Enablement Issues in Pharmaceutical Claims

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Overview

- Challenge of Broad Compound Claim
- Compound Enablement Considerations/In re Wands
- Enabled vs. Non-enabled Invention
- Compound Examples
- Support of Disclosure
- Possible Ways to Rebut Rejection
- Composition and “method of use” examples

Typical Compound Claim

- Claims are directed to a broad genus of compounds including “R” groups, variables, and other types of combinations and permutations which are defined around some type of core structure.

  - Example

    - Markush type claim.

    - Multiple variable core – core may be a heterocyclic ring consisting of oxygen, nitrogen, sulphur and carbon atoms in different positional combinations.

Examiner/Applicant Challenge

- How can we limit the scope of the allowed genus of compounds so that it provides reasonable protection for applicant's invention?

- Is there unpredictability/undue experimentation in today's drug discovery?

Examiner/Applicant Challenge

- Drug Discovery has become more advanced and sophisticated in the last 10 years:

  -Combinatorial Chemistry – creating diverse member libraries

  -Drug design using X-ray crystallography and diffraction patterns

  -Recognizing cell surface receptors as key targets

- Drug discovery is one of the most expensive types of inventions; it can cost millions to bring a single new drug to market.

35 U.S.C. §112, first paragraph

- "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

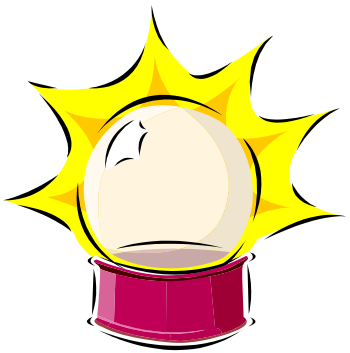
35 U.S.C. §112, first paragraph

- "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."
  - United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (citing Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81,94 (Fed. Cir. 1986))

Enablement Considerations

MPEP § 2164.05

- "In making the determination of enablement, the examiner shall consider the original disclosure and all evidence in the record, weighing evidence that supports enablement against evidence that the specification is not enabling."



Examiner Burden

- To hold that a disclosure is not enabling, the examiner must provide evidence or technical reasoning substantiating those doubts.
- Without a reason to doubt the truth of the statements made in the application, the application must be considered enabling.
  - Additional factors, such as teachings in references, will be available to substantiate any doubts that the asserted scope of enablement is in fact commensurate with the scope of protection sought.

    In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513, (Fed. Cir. 1993); In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

In re Wands, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)

- The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the relevant factual considerations.

Wands Factors/Considerations

- The nature of the invention
- The level of skill in the art
- The state of the prior art
- The predictability or lack thereof in the art
- The amount of direction or guidance present
- The presence or absence of working examples
- The breadth of the claims
- The quantity of experimentation needed

Wands Factors/Considerations

- It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others.

- The examiner's analysis must consider all the evidence related to the Wands factors relevant to the case, and any conclusion that the disclosure is not enabling must be based on the evidence as a whole.

Enabled vs. Non-enabled Invention

- There may be a scope of enablement issue because there is only a limited subgenus of compounds within the claims which are enabled through sufficient guidance in the specification by way of:

  -working examples

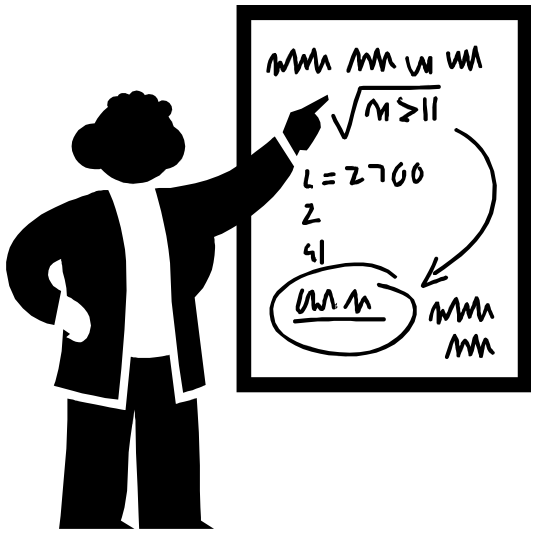
  -preparation of certain compounds

  -description of terminology

  -pharmacological data

Enabled vs. Non-enabled Invention

- The examiner must, by applying the Wands factors, consider whether the scope of the genus is consistent or is not consistent with the enablement support within the original disclosure.



Disclosure in Specification

- The claims are drawn to a broad genus, various unrelated subgenuses and an immense number of species.
- The specification discloses 5 species having the same core possessing a desired activity.
  - Ex.1: Tryptamine compound to treat vascular headaches
  - Ex.2: Tryptophan compound to treat depression
- The specification provides an assay to determine if a compound possesses the desired activity.

Disclosure in the Specification

- The guidance in the specification is not commensurate with the scope of the claim.
- Therefore, it will be difficult to predict what other chemical compounds within the broad genus will possess the desired activity, thus creating an extraordinary amount of trial and error experimentation to identify the active chemical compounds.

Enabled vs. Non-enabled Conclusion

- The minimal guidance and evidence in the disclosure of the specification regarding the genus, subgenus, working examples, assays, along with the fact that the breadth of the instant claim covers an extremely broad genus comprising an immense number of species would be unpredictable and lead a skilled artisan to perform undue experimentation to practice the full scope of the claimed subject matter.

Possible Ways to Rebut Rejection

- Provide additional support and guidance regarding the broad genus.
  - Demonstrate there is more than one subgenus within the broad genus which possesses the desired activity.
- Provide additional working examples to demonstrate that a high percentage of species which fall within the genus, in fact, are biologically active.
    - If needed, provide more assays to demonstrate the activity of the instant compounds.

Composition Example

1. A pharmaceutical composition for preventing liver necrosis comprising compound A.
2. A prophylactic pharmaceutical composition comprising compound A.
3. A pharmaceutical composition comprising compound A.

Method Example

1. A method of treating cancer in a patient comprising administering to said patient a daily unit dose of compound A of 10 mg/kg of body weight for at least 7 consecutive days.
2. A method of preventing prostate cancer comprising administering compound A in a daily dose of 10 mg/kg of body weight for 20 consecutive days.
3. A method of treatment of cancer, liver necrosis, obesity, diabetes, depression, inflammation, and asthma comprising administering compound A in an effective amount.

Take Home Message

- The specification needs to provide sufficient coupled with the level of skill in the art, to enable one to make and use the full scope of the claimed invention.
  - Where the scope of the claims is broad, more guidance, working examples and indications of predictability will be beneficial to support enablement for the full scope of the claimed invention.
  - This support could be a key to effectively responding to a scope of enablement rejection.

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QUESTIONS?

THANK YOU