

# Four Weeks to Go – Are You Current With Recent USPTO Rule Changes?

November 19, 2008

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## ■ Speakers:

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## Written Description (1)

- Source Material
  - Written Description Guidelines (“WDG”) (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001) available at <http://www.uspto.gov/web/menu/current.html#register>
  - New Written Description Training Materials (“NWDG”), Revision 1 of the Written Description Training Materials, posted April 11, 2008, available at <http://www.uspto.gov/web/menu/written.pdf>

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## Written Description (2)

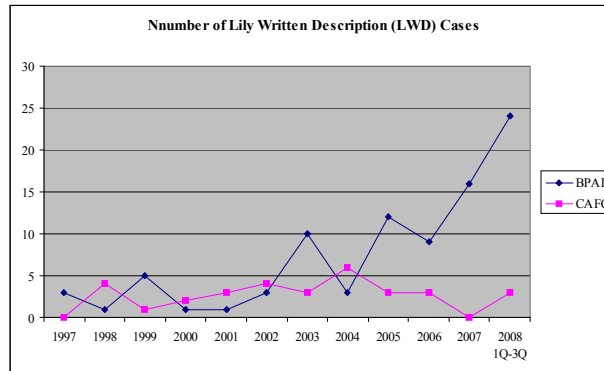
- The Written Description Requirement presented by John LeGuyader, Director Technology Center, 1600,
  - West Coast Road Show 2008, November 12, 2008

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## New Guidelines

Incorporates principles of recent case law into examination



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## Overview of Revised Guidelines (1)

- Evaluation of Priority Benefit for Claimed Subject Matter
- Evaluation of New Matter
- Claiming DNA by Partial Structure or Homology and/or Function

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## Overview of Revised Guidelines (2)

- Claiming Proteins by Partial Structure or Homology and/or Function
- Claiming Antibodies
- Combined WD/Enablement Rejections



## Examiner's Analysis (1)

- Determine scope of each claim and examine claim consistent with broadest interpretation
- Review specification for support for each claim element
  - Factors: Actual or construction reduction to practice; methods to carry out the claimed invention throughout its full scope; level of skill and knowledge in the art, including predictability in the art



## Examiner's Analysis (2)

- Each claim element must be explicitly or implicitly supported in the specification
- Description as filed is presumed adequate
- To rebut presumption, Examiner must provide reasoned basis. Unsupported allegation of unpredictability in the art is insufficient



## DNA Claims (1)

- Claim 1: An isolated DNA comprising SEQ ID NO. 1.
  - Interpreted as SEQ ID NO. 1 and additional sequences or elements upstream and downstream to SEQ ID NO. 1.
    - Can be EST, complete ORF, conserved domain of genus
  - No WD issue if SEQ ID NO. 1 is provided in the specification



## DNA Claims (2)

- DNA claimed by percent identity or encoding a specified protein or polypeptide, where the sequence of the protein or polypeptide is known
- No WD issue because only a limited number of codons can encode a specific amino acid and/or with the aid of computer, one could identify all nucleic acids that encode a polypeptide



## DNA Claims (3)

- Claims to a genus of isolated DNAs that are linked by a partial structure and a common function
  - Examples:
    - An isolated DNA that encodes a polypeptide comprising SEQ ID NO. 2, wherein the polypeptide has activity X.
    - An isolated DNA encoding a polypeptide having at least 80 % amino acid sequence identity to SEQ ID NO. 2, wherein the polypeptide has activity X.
    - An isolated allele of the DNA encoding a polypeptide having activity X.



## DNA Claims (4)

- WD issues unless there is clearly disclosed structure/function relationship or such structure/function relationship is known in the art
  - Known or disclosed which amino acids are necessary to confer function X as claimed
    - Can be specific domains within a protein that confer function, e.g., binding domain
  - Known or disclosed correlation between allelic variants and coding function



## Protein Claims

- Analysis is similar to DNA claims – need disclosed structure/function relationship to support genus related by function
- Claiming partial protein sequences – don't need complete amino acid sequence – Office acknowledges that biochemical characterization will uniquely identify protein, e.g., apparent MW, binding function, method to isolate full-length protein



## Antibody Claims (1)

- Characterization of the antigen is key
  - No WD issue to antigen whose sequence or identity is well known
  - WD issues arise when claiming antibodies to class of antigens defined by function or homology (e.g., disclose murine antigen but human antigen has not yet been isolated)



## Summary

- Claims are examined consistent with the broadest interpretation
- Must be disclosed or known correlation between structure and function if claimed genus is linked by function
- No per se rules as to how many species are necessary to support a genus





## Chemicals and Pharmaceutical Compounds

- WD is met when the specification either:
  - 1) Literally describes the claimed compound by structure or name, or
  - 2) Inherently describes the claimed compound through a description that establishes that the claimed compound was in possession of the applicant as of the filing date of the application

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## Chemicals and Pharmaceutical Compounds

- **Factors to Consider:**
  - Complete or partial compound structure
  - Physical or chemical properties
  - Functional characteristics coupled with correlation between function and structure
  - Actual reduction to practice
  - Level of skill and knowledge in the art
  - Predictability in the art

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## Chemicals and Pharmaceutical Compounds

### ■ Inherent Written Description:

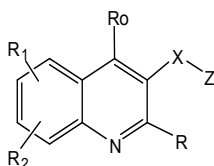
- A process that describe the preparation of only one of two possible stereoisomers (the 6- $\beta$ -methyl) provides WD of the 6- $\beta$ -methyl isomer even if applicant did not know of configuration when filed and did not name the isomer because the process only produced one isomer. *Petisi v. Rennhard*, 363 F.2d 903 (C.C.P.A. 1966)
- Post filing data (Rule 132 Dec) may be used to support a compound having a 16- $\alpha$ -hydroxy steroid that was not disclosed in the spec. because the product is an "inherent characteristic" of the compound. *In Re Magerlein*, 346 F.2d 609 (C.C.P.A, 1965)

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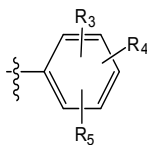
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## Chemicals and Pharmaceutical Compounds

Wattanas Genus:

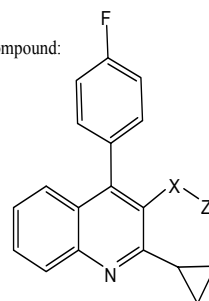


R and R<sub>0</sub> = C<sub>1-6</sub>alkyl, C<sub>3-7</sub>cycloalkyl or



R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> = H, C<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkoxy, trifluoromethyl, fluoro, chloro, phenoxy, benzyloxy or hydroxy.

Fujikawa Compound:



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## Looking Ahead

- For FY 2009
  - Written Description Examination Guidelines for chemical and pharmaceutical claims
  - Application of In re Bilski to medical diagnostic claims

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## Appeal Rules

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## Why, What, When?

- Rapid increase in the number of appeals, over 6000 expected in 2008
- “More objective rules;” “fewer returned briefs;” and “promote concise and precise writing.”
- Any brief filed on or after December 10, 2008
- *Ex parte* only



## Five Important Changes

- An Appellant can petition for an extension of time both to file a Reply Brief and to request an Oral Hearing
- No supplemental Examiner's Answer therefore, the time for filing a request for oral argument is determined from the date that the Examiner's Answer is mailed
- The issues to be considered on appeal are limited to those that the Appellant raises in the Appeal Brief
- The Examiner's Answer to the Appeal Brief may not include new grounds of rejection
- There are strict new requirements for the **Appeal Brief**, the Reply Brief, and the Request for Rehearing.



## Content of Appeal Brief §41.37(e)

- (1) Statement of real party of interest - §41.37(f)
- (2) Statement of related cases - §41.37(g)**
- (3) Jurisdictional statement - §41.37(h)**
- (4) Table of contents (TOC) - §41.37(i)**
- (5) Table of authorities - §41.37(j)**
- (6) [Reserved]
- (7) Status of amendments - §41.37(l)
- (8) Grounds of rejections to be reviewed - §41.37(m)
- (9) Statement of facts - §41.37(n)**
- (10) Argument - §41.37(o)**
- (11) Appendix - §41.37(p)-(u)**



## (2) Statement of Related Cases - §41.37(g)

- Old (§41.37(c)(1)(ii)) – “known to appellant, the appellant’s legal representative, or assignee...”
- New – “known to any inventors, any attorneys or agents who prepared or prosecuted the application on appeal and any other person who was substantively involved in the preparation or prosecution of the application on appeal.”



### (3) Jurisdictional Statement - §41.37(h)

- Purpose is to establish jurisdiction of the Board to consider the appeal.
- Must include:
  - A statement of the statute under which appeal is taken
  - The date of the Final Office Action
  - The date the Notice of Appeal was filed
  - The date the Appeal Brief is being filed
  - If applicable, the date an extension of time was requested and the date the request was granted (if known)



### (4) Table of Contents - §41.37(i) & (5) Table of Authorities - §41.37(j)

- Table of Contents
  - Shall list each of the sections required to be in the appeal brief per §41.37(e) with page numbers
- Table of Authorities
  - Must list all cases (alphabetically arranged), statutes, and other authorities used in the appeal brief with the page number(s) where each case, statute, and other authority is cited in the brief



## (9) Statement of Facts - §41.37(n)

- Shall set out the material facts relevant to the rejections on appeal
- Facts shall be supported by a reference to a specific page, line, or paragraph number from a document in the record
- Facts shall be set out in an “objective” and “non-argumentative” manner



## (9) Statement of Facts - Cont'd.

- Should be set out in short declarative sentences (preferably numbered)
- Each declarative sentence should address a single fact
- The facts should address at least:
  - The scope and content of the prior art,
  - Any differences between the claim on appeal and the prior art, and
  - The level of skill in the art



## (10) Argument - §41.37(o)

- Any finding made or conclusion reached by the Examiner that is not challenged will be presumed to be correct
- For each argument, Appellant must identify **where** the argument was made in the first instance or state that the argument has not previously been made
- Examiner Appellant must identify claims argued separately by placing them under a subheading identifying the claim by number



## (10) Argument - Cont'd.

- Any doubt as to whether claims have been argued separately will be resolved against Appellant (i.e., claims will be deemed to have been argued as a group)
- In identifying any point made by the Examiner, Appellant shall refer to a page and, where appropriate, a line or paragraph of a document in the record
- Any claim not included in the “claim support and drawing analysis section” or “means or step plus function analysis section” of the appendix cannot be separately argued





## (10) Argument - Cont'd.

- Unless Appellant plans to separately argue the patentability of a claim, Appellant should not discuss or refer to the claim in the argument section of the appeal brief
- The appeal brief may not incorporate another argument or paper by reference



## (11) Appendix

- Claims section - §41.37(p)
  - Clean copy with status identifiers
- Claim support and drawing analysis section - §41.37(r)
  - Annotated copy of each independent claim and separately argued dependent, i.e. support found in specification in **boldface** between braces ( { } )
- Means or step plus function analysis section - §41.37(s)
  - Annotated copy of each independent claim or separately argued dependent claim which Appellant regards as having a means or step plus function element, i.e. support found in specification in **boldface** between braces ( { } )



## (11) Appendix Cont'd.

- Evidence section - §41.37(t)
  - Only papers entered by the Examiner, i.e. affidavits/declarations, evidence filed prior to and after the notice of appeal
- Related cases section - §41.37(u)
  - Copies of orders and opinions required to be cited in the “statement of related cases” section of the Appeal Brief



## Format Changes of Appeal Brief - §41.37(v) (1), (2) & (4)-(6)

- The entire brief must be double spaced (but not headings, TOC, TOA, signature, cert. of service)
  - Block quotations must be indented and can be 1½ or double spaced
- The font size shall be 14 point, including the font for block quotations and footnotes.
- 30 pages only!
  - §41.(e)(8) grounds of rejection to be reviewed, §41.(e)(9) statement of facts, and §41.(e)(10) argument
  - A request to exceed the 30 page limit must be made by petition 10 calendar days prior to the due date of the brief



## Additional Key Regulations

- Old §41.31(b) that a notice of appeal need not be signed has been removed.
- Examiner's Answer - §41.39
- Reply Brief - §41.41
- Oral Hearing - §41.47
- Rehearing - §41.52
- Sanctions - §41.56



## Practice Considerations

- File as many appeal briefs as possible before the change as new rules will likely increase costs by 30% to 50%!!
- Interview early and often to resolve as many issues as soon as possible.
- Preappeal conferences (According to PTO, only 56.6% of cases in Group 1600 proceed to appeal).
- Consider filing after final responses with all arguments that will be addressed on appeal.
- Strictly adhere to the guidelines for organizing the Appeal Brief even if nothing is to be placed in a section.
- To avoid unnecessarily waiving, address all conclusions reached and findings made by the Examiner.



## Resources

- Federal Register Notice
  - <http://www.uspto.gov/web/offices/com/sol/notices/73fr32938.pdf>
- A special thank you to Paul Hunter and Christopher Kalafut, both of Foley's Madison Office

