Pharmaceutical Composition Claims and Enablement

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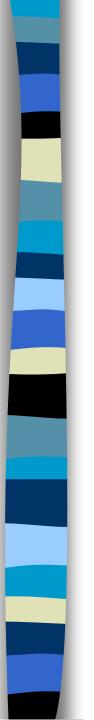
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MPEP 2164.01(c)

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



- Claim:
- "A composition for use in treating Alzheimer's Disease in humans comprising compound X."



- Claim:
- "A pharmaceutical composition comprising compound X."



Pharmaceutical

- Steadman's Medical Dictionary (24th Edition, 1982)
- pharmaceutical" means "relating to pharmacy or to pharmaceutics"



Pharmacy

- Steadman's Medical Dictionary (24th Edition, 1982)
- 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 (24th 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



- 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.

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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.

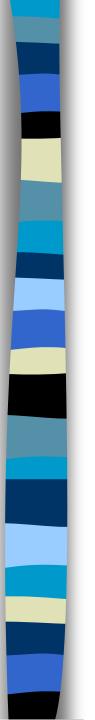


Enablement Vs. Art Rejection

Not necessarily contradictory

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

Breathe life and meaning?



- 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.