

# Pharmaceutical Composition Claims and Enablement



Robert J. Hill, Jr.

Quality Assurance Specialist

Technology Center 1600

703-308-4314

[Robert.Hill@uspto.gov](mailto:Robert.Hill@uspto.gov)



## MPEP 2164.01(c)

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



# Example 1

- Claim:
- “A composition for use in treating Alzheimer’s Disease in humans comprising compound X.”



## Example 2

- Claim:
- “A pharmaceutical composition comprising compound X.”



# Pharmaceutical

- Steadman's Medical Dictionary (24<sup>th</sup> Edition, 1982)
- “pharmaceutical” means “relating to pharmacy or to pharmaceuticals”



# Pharmacy

- Steadman's Medical Dictionary (24<sup>th</sup> Edition, 1982)
- 1. The practice of preparing and dispensing drugs.
- 2. A drugstore.
- **Clinical p.**, a branch of p. practice that emphasizes the therapeutic use of drugs rather than the preparation and dispensing of drugs.



# Drug

- Steadman's Medical Dictionary (24<sup>th</sup> Edition, 1982)
- A therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease in man and animal.



# Drug

- Ansel et al (Pharmaceutical Dosage Forms and Drug Delivery Systems, Seventh Edition)
- An agent intended for use in the diagnosis, mitigation, treatment, cure, or prevention of disease in humans or in other animals.





# Pharmaceutical Use

- A working definition:
- Any use, other than as food, wherein a substance is used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals.



# Pharmaceutical Use Examples

- Administering vitamin supplements (preventing disease)
- Using labeled antibodies for *in vivo* imaging (diagnosing disease)
- Administering a substance to alleviate a symptom of a disease (alleviating or treating disease)
- Administering an antibiotic (curing bacterial infection)



# An Interesting Example

- Administering an antigenic substance:

Vaccination  
versus  
Antibody Collection



## Example 3

- Claim:
- “A pharmaceutical composition comprising protein X.”
- Two disclosed uses for compound X:
  - Curing skin cancer.
  - Producing antibodies which can then be used in an in vitro assay to diagnose skin cancer.



## MPEP 2164.01(c)

- “In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient”



## Take Home Lesson

- Try to avoid reciting a use in compound/composition claims.
- Make sure there is at least some enabled in vitro use for the compound/composition.



# Enablement

Vs.

# Art Rejection

□ Not necessarily contradictory

- Enablement training materials
- Part III.C.
- <http://www.uspto.gov/web/offices/pac/dapp/oppd/1pecba.htm>

□ Breathe life and meaning?



## Example 4

- Claim:
- “A composition for use in curing Alzheimer’s Disease in humans comprising compound X.”





## Take Home Lesson (Reprise)

- Try to avoid reciting a use in compound/composition claims.
- Make sure there is at least some enabled in vitro use for the compound/composition.