35 U.S.C. § 112, first paragraph and the Wands Analysis

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35 U.S.C. § 112, first paragraph enablement

- "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)
- A patent need not teach, and preferably omits, what is well known in the art.

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."

Test for Enablement

- Determine of scope of the claimed invention
- Ascertain if the teachings in the specification are commensurate in scope such that one of skill in the art could practice the invention (over its full scope) without undue experimentation

For Example

- If one skilled in the art could obtain such information without undue experiementation, then it is not necessary to specify the dosage or method of use.

- If one of ordinary skill would be able to discern an appropriate dosage or method of use based on knowledge of compounds having similar physiological or biological activity without undue experimentation, this will be sufficient to satisfy 35 U.S.C. 112.

If on the other hand….

- The use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied in the disclosure.

- The information regarding dosage or method of making and using cannot readily be discerned from the prior art and the disclosure, then an inquiry into the level of experimentation necessary to ascertain this information is appropriate.

Standard for Enablement

- The standard for determining whether the specification meets the enablement requirement:
  - Is the experimentation needed to practice the invention undue or unreasonable?
    - Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916)
    - M.P.E.P. 2164.01

Undue Experimentation

- The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue.
  - (In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976))

Undue Experimentation

- There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

  -M.P.E.P. 2164.01

In re Wands, 858 F.2d 731, 8 USPQ2d 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.

Wands Factors

- the nature of the invention
- 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 relative skill of those in the art
- the quantity of experimentation needed

Undue Experimentation and Enablement

- 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 each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

Undue Experimentation and Enablement

- A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.
  - In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Wands Factors

- Provide a framework for analyzing the level of experimentation required of one of skill in the art
- Not all factors are relevant for every enablement determination
- Wands Factor format used in Enzo Biochem Inc. v. Calgene Inc. (CAFC) 52 USPQ2d 1129 has been adopted by the Board of Patent Appeals and Interferences

Predictability and state of the art and the Enablement Requirement

- The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art.

- The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention.
  - In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Predictability and state of the art and the Enablement Requirement (con't.)

- The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification.
- In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling.
-M.P.E.P. 2164.03

The Enablement Continuum

Level or bar for enablement increases

Example A

- Claim 1. A chemical complex having Formula I.
- Claim 2. A pharmaceutical composition comprising the complex of claim 1 and a pharmaceutically acceptable carrier.
- Claim 3. A method of lowering the level of X in a cell or tissue, the method comprising contacting said cell or tissue with the complex of claim 1 in an amount sufficient to lower the level of X in said cell or tissue. (X is a type of oxygen radical)
- Claim 4. A method of treating or preventing a pathology by lowering the level of X in a subject by administering to said subject in need thereof a therapeutically effective amount of the complex of claim 1.
- Claim 5. The method of claim 5 wherein said pathology is selected from the group consisting of Alzheimer's disease, stroke, AIDS, dementia, autoimmune diseases, cancer, septic shock, chronic inflammation and atherosclerosis.

Example A: Facts

- The specification teaches how to make the complex having Formula I.
- The specification contains a single in vitro example in which cells in culture that have been exposed to the complex have lower levels of X relative to control cells.
- The specification does not establish a cause-effect relationship between the level of X and any disease, but teaches that the level of X is associated with pathologies enumerated in claim 5.

Example A: Wands Analysis

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

Example A: Wands Analysis

- The nature of the invention is drawn to the treatment and prevention of pathologies through the administration of a chemical complex.
- The breadth of the claims is broad because it encompasses:
  > both in vitro and in vivo contexts (claims 3-5)
  > both treatment and prevention (claims 4-5)
  > pathologies with vastly different etiologies or unknown etiologies (claim 5)
  > pathologies beyond those in claim 5 (claim 4)

Example A: Wands Analysis

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

Example A: Wands Analysis

- Look to the prior art for:
  > teachings of similar complexes, their role in reducing levels of X and treatment or prevention of pathologies
  > the etiologies of the claimed diseases, discern if they are shared or are divergent or even known
  > information about the levels of X and association with pathologic conditions
  > the level of X causing a disease or a symptom or is it a downstream effect?
  > the ability to predict that an individual will develop one of the claimed diseases (implications for preventative measures)

Example A: Wands Analysis

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

Example A: Wands Analysis

- Look to the specification for:
  > extension of knowledge of the prior art
  > guidance to overcome challenges, obstacles, hurdles recognized in the art
  > working examples: their absence is not fatal; however they are a form of teaching that could enable the skilled artisan to practice the claimed invention

Example A: Wands Analysis

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

Example A: Wands Analysis

- The relative skill of those in chemical and biological arts is high.

Example A: Wands Analysis

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

Example A: Wands Analysis

- The quantity of experimentation will be determined by how well the state of the prior art and its predictability mesh with the teachings of the disclosure.
- If these sources of knowledge available to the skilled artisan do not complement each other, then the skilled artisan must resort to empirical experimentation to practice the claimed invention, which could be undue (because of the factors discussed above).

Example A: Wands Analysis

- Consideration of all the evidence leads to a determination for enablement
- Possibilities for Example A, claims 3-5:
  > Claim 3 may only be enabled for in vitro embodiments
  > Claims 4-5 may only be enabled for treatment of only those diseases in which there is a cause/effect nexus between the levels of X and the disease (higher than mere association)
  > Claims 4-5 may only be enabled for prevention of those diseases for which the skilled artisan can appropriately identify who will develop the disease in the future.

Example B

Claim 1. A viral vector comprising:

a virus comprising a cell binding receptor on the surface thereof and a gene of interest, not normally present in the virus, inserted within the DNA of the virus.

Claim 2. A pharmaceutical composition comprising a therapeutically effective amount of the vector of claim 1 and a pharmaceutically acceptable carrier.

Claim 3. A method for introducing a gene of interest into a cell comprising contacting said cell with the vector of claim 1.

No limitation of Use

- When a product claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection based upon a lack of enablement.

Example B (con't)

- The specification discloses an in vitro use for the viral vector of claim 1 and clearly discloses how to make and use the viral vector in the in vitro environment. Since claim 1 does not recite any environment of use, only one enabled use covering the scope of the claim is needed to enable the claim. Therefore, the disclosure with respect to the in vitro use of the viral vector is sufficient to enable claim 1 and it would be inappropriate to include claim 1 in a rejection under 35 U.S.C. 112, first paragraph. (Emphasis added).

Example B (con't)

- What about claim 3?
- The scope encompasses both in vitro and in vivo methods.
- A Wands analysis is required to determine enablement or scope of enablement.

Intended Use Limitation

- When a compound or composition is limited by a particular use, enablement of that claim should be evaluated based on that limitation.

See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Example C

- Consider the following….

> A viral vector for use in gene therapy comprising:
a virus comprising a cell binding receptor on the surface thereof and a gene of interest, not normally present in the virus, inserted within the DNA of the virus.

> A viral vector comprising:
a virus comprising a cell binding receptor on the surface thereof and a therapeutic gene of interest, not normally present in the virus, inserted within the DNA of the virus.

> A viral vector for delivering a gene of interest to a cell comprising:
a virus comprising a cell binding receptor on the surface thereof and a gene of interest, not normally present in the virus, inserted within the DNA of the virus.

Example C (con't)

- Each of the claims on the previous slide contain an intended use:
  - > gene therapy
  - > expression of a therapeutic gene
  - > delivery of a gene of interest into a cell
- The Wands factor analysis continues with determining the scope of the claims.

Example D

- A method for preventing a symptom of herpes simplex virus (HSV) infection in an individual who has been exposed to HSV, comprising administering a composition comprising an immunostimulatory oligonucleotide sequence in an amount sufficient to prevent a symptom of HSV infection.

Example D (con't)

- Facts:
  - >Some Immunostimulatory oligonucleotide sequences (CpG) are known in the art and are presented in the specification
  - >Specification presents a working example using the art accepted guinea pig model for HSV infection
  - >Art indicates that the guinea pig model, while accurate for studying the development of HSV infection, is not predictive of CpG oligonucleotide sequences that will stimulate an immune response in human individuals

Example D (con't)

- Enablement determination through the Wands factor analysis may turn on less than all factors
- Here, the specification exemplifies an appropriate animal model…on the other hand, there is evidence that this model is not predictive of therapeutic results
- Other considerations include role of immune responses stimulated by immunostimulatory oligonucleotide sequences (CpG) resp in prevention as opposed to treatment
- The enablement determination balances all of these considerations.