



# Red Flag Terminology

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## *35 U.S.C. 112, second paragraph*

- Allows the public to determine exactly what the boundaries of the claimed inventions are.



## *... In light of the specification*

- Although a claim should be interpreted in light of the specification, it is improper to read limitations contained in the specification into the claims.

## ... *In light of the specification*

- Acceptability of the claim language depends on whether one of the ordinary skill in the art would understand what is claimed, in light of the specification.
- There are no *per se* rules. Questions of indefiniteness are determined on a case-by-case basis.

# *Relative language*

- The fact that claim language-including terms of degree- may not be precise, does not automatically render the claim indefinite under 112(2)

# *Red Flag Terms*

## Relative terms:

- “essentially”
- “about” or “at least about”
- “small amount”
- “at least about”
- “substantially”
- “not less than about”
  - “m is *not less than about 5*” or “wherein the temperature range is comprising at least about 90° C”
    - May reject under 112, 2nd

# *Red Flag Terms, continued*

## Metabolite(s)

- “A compound of formula I ... and its metabolites, solvates or salts thereof.”
  - May reject under 112, first and/or second paragraph

## Residue

- “B is a residue capable of binding to a compound.”
- “Y is a residue of an azole compound.”
- “R<sub>2</sub> is an alkyl residue.”
  - May reject under 112

## *Red Flag Terms, continued*

- Analogues thereof
- Derivatives thereof
- Or derivatives or analogues thereof
- Derived from
  - “A compound of formula II...and its pharmaceutically acceptable salts *or derivatives* thereof.”
  - “A is *derived from* a group...”
    - May reject under 112, first and/or second paragraph



## *Red Flag Terms, continued*

- Prodrugs
- Functional derivatives
- Esters
  - “A compound of formula III ... and its *prodrugs, esters, functional derivatives* or pharmaceutically acceptable salts thereof.”
    - May reject under 112, first and/or second paragraph

## *Red Flag Terms, continued*

- Precursor(s)
- Linking group(s)
- Organic moiety
  - “A Ketorolac compound and its precursors”
  - “X is a *linking group* or an *organic moiety*”
    - May reject under 112, first and/or second paragraph
    - Suggestion-define what the linking group consists of.

## *Red Flag Terms, continued*

- Generic phrase followed by a specific phrase
  - “such as”; “including”; “preferably”
  - “for instance”; “for example”
    - “Y is a cycloalkyl group *such as* cyclopropyl.”
    - “R<sub>1</sub> is a halogen atom, *preferably* bromine.”
      - May reject under 112, first and/or second paragraph
      - Suggestion-put specific embodiment (bromine) into a depending claim.

## *Red Flag Terms, continued*

- Markush Language
  - Correct Markush format
  - “X is selected from the group consisting of A, B, C, and (or) D.”
  - “X is A, B, C, or D.” (alternative)
- “Comprising” in Compound Claims
  - “A compound of formula III *comprising* ...” is open ended and is rejected under 112, 2nd.
  - Suggestion- change “*comprising*” to --*consisting of*--.

## *Red Flag Terms, continued*

- Claims drawn to *drugs*
  - Claim 1 is recited as “A compound of formula I consisting of ...”
  - Claim 7 is recited as “A *drug* of formula I consisting of ...”
    - Considered substantial duplicate claim

## *Red Flag Terms, continued*


- Non-statutory “**USE**” claims
  - “Use of a thiazoline compound for a fibrinogen receptor antagonist.”
  - “Use of a thiomorpholine compound for a pharmaceutical preparation.”
    - Reject under 101 and 112, first paragraph



## *Take Home Message*

*The claims will be read in light of the specification to determine proper enablement, support and description of the claimed language.*

*This can be achieved by providing sufficient guidance in the specification on the claim terminology, either by presenting examples, properly defining phrases and terms and/or referring to journal articles.*



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