35 U.S.C. § 112 Supplementary Examination Guidelines

Biotechnology/Chemical/Pharmaceutical Customer Partnership Meeting

September 13, 2011



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Supplementary Examination Guidelines

- The Supplementary §112 Examination Guidelines were published in the Federal Register on February 9, 2011.
 - See Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. § 112 and for Treatment of Related Issues in Patent Applications, 76 FR 7162 (Feb. 9, 2011), available at http://www.uspto.gov/patents/law/notices/2011.jsp.
 - The corresponding Memorandum to the Examining Corps is available at http://www.uspto.gov/patents/law/exam/memoranda.jsp.



Supplementary Examination Guidelines

- <u>Purpose</u>: Assist the Examining Corps in evaluating claims for compliance with §112, ¶2, and other patentability requirements related to enhancing the quality of patents.
- Goal: Ensure that the scope of any patent rights granted is clear and supported by the invention disclosed to the public.
 - Section 112 is a valuable tool for examiners to accomplish this goal.



Supplementary Examination Guidelines

The guidelines include the following:

- Guidance for determining, under the broadest reasonable interpretation, whether the metes and bounds of the claimed invention are clear under §112, ¶2;
- Instructions for rejecting non-compliant dependent claims under §112, ¶4 as unpatentable rather than objecting to the claims;
- Factors to be considered when examining functional claim language to determine whether the claim scope is clear and precise under §112, ¶2;
- Guidance for determining whether a claim limitation invokes §112, ¶6 and whether a §112, ¶6 limitation complies with §112, ¶2;



Supplementary Examination Guidelines

The guidelines include the following (cont.):

- Supplemental information for examining computer-implemented functional claim limitations with respect to written description and enablement requirements under §112, ¶1, and rejections under §§102 and 103;
- Guidance for examining Markush claims with respect to the definiteness requirement under §112, ¶2, and a judicially based rejection as an "improper Markush grouping"; and
- Compact prosecution procedures for resolving §112 issues.



Step I. Interpreting the Claims – Broadest Reasonable Interpretation



Broadest Reasonable Interpretation

Give the claim the **broadest reasonable interpretation** (BRI) consistent with the specification as it would be interpreted by one of ordinary skill in the art.

- Why do we apply BRI?
 - An application claim can be amended and interpreted during prosecution to make the meaning clear, but a patent claim is fixed and, when possible, will be interpreted in favor of validity.
 - As a result, the USPTO uses a lower threshold of ambiguity for definiteness.



Broadest Reasonable Interpretation (cont.)

- Why does it matter?
 - Giving a claim its BRI during prosecution will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified.
- What does BRI mean?
 - The interpretation should be based on what is reasonable, not what is possible, and should be viewed in light of the specification and how one of ordinary skill in the art would interpret it.



Broadest Reasonable Interpretation (cont.)

- Where do you start?
 - Claim terms should be given their plain meaning unless the application clearly sets forth a different definition in the specification as filed.
 - Plain meaning means the ordinary and customary meaning given to that term by those of ordinary skill in the art at the time of the invention.
 - Sources of the meaning include words of the claims, specification, drawings, and prior art.
 - See also MPEP § 2111.



Step II. Determining Whether Claim Language Is Definite



Determining Whether Claim Language Is Definite

- How is it determined whether a claim clearly and precisely defines the patent rights?
 - Use the definiteness requirement of §112, ¶2.
 - This is a statutory requirement and cannot be waived.
 - An indefinite claim is not patentable, and therefore it must be rejected under §112, ¶2.



Determining Whether Claim Language Is Definite (cont.)

- The test is whether, under the BRI, the metes and bounds of the claimed invention are clear.
 - Can you draw the boundary between what is covered by the claim and what is not covered?
 - A boundary cannot be drawn if there is more than one reasonable interpretation of what is covered.
 - This means that it is unclear as to where the boundary should be drawn.



Determining Whether Claim Language Is Definite (cont.)

- Do not confuse breadth with indefiniteness.
 - For example, a genus claim covering multiple species is broad, but not indefinite because of its breadth, which is otherwise clear.
 - However, a genus claim that can be interpreted in such a way that it is not clear which species are covered would be indefinite (e.g., there is more than one reasonable interpretation of which species are included in the claim).



Determining Whether Claim Language Is Definite (cont.)

Areas where questions of definiteness commonly arise:

- Terms of degree
- Subjective terms
- Correspondence between specification and claims
- Improper dependent claims
- Functional claiming
- Lack of corresponding structure for a §112, ¶6 limitation
- Markush groups



Terms of Degree



Supplementary §112 Examination Guidelines Terms of Degree

- When a term of degree is used, there must be some standard for measuring that degree:
 - The specification should provide some standard for measuring that degree; or
 - There should be a standard that is recognized in the art for measuring the meaning of the term of degree.
- Without a standard for measuring, the claim is indefinite because the boundaries cannot be determined.



Terms of Degree (cont.)

- An appropriate applicant response to an indefiniteness rejection based on a term of degree includes, for example:
 - Demonstrating that the specification provides examples or teachings that can be used to measure a degree even without a precise numerical measurement; or
 - Submitting a declaration under 37 CFR 1.132 showing examples that meet the claim limitation and examples that do not.



Subjective Terms



Supplementary §112 Examination Guidelines Subjective Terms

- Similar to a term of degree, a subjective term must be objectively measureable.
- The specification should provide some objective standard for measuring the scope of the term.
- <u>Example</u>: a claim recites a computer interface screen with an aesthetically pleasing look and feel.
 - The claim is indefinite because the term "aesthetically pleasing" depends solely on the subjective opinion of the person selecting the features to be included on the interface screen.



Subjective Terms (cont.)

- An appropriate applicant response to an indefiniteness rejection based on a subjective term includes, for example:
 - Evidence that the meaning of the term can be ascertained by one of ordinary skill in the art when reading the disclosure; or
 - An amendment to the claim to remove the subjective term.



Claims Must Find Clear Support in the Specification



Clear Support in the Specification

- Correspondence between the specification and claims is required by 37 CFR 1.75(d)(1).
 - Claim terms must find clear support or antecedent basis in the specification so that the meaning of the terms can be ascertained by reference to the specification.
- To meet §112, ¶2, the meaning of the terms must be readily discernable to a person of ordinary skill in the art.
 - The specification must provide guidance on the meaning of the terms (e.g., by using clearly equivalent terms).
 - The exact terms, however, are not required to be used in the specification.



Clear Support in the Specification (cont.)

- If the claims do not find clear support in the specification, object to the specification.
- If the claim terms have inconsistent or conflicting meaning with the specification, also reject the claim as indefinite under §112, ¶2.



Clear Support in the Specification (cont.)

- An appropriate applicant response to an objection based on lack of support in the specification and/or a rejection based on inconsistency between a claim term and the specification includes, for example:
 - An amendment to the specification to provide clear support or antecedent basis for the claim terms without introducing any new matter; or
 - An appropriate amendment to the claim.



Rejections Under §112, ¶4 for Improper Dependent Claims



Improper Dependent Claims

- Under §112, ¶4, a dependent claim is statutorily required to:
 - Contain a reference to a previous claim in the same application, and
 - Specify a further limitation of the subject matter claimed.
- If it does not satisfy these requirements, the claim should be **rejected** under §112, ¶4, rather than being objected to, and then examined on its merits, as best understood.
- An appropriate applicant response to a rejection under §112, ¶4 includes, for example:
 - Writing the claim in independent form;
 - Making an appropriate amendment to the dependent claim; or
 - Presenting a sufficient showing that the dependent claim complies with the statutory requirements.



Improper Dependent Claims

- An improper dependent claim includes, but is not limited to:
 - 1. A claim that omits an element from the independent claim.
 - 2. A claim that fails to add a limitation to the independent claim.
- Example of an improper dependent claim:
 - 1. A pipe coupling comprising: an elongated cylinder and a nickel fitting secured to the cylinder.
 - 2. The pipe coupling of claim 1, wherein the fitting is metal.

Claim 2 does not further limit claim 1 as metal is less limiting than nickel.



Functional Claiming



Functional Claiming

- Functional claiming means the claim recites a feature using functional terms.
 - Reciting what the feature does rather than what the feature is.
- Permissible when the scope is clear, or when means-plusfunction format is used.
- In functional claiming (not in means-plus-function format), typically some structure will be recited followed by its function.
 - Example: A conical spout (structure) that allows several kernels of popped popcorn to pass through at the same time (function).



- Problems associated with functional claiming:
 - When a claim merely recites a description of a problem to be solved or a function or result achieved by the invention, the boundaries of the claim scope may be unclear.
 - Unlimited functional claim limitations that extend to all means of resolving a problem may not be adequately supported by the written description or may not be commensurate in scope with the enabling disclosure.
 - When the claim does not recite the particular structure that accomplishes the function, all means of resolving the problem may be encompassed by the claim.



- How to determine whether the functional limitation is definite?
 - Highly dependent on the applicant's disclosure and the knowledge of those of ordinary skill in the art.
 - Example: a claim reciting substantially pure carbon black in the form of commercially uniform, comparatively small, rounded smooth aggregates having a spongy or porous exterior.
 - Problems associated with the limitation:
 - 1. Commercially uniform only means the degree of uniformity that commercial buyers desire;
 - Comparatively small has no meaning because no standard for comparison is given;
 - 3. Spongy and porous are synonyms and are not helpful in distinguishing the invention from the prior art.



- Factors useful for determining whether functional language is indefinite include:
 - 1. Whether there is a clear cut indication of the scope of the subject matter covered by the claim;
 - Whether the language sets forth well-defined boundaries of the invention or only states a problem solved or a result obtained; and
 - 3. Whether one of ordinary skill in the art would know from the claim terms what structure or steps are encompassed by the claim.
 - This list is not exhaustive.



Supplementary §112 Examination Guidelines Functional Claiming (cont.)

- Claims that mix apparatus and method limitations (such as functions or actions of a user) are indefinite when the boundaries are unclear.
- Note recent example of In re Katz (Fed. Cir. 2011):
 - Claim: A system with an interface means for providing automated voice messages...to certain of said individual callers, wherein said certain of said individual callers digitally enter data.
 - The italicized claim limitation is not directed to the system, but rather to actions of the individual callers, which creates confusion as to when direct infringement occurs. The claim is indefinite.



- An appropriate applicant response to an indefiniteness rejection is to resolve the ambiguity by, for example:
 - Using a quantitative metric (e.g., numeric limitation for a physical property) rather than a qualitative functional feature;
 - 2. Demonstrate that the specification provides a formula for calculating a property along with examples that meet the claim limitation and examples that do not;
 - 3. Demonstrate that the specification provides a general guideline and examples sufficient to teach a person skilled in the art when the claim limitation is satisfied; or
 - 4. Amend the claims to recite the particular structure that accomplishes the function.



Means-Plus-Function Claim Limitations and Other Non-Structural Claim Terms that Invoke §112, ¶6



Claim Limitations Under §112, ¶6

For any claim limitation that recites a term and associated functional language:

- 1. Determine, under BRI, whether the limitation invokes §112, ¶6;
 - This is a limitation-by-limitation analysis because §112, ¶6 applies to claim limitations, not claims in general.
- 2. If the limitation invokes §112, ¶6,
 - Interpret the scope of the claim limitation to include the structure specifically disclosed in the specification for achieving the recited function and equivalents to that structure.
- 3. If the specification does not disclose the structure (or sufficient structure) for achieving the recited function of the §112, ¶6 limitation,
 - Reject the claim under §112, ¶2 because the claim scope is indefinite.



Claim Limitations Under §112, ¶6 (cont.)

1. Determining whether the limitation invokes §112, ¶6.

- Why is this important?
 - The BRI of a limitation may change depending on whether §112, ¶6 is invoked.
 - If §112, ¶6 is **not** invoked, the limitation must be interpreted under BRI in light of the specification and the prior art.
 - The scope of the claim is not limited to the specific structure disclosed in the specification.
 - Limitations cannot be imported to the claim from the specification.



- For example, compare "filter" (not invoking §112, ¶6) with "means for separating particulates from a solution" (invoking §112, ¶6):
 - A "filter" may have a broader meaning and thus be anticipated by more prior art.
 - A "means for separating particulates from a solution" may have a narrower meaning when the structure identified in the specification for separating particulates is one specific type of filter, and therefore can only be anticipated by that particular type of filter and its equivalents.



Claim Limitations Under §112, ¶6 (cont.)

How to make this determination?

- A. Does the claim limitation use the phrase "means for" or "step for" coupled with functional language?
 - If it does, there is a strong presumption that §112, ¶6 is invoked.
 - This presumption is overcome if the limitation includes the structure necessary to perform the recited function.
 - Thus, a claim limitation will invoke §112, ¶6, if:
 - It uses the phrase "means for" or "step for,"
 - The phrase is modified by functional language, and
 - The limitation does not include the structure necessary to perform the claimed function.



Claim Limitations Under §112, ¶6 (cont.)

- B. Does the claim limitation use a **non-structural term** (a term that is simply a substitute for "means for") coupled with functional language?
 - <u>For example</u>, the following can be non-structural terms used in place of "means for":

mechanism for

element for

- module for

member for

device for

apparatus for

- unit for

machine for

component for

system for

- A claim limitation will invoke §112, ¶6, if:
 - It uses a non-structural term without any structural modifier,
 - The term is modified by functional language, and
 - The limitation does not include the structure necessary to perform the claimed function.



- C. What if the claim limitation uses a **structural modifier** before the non-structural term?
 - A limitation will **not** invoke §112, ¶6 if it uses a **structural modifier** before the non-structural term.
 - For example, "filter system for filtering particulates" will **not** invoke §112, ¶6 because the non-structural term "system for" is preceded by the modifier "filter" which has a known structural meaning in the art.
 - A limitation may invoke §112, ¶6, however, if it uses a nonstructural modifier before the non-structural term.
 - <u>For example</u>, non-structural terms (*e.g.*, "mechanism," "element," and "member") preceded by modifiers that do not have any known structural meaning in the art may invoke §112, ¶6: "colorant selection mechanism," "lever moving element," and "moving link member."



- D. What if the claim limitation uses a **structural term** coupled with functional language?
 - A limitation will **not** invoke §112, ¶6, if it uses a structural term.
 - For example, the following structural terms have been found not to invoke §112, ¶6:
 - circuit for
 - detent mechanism
 - digital detector for
 - reciprocating member
- connector assembly
- perforation
- sealingly connected joints
- eyeglass hanger member



Claim Limitations Under §112, ¶6 (cont.)

E. How to determine whether a claim term associated with the function is structural?

- Check whether the specification provides a description of the claim term that would be sufficient to inform one of ordinary skill in the art that the term denotes structure.
- Determine whether there is evidence that the term has achieved recognition as a noun denoting structure – look at general and subject matter specific dictionaries.
- Evaluate whether there is evidence in the prior art that the claim term has an art-recognized structure to perform the claimed function.



Claim Limitations Under §112, ¶6 (cont.)

2. Identifying the corresponding structure disclosed in the specification.

- Why is this important?
 - Under the BRI, the claim scope of a limitation that invokes §112,
 ¶6 is limited to the structure specifically disclosed in the specification for achieving the recited function and equivalents to that structure.
- How to identify the corresponding structure in the specification?
 - Review the specification from the point of view of one skilled in the art.
 - Determine whether the specification clearly links the structure to the claimed function.
 - Determine whether the disclosure contains sufficient structure to perform the claimed function.



- 3. If the specification lacks the corresponding structure (or sufficient structure), the claim must be rejected as indefinite under §112, ¶2.
 - Why is this important?
 - If the specification does not disclose sufficient structure to perform the claimed function of a §112,
 ¶6 limitation, the claim scope will not be clear, and will amount to pure functional claiming.
 - A bare statement that known techniques can be used is not sufficient to support a §112, ¶6 limitation.



- A rejection under §112, ¶2 is also appropriate:
 - When it is unclear whether a claim limitation invokes §112, ¶6; or
 - When the specification fails to clearly link the corresponding structure to the claimed function of a §112, ¶6 limitation.
 - A requirement for information under 37 CFR 1.105 may be made to require the identification of the corresponding structure.



Supplementary §112 Examination Guidelines Claim Limitations Under §112, ¶6 (cont.)

- What if the preamble recites the phrase "means for" coupled with functional language?
 - A rejection under §112, ¶2 is appropriate if it is unclear whether the preamble is reciting a meansplus-function limitation or whether the preamble is merely stating an intended use.
 - However, if a structural or non-structural term is merely used with the word "for" in the preamble, the preamble should not be construed as a limitation invoking §112, ¶6.



Markush Claims

- 1. Indefiniteness Rejection
- 2. "Improper Markush Grouping" Rejection



Supplementary §112 Examination Guidelines Markush Claims

1. Indefiniteness Rejection under §112, ¶2

- A "Markush" claim recites a list of alternatively useable species.
 - It is commonly formatted as: "selected from the group consisting of A, B, and C," but this format is not a requirement.
- Problem arises when a Markush group is so expansive that persons skilled in the art cannot determine the metes and bounds of the invention.
- The test is whether one of ordinary skill can envision all of the members of the Markush group.
- If not, the Markush claim may be rejected as indefinite under §112, ¶2 because the metes and bounds of the claim are unclear.



Supplementary §112 Examination Guidelines Markush Claims (cont.)

2. "Improper Markush Grouping" Rejection

- A Markush claim may be rejected under the judicially approved "improper Markush grouping" doctrine when the claim contains an improper grouping of alternatively useable species.
- A claim contains an "improper Markush grouping" if:
 - The species of the Markush group do not share a "single structural similarity,"
 - Meaning they do not belong to the same recognized physical or chemical class or same art-recognized class, or
 - 2. The species do not share a common use,
 - Meaning they are not disclosed in the specification or known in the art to be functionally equivalent.
 - If 1 or 2 apply, then an "improper Markush grouping" rejection should be made.



Supplementary §112 Examination Guidelines Markush Claims (cont.)

- An appropriate applicant response includes:
 - Amending the claims to include only the species that share a single structural similarity and a common use, or
 - Presenting a sufficient showing that the species in fact share a single structural similarity and a common use.
- An election of species can be required in order to conduct examination directed to a species or group of indistinct species.
 - If the species or group of indistinct species is not found in the prior art, extend the search to the species that share a single structural similarity and common use.



Step III. Compact Prosecution Procedures for Resolving §112 Issues



Resolving Indefinite Claim Language

A. Establish a Clear Record

- The Office actions and responses should represent a clear and accurate picture of the Office's consideration of patentability.
 - When making a rejection under §112, ¶2 based on a claim term or phrase that is indefinite, clearly communicate the findings and reasons that support the rejection by identifying the term or phrase and explain why it is indefinite.
 - For example, explain why the meaning of a term is uncertain, the boundaries of the limitation are not clear, or the limitation is too subjective to be measured. See also MPEP § 2173.05.



Supplementary §112 Examination Guidelines Resolving Indefinite Claim Language (cont.)

- Focus on the threshold requirements of clarity and precision to make a rejection.
 - If the examiner believes more suitable or precise language is available but the claim does not cross the threshold of being indefinite, a suggestion of improved language should be made rather than a rejection.
 - If more information is necessary to determine clarity, a requirement for information under 37 CFR 1.105 may be appropriate. See MPEP § 704.10.



Supplementary §112 Examination Guidelines Resolving Indefinite Claim Language (cont.)

- If a rejection is made and overcome, ensure that the record is clear as to how the indefiniteness has been resolved.
 - If the record does not speak for itself, add clarifying remarks in the next action or notice of allowability.
- If the record is not clear upon allowance, prepare reasons for allowance to explain, for example, a claim interpretation that may not be readily apparent or an interpretation discussed during an interview.
 - Ensure that unwarranted interpretations are not placed upon the claims.



Resolving Indefinite Claim Language (cont.)

- State on the record which claim limitations are being interpreted under §112, ¶6.
 - If the phrase "means for" or "step for" are not used, explain why the claim limitation is invoking §112, ¶6.
 - For example, identify the claim limitation that uses a nonstructural term coupled with functional language.
 - Identify the corresponding structure disclosed in the specification that performs the claimed function if it is not readily apparent.
 - At the time of allowance, ensure that any §112, ¶6 limitations have been clearly identified as such and an appropriate explanation has been provided, or include an explanation in the reasons for allowance.



Resolving Indefinite Claim Language (cont.)

B. Practice Compact Prosecution

- Clearly articulate all appropriate rejections early in the prosecution.
- Review each claim for compliance with every statutory requirement for patentability and reject each claim on all reasonable grounds to avoid piecemeal examination.
- When making both a §112, ¶2 rejection and a rejection over prior art, state on the record how the claim term or phrase that is indefinite is being interpreted.



Resolving Indefinite Claim Language (cont.)

- Open lines of communication, especially when indefiniteness can be resolved through an interview.
 - Issues of clarity and interpretation of claim scope can lend themselves to resolution through an examiner-initiated interview when appropriate.
 - Record substance of interview, for example why a claim term is not clear, why a term is inconsistent with the specification, why the term does or does not invoke §112, ¶6, and what are the proposed claim amendments.



For more information:

- Examiner Training Materials (e.g., Best Practices in Compact Prosecution and Effective Interview Practice) are available at http://www.uspto.gov/patents/law/exam/exmr_training_material s.jsp.
- Memoranda to the Examining Corps are available at http://www.uspto.gov/patents/law/exam/exmr_training_material s.jsp.
- Recent Published Examination Guidelines are available at http://www.uspto.gov/patents/law/notices/2010.jsp and http://www.uspto.gov/patents/law/notices/2011.jsp.



Thank You