an interference (the party with the earlier priority date)
- Strategies
  - File a series of provisional applications (e.g., after each experiment)
    - PTO filing fee only \$220
    - Reduces the attorney fees for a nonprovisional application
    - Does not reduce patent term
    - Fast protection of a potential commercial embodiment
  - Use claims to guide further experimentation

## Objectives and Strategies (con'd)

- Beware: experiments must be complete within one year of the first filed provisional application
- Beware: weak provisional applications may provide a false sense of security

## Publication Pitfalls

- A provisional application can be filed the same day as the first day of publication to preserve foreign rights
  - Beware of early on-line publication
  - Dangers of scant provisionals
- A U.S. provisional or nonprovisional application can be filed within one year of publication to preserve U.S. rights
- A continuation-in-part (CIP) should be filed before publication of the parent (for foreign rights) or within one year of publication (U.S. rights)
  - Reduced patent term
  - Priority is limited to subject matter supported by the parent

# Paradigm For Filing An Application

- Inventor conducts a successful experiment
- Inventor submits an invention disclosure
- Claims are drafted
- A first provisional application is filed
- Additional experiments are conducted
- A second provisional application is filed
- File a U.S. nonprovisional and a PCT application within one year from filing first provisional application

Thank you.

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