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A Systematic Approach to 112(b)

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Objective

To provide a systematic approach to claim language analysis (BRI) and writing a rejection for compliance with 35 U.S.C. 112(b).

- Unless indicated otherwise all examples herein are hypothetical.
- Examiners are **NOT** required to use these methods of analysis to determine if 112(b) issues exist or to write up 112(b) rejections.
- Examples of indefiniteness sometimes do not require the systematic analysis such as that which is advocated here.
- Examples of limitations which are *per se* indefinite:
 - A claim dependent on a canceled is *per se* indefinite without any further analysis. See MPEP § 608.01(n) Dependent Claims [R-10.2019] Subsection V.
 - A method claim without a method step. – MPEP § 2173.05(q):

Systematic method

The systematic method presented here has three steps:

- **First: Analyze the claim language using the broadest reasonable interpretation (BRI).**
 - During examination, a claim must be given its broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art.
 - Because the applicant has the opportunity to amend claims during prosecution, giving a claim its broadest reasonable interpretation will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified. See MPEP 2173.01 (I)
- **Second: Determine if the metes and bounds of the claims are clear.**
 - During examination, after applying the broadest reasonable interpretation to the claim, if the metes and bounds of the claimed invention are not clear, the claim is indefinite and should be rejected.
- **Third: When writing the rejection.**
 - The examiner must provide a **sufficient and clear explanation** on the record as to why the claim limitations do not meet the requirements of the statute.

Why consider a systematic method?

- The systematic method taught here focuses on providing a clear record and does not rely on trying to fit a claim into a teaching example.
- The method helps the examiner to:
 - Analyzing disclosure and claims for compliance with 35 USC 112
 - Making the records, taken as a whole, reasonably clear and complete.

Indefinite claim language

- A rejection under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, is appropriate based on the examiner's determination that a claim term or phrase is *prima facie* indefinite.
 - Only by providing a complete explanation in the Office action as to the basis for determining why a particular term or phrase used in the claim is **indefinite** will the examiner enhance the clarity of the prosecution history record.
 - The examiner should **provide enough information** in the Office action to permit applicant to make a meaningful response, as the indefiniteness rejection requires the applicant to explain or provide evidence as to why the claim language is not indefinite or amend the claim.
 - **See MPEP 2173.02(III)(A-B) [R-10.2019]**

Training modules

Modules	Examples
1. Antecedent basis	<u>1a</u> , <u>1b</u> , <u>1c</u> ,
2. Breadth vs. indefiniteness	<u>2a</u>
3. Unclear terms/relative terms	<u>3a</u> , <u>3b</u> ,
4. Exemplary language	<u>4a</u>

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A systematic approach to 112(b)

Module 1a

Antecedent basis

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through nanopores and determining by sequencing the nucleotide sequence of the polynucleotide.
5. The method of claim 1 wherein said nanopores comprise substantially identical nanopores.
6. The method of claim 5 wherein said protein nanopores further comprise alpha hemolysin.

Is there an Issue?

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

Is there a clear antecedent basis in the independent claim for the phrase “said protein nanopores” in claim 6?

- Independent claim 1 recites a method of sequencing a polynucleotide by translocating it through nanopores.
- The independent claim makes no mention of any proteins, and none appears to be inherent to the method.
- Dependent claim 6 refers to “said protein nanopores.”

Rule(s):

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

- **MPEP 2173.05(e): Lack of Antecedent Basis [R-07.2015]**
 - “A claim is indefinite when it contains words or phrases whose meaning is unclear. In re Packard, 751 F.3d 1307, 1314, 110 USPQ2d 1785, 1789 (Fed. Cir. 2014). The lack of clarity could arise where a claim refers to ‘said lever’ or ‘the lever,’ where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference.”
- **MPEP 2173.02(II): Threshold requirement of clarity and precision. [R-10.2019]**
 - “If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, is appropriate.

Analysis using BRI

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

Claim 6 refers to “said protein nanopores,” but neither claim 5 nor claim 1, in the dependency chain, refer to protein nanopores or nanopores of any specific kind.

- Under a broadest reasonable interpretation (BRI), words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification.
- The plain meaning of a term means the ordinary and customary meaning given to the term by those of ordinary skill in the art at the time of the invention.
- The ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, drawings, and prior art.

See 2111.01 (I) Plain Meaning [R-10.2019]



Analysis cont.

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein said **protein nanopores** further comprise alpha hemolysin.

The specification teaches:

- [0032] Nanopores used with the invention may be **solid-state nanopores, protein nanopores, or hybrid nanopores** comprising protein nanopores or organic nanotubes such as carbon nanotubes, configured in a solid-state membrane, or like framework.

Analysis cont.

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

- What is the BRI of the term Nanopore?
 - The term nanopore has the art accepted meaning of:
 - a pore or cavity with dimensions of only a few nanometers.
 - There is no definition in the specification that limits nanopores to protein nanopores.
 - The use of the terms in the prior art does not limit the term nanopore.

The conclusion:

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

Based on the analysis what is the examiner's conclusion?

- The term "protein nanopores" lacks antecedent basis.
 - The claim fails to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

What should be in the rejection?

The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

- The examiner should avoid a conclusionary rejection which merely states that claim 6 is indefinite because it lacks a clear antecedent basis.
 - A complete rejection should include:
 - The analysis of the claim element in view of MPEP/Rule
 - The conclusion of that analysis.
 - If appropriate a statement as to how to obviate the rejection.

Writing the rejection

The form paragraph

The examiner should explain their conclusion

The detailed BRI analysis here provides a clear record of the systematic analysis of the claim limitation.

Suggestion on how to overcome the rejection.

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The claims

1. A method of determining a nucleotide sequence, comprising the steps of: translocating at least one single stranded polynucleotide through **nanopores** and sequencing the nucleotide sequence of the polynucleotide.

5. The method of claim 1 wherein said **nanopores** comprise substantially identical nanopores.

6. The method of claim 5 wherein **said protein nanopores** further comprise alpha hemolysin.

Claim 6 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 6 refers to “said protein nanopores,” but neither claim 5 nor claim 1, in its dependency chain, refer to protein nanopores or nanopores of any specific kind.

The specification at paragraph 0032 establishes that the term nanopores used in the invention may be solid-state nanopores, protein nanopores, or hybrid nanopores that comprises protein nanopores, organic nanotubes, such as carbon nanotubes. However, because all nanopores are not protein nanopores, the recitation of “said protein nanopores” in claim 6 is indefinite as it is unclear if applicant intends to further limit “nanopores” in claim 1 or in fact the nanopores in claim 1 are limited to protein nanopores.

Amending claim 6 to recite “said nanopores” would obviate the rejection.



A systematic approach to 112(b)

Module 1b

Antecedent basis

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

This patented claim was found not to be invalid on the ground of indefiniteness in *Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006). In the slides that follow, it is analyzed under the approach for claims under examination as outlined in the MPEP, rather than under the “insolubly ambiguous” approach used by courts for determining definiteness of a patented claim.

Is there an Issue?

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- Does the lack of “direct” corresponding language for “said zinc anode” result in a lack of clear antecedent basis and indefiniteness?
 - Independent claim 1 recites an electrochemical cell comprising an alkaline electrolyte with a cathode and anode component;
 - Antecedent basis for “said zinc anode”, within the same claim, does not directly correspond to an “anode gel comprised of zinc as the active anode component.”

Rule(s)

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- **MPEP § 2173.05(e) Lack of Antecedent Basis [R-08.2017]**
 - “A claim is indefinite when it contains words or phrases whose meaning is unclear. *In re Packard*, 751 F.3d 1307, 1314 (Fed. Cir. 2014) ... Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992).”
- **MPEP 2173.02(II): Threshold requirement of clarity and precision. [R-10.2019]**
 - “If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, is appropriate.

Analysis using BRI

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- When the meaning of the claim would reasonably be understood by persons of ordinary skill when read in light of the specification, the claim is not rendered indefinite for lack of "*ipsis verbis*" support (i.e. "in the same words")
- Can a person of ordinary skill in the art understand the claim scope of "said zinc anode?"
 - It is apparent that "anode gel" is by implication the antecedent basis for "said zinc anode."

Analysis cont.

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- The specification teaches:
 - [002] Electrochemical cells are composed of an anode gel component comprised of active zinc metal in which the anode gel possesses expansion upon discharge of preferably less than 25% for 161 minutes to 15% depth of discharge at 2.88A.

Analysis cont.

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- What is the BRI of the term of “said zinc anode?”
 - Electrochemical cells in the art are composed of electrolytes, a cathode and an anode component consistent with the specification.
 - The specification clearly describes an electrochemical cell consistent with the claimed invention.

The conclusion

The claim

1. An electrochemical cell comprising an alkaline electrolyte, a cathode comprising manganese dioxide as an active cathode component, and an anode gel comprised of zinc as the active anode component, wherein the cell contains less than 50 parts of mercury per million parts by weight of the cell and said zinc anode has a gel expansion of less than 25% after being discharged for 161 minutes to 15% depth of discharge at 2.88A.

- Based on the analysis what is the examiner's conclusion?
- In claim 1, the term "said zinc anode" has antecedent basis to the term "anode gel comprised of zinc as the active anode component" and is definite since one of ordinary skill in the art would understand the claim scope, despite a lack of *ipsis verbis* support.
- Accordingly, a rejection under 112b for "lack of antecedent basis" would be improper.
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A systematic approach to 112(b)

Module 1c

Antecedent basis

The claims

Claim 61. The composition of **claim 32**, wherein the concentration of **the reactant** is less than 300nM.

- Claim 32 recited a reactant to which claim 61 is directed.
- Claim 32 has been canceled in the previous applicant's response.

Claim 61. The composition of **claim 32**, wherein the concentration of **the reactant** is less than 300nM.

Is there an Issue?

- How do you treat a claim which depends upon a canceled claim?
 - Should the examiner set forth a rejection under 112(b) for the lack of a clear antecedent basis?
 - Should the examiner object to the claim?
- Should the examiner address claim 61 limitation “the concentration ... less than 300nm” under 112b?

Rule(s)

Claim 61. The composition of **claim 32**, wherein the concentration of **the reactant** is less than 300nM.

- MPEP § 608.01(n) Dependent Claims [R-10.2019] Subsection V.
 - “If the base claim has been canceled, a claim which is directly or indirectly dependent thereon should be rejected as incomplete. If the base claim is rejected, the dependent claim should be objected to rather than rejected, if it is otherwise allowable.”;
- MPEP § 2173.05(e) Lack of Antecedent Basis [R-08.2017]
 - “A claim is indefinite when it contains words or phrases whose meaning is unclear. *In re Packard*, 751 F.3d 1307, 1314 (Fed. Cir. 2014). The lack of clarity could arise where a claim refers to “said lever” or “the lever,” where the claim contains no earlier recitation or limitation of a lever ... ” ;

Analysis using BRI

Claim 61. The composition of **claim 32**, wherein the concentration of **the reactant** is less than 300nM.

- For purposes of writing a 35 U.S.C. § 112b rejection:
 - Claim 61 is dependent on a canceled claim (i.e. claim 32) and is therefore “incomplete.” See MPEP § 608.01(n)(V).
- and additionally for the present claim:
 - The claim 61 limitation (“The composition” and “the reactant ...”) lacks antecedent basis from canceled base claim 32. See MPEP § 2173.05(e).
 - This helps applicant further correct an antecedent issue, upon subsequent amendment.

Conclusion

Claim 61. The composition of **claim 32**, wherein the concentration of **the reactant** is less than 300nM.

- Claim 61 is indefinite as being both incomplete, by its dependence on a cancelled claim, and for lack of antecedent basis for its limitation which is no longer present due to the cancellation of base claim 32.

Writing the rejection

The form paragraph

The examiner should explain their conclusion

No detailed BRI analysis is required here because nothing is set forth in the specification or in the prior art that could correct the issue.

Suggestion on how to overcome the rejection.

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Claim 61. The composition of claim 32, wherein the concentration of the reactant is less than 300nM.

Claim 61 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 61 is indefinite as being both incomplete, by its dependence on a cancelled claim; and for lack of antecedent basis for its limitation ("The composition ...") which is no longer present due to the cancellation of base claim 32.

Amending claim 61 to refer to a claim which recites the reactant in the composition, or deleting the claim, would obviate the rejection.



A systematic approach to 112(b)

Module 2

Breadth vs. indefiniteness

The claim

1. A method of controlling an insect, said method comprising: providing an insect inhibitory amount of a KILL1 insect inhibitory protein, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

Is there an Issue?

The claim

1. A method of controlling an insect, said method comprising: **providing an insect inhibitory amount of a KILL1 insect inhibitory protein**, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

- How is the insect controlled in claim 1, as there is only one active method step (the “providing” step)?
 - Is the claim indefinite because it does not recite an active step for controlling an insect?
 - Does the breadth of claim 1 raise an indefiniteness issue?”
 - There is only a providing step.
 - There is no direction as to the specific method used to accomplish the action called for in the preamble of the claim.

Rule

The claim

1. A method of controlling an insect, said method comprising: **providing an insect inhibitory amount of a KILL1 insect inhibitory protein**, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

- MPEP 2172.01 Unclaimed Essential Matter [R-10.2019]
 - If a claim fails to interrelate essential elements of the invention as defined by applicant(s) in the specification, the claim may be rejected under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph, as indefinite.
- MPEP 2173.04. Breadth Is Not Indefiniteness [R-10.2019]
 - Breadth of a claim is not to be equated with indefiniteness.
 - A broad claim is not indefinite merely because it encompasses a wide scope of subject matter provided the scope is clearly defined.
 - But a claim is indefinite when the boundaries of the protected subject matter are not clearly delineated and the scope is unclear.
 - For example, a genus claim that covers multiple species is broad, but is not indefinite because of its breadth, which is otherwise clear. But a genus claim that could be interpreted in such a way that it is not clear which species are covered would be indefinite (e.g., because there is more than one reasonable interpretation of what species are included in the claim).

Analysis using BRI

The claim

1. A method of controlling an insect, said method comprising:
providing an insect inhibitory amount of a KILL1 insect inhibitory protein, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

Claim 1 refers to “providing an insect inhibitory amount of a KILL1 insect inhibitory protein” but does not specify how the protein is to be applied.

- In the analysis phase the examiner begins with the plain meaning of the claim. That is, the examiner determines the BRI of the term.
- To determine the BRI, the examiner may look to the prior art and also the specification to see if there is a limiting definition of how the protein is applied to inhibit the insect.

Analysis cont.

The claim

1. A method of controlling an insect, said method comprising: **providing an insect inhibitory amount of a KILL1 insect inhibitory protein**, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

The Specification teaches:

- That there are multiple ways in which the insect inhibitory protein can be provided.
 - [0052] Providing an inhibitory protein includes, for example, spraying the insect with an inhibitory amount of the insect inhibitory protein, transgenically expressed in a vulnerable plant, externally applied to vulnerable plants, and as part of a seed treatment (external application to plant part).
 - The statement in [0052] does not limit the breath of providing an insect inhibitory protein.
- The plain meaning of “providing” in the prior art means to make available for use; supply.

Analysis cont.

The claim

1. A method of controlling an insect, said method comprising:
providing an insect inhibitory amount of a KILL1 insect inhibitory protein, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

- What is the BRI of “providing an insect inhibitory protein”?
 - The limitation of “providing” based on the specification and the prior art means that the inhibitory protein does not have to be applied to an insect.

Analysis cont.

The claim

1. A method of controlling an insect, said method comprising:
providing an insect inhibitory amount of a KILL1 insect inhibitory protein, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

- Does the preamble limit the claim or merely set forth an intended use?
 - **MPEP 2111.02 [R-10.2019]**
 - If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim
 - **Additionally, MPEP 2111.02 (II)**
 - "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, **the purpose or intended use of the invention**, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction."

Conclusion

The claim

1. **A method of controlling an insect**, said method comprising:
providing an insect inhibitory amount of a KILL1 insect inhibitory protein, wherein said insect inhibitory protein comprises a polypeptide sequence comprising 90% sequence identity to SEQ ID No. 1.

- Is claim 1 indefinite?
 - No.
 - The preamble should be given patentable weight and implicitly requires the claim to provide the insect inhibitory protein to an insect.
 - Therefore an active method step of applying the insect inhibitory protein to an insect is not required in the claim to make it definite.
 - The BRI of claim 1 includes a generic application of the insect inhibitory protein to an insect. Although there are many specific application examples described in the specification, there is no ambiguity in the claims.

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A systematic approach to 112(b)

Module 3a

Unclear/relative terminology

The claim

Claim 1. A method of introducing a desired trait into cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with a gene that confers yield stability, and regenerating a plant from the transformed cell, wherein said regenerated plant has **increased yield stability**.

Is there an issue?

Claim 1. A method of introducing a desired trait into cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:
transforming a cell of said cotton cultivar Fluffy with a gene that confers yield stability, and regenerating a plant from the transformed cell, wherein said regenerated plant has **increased yield stability**.

What are the metes and bounds of the phrase “increased yield stability”?

- Do the recitations “increased” and “yield stability”, or both, render the claim indefinite under 35 U.S.C. 112(b)?

Rule(s)

Claim 1. A method of introducing a desired trait into cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:
transforming a cell of said cotton cultivar Fluffy with a gene that confers yield stability, and regenerating a plant from the transformed cell, wherein said regenerated plant has **increased yield stability**.

- **MPEP 2173.05(b):** Relative Terminology [R-08.2017]
 - "The use of relative terminology in claim language, including terms of degree, does not automatically render the claim indefinite under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph. *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.
- **MPEP 2173.05(b)(IV):** Subjective Terms [R-08.2017]
 - "When a subjective term is used in the claim, the examiner should determine whether the specification supplies some standard for measuring the scope of the term, similar to the analysis for a term of degree."
- **MPEP 2173.05(a):** THE MEANING OF EVERY TERM SHOULD BE APPARENT [R-07.2015]
 - "The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Claim language may not be "ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention." *Packard*, 751 F.3d at 1311."

Analysis using BRI

Claim 1. A method of introducing a desired trait into cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:
transforming a cell of said cotton cultivar Fluffy with a gene that confers yield stability, and regenerating a plant from the transformed cell, wherein said regenerated plant has **increased yield stability**.

- Claim 1 refers to “increased yield stability.” In the analysis phase the examiner first looks to the specification to see what applicant considers to be the meaning of this phrase.
 - At [0021] of the specification “yield stability” is recited within a listing of traits that could be introduced into cotton plants, and teaches that various types of genes can be transformed into cotton plants to increase yield stability.
 - The specification at [0034] teaches numerous types of transgenes that can be introduced into cotton cultivar Fluffy to provide one or more desired traits. To determine the effect of a transgene on cultivar Fluffy, the phenotype of a transformed Fluffy plant is compared to an untransformed Fluffy plant. Thus the specification teaches that the term “increased” refers to the untransformed Fluffy cultivar.
- The examiner next looks to the prior art.
 - A search of the prior art revealed that ‘yield stability’ refers to how stable the yield of a crop plant is from one year to another. The prior art shows there are various types of genes that can affect yield stability, such as those that confer drought-resistance, insect-resistance or disease-resistance.

Conclusion

Claim 1. A method of introducing a desired trait into cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:
transforming a cell of said cotton cultivar Fluffy with a gene that confers yield stability, and regenerating a plant from the transformed cell, wherein said regenerated plant has **increased yield stability**.

- Yield 'stability' may appear to be a relative term.
 - However, the prior art shows it to be a term of the art. One of ordinary skill in the art understands this term, and can interpret the metes and bounds of the claim so as to understand how to avoid infringement.
- In claim 1 "increased" is linked to the regenerated transformed plant (end product), the gene conferring yield stability and untransformed cotton cultivar Fluffy (starting material).
 - Further, the specification teaches that transformed Fluffy plants are compared to untransformed Fluffy plants. It is apparent that the end product in claim 1 is to be compared to the starting material. The term "increased" does not render the claim indefinite.
- Although no rejection should be made, the examiner may set forth a claim interpretation for purposes of clarity.

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A systematic approach to 112(b)

Module 3b

Unclear/relative terminology

The claim

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

Is there an Issue?

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

- Would the person of ordinary skill in the art understand the phrase, "**Sumkinda-like**"?

Rule(s)

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

- **MPEP 2173.05(b):** Relative Terminology [R-08.2017]

- "The use of relative terminology in claim language, including terms of degree, does not automatically render the claim indefinite under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph. *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art....."

- **MPEP 2173.05(b)(III)(E):** "Type" [R-08.2017]

- "The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite."



Analysis using BRI

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

Claim 3 refers to **Sumkinda-like** gene. In the analysis phase the examiner first looks to the specification to see what applicant considers to be the meaning of this phrase.

- The specification at [0023] teaches that in cotton **Sumkinda** gene confers resistance to aphids and stink bugs, but not other insect pests.
- At [0024] the **Sumkinda** gene was identified and isolated from *Gossypium hirsutum*; and that the gene has been successfully bred into cotton varieties that do not comprise the **Sumkinda** gene.
- The encoded gene product does not show any significant sequence similarity to other insect resistant polypeptides known in the prior art having activity against aphids or stink bugs or any other cotton pest. The mechanism of action of the **Sumkinda** gene product has not yet been characterized.
- The specification recites both '**Sumkinda**' and '**Sumkinda-like**' within a list of genes that confer insect resistance to plants, but does not provide any other information about the **Sumkinda-like** gene.
- **Sumkinda** gene is known in the prior art but the prior art is silent as to **Sumkinda-like** gene

Conclusion

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

- Homologs of the **Sumkinda** gene are not known, nor is the mechanism of action of the gene product.
- Other insect resistance genes conferring resistance against the same insects as **Sumkinda** are known.
- But it is unclear whether such genes are encompassed by "**Sumkinda-like**", whether their gene products must also possess the same mechanism of action as **Sumkinda**, etc. This makes the metes and bounds of claim 3 unclear, rendering the claim indefinite.

Writing the rejection

The form paragraph

The examiner should explain their conclusion

The detailed BRI analysis here provides a clear record of the systematic analysis of the claim limitation.

If no suggestion on how to overcome the rejection can be made the examiner should not make a statement.

Note: The raising of a 112(b) does not preclude the raising of other applicable issues, such as 112(a).

Claim 3. A method of conferring insect-resistance to a plant of cotton cultivar Fluffy, seed of which was deposited under ATCC No. PTA-67932, comprising:

transforming a cell of said cotton cultivar Fluffy with an insect-resistance gene, said gene is chosen from **Sumkinda** gene or **Sumkinda-like** gene, and regenerating a plant from the transformed cell.

Claim 3 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The recitation, “Sumkinda-like gene”, is a relative term that renders the claim indefinite.

The specification at [0023] teaches that the cotton Sumkinda gene has been isolated; that its encoded gene product confers resistance to aphids and stink bugs, and does not show any significant sequence similarity to other known insect resistant polypeptides in the prior art; that its mechanism of action has not been characterized. The specification recites, “Sumkinda” and “Sumkinda-like” within a list of genes that confer insect resistance to plants, but does not provide any other information about the Sumkinda-like gene.

Given that the specification does not define what is meant by “Sumkinda-like”; the specification does not describe the difference between “Sumkinda” and “Sumkinda-like” genes; that the Sumkinda gene product does not show any significant sequence homology to other insect resistance polypeptides; one skilled in the art would not understand the metes and bounds of the term.



A systematic approach to 112(b)

Module 4

Exemplary language

The claim

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever such as aspirin.

Is there an Issue?

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

Is the phrase “pain reliever **such as** aspirin” clear as to the intended scope of the second component of the claimed composition?

Exemplary claim language-MPEP 2173.05(d)

Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

- (A) "R is halogen, **for example**, chlorine";
- (B) "material **such as** rock wool or asbestos" Ex parte Hall, 83 USPQ 38 (Bd. App. 1949);
- (C) "lighter hydrocarbons, **such, for example**, as the vapors or gas produced" Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949);
- (D) "normal operating conditions **such as** while in the container of a proportioner" Ex parte Steigerwald, 131 USPQ 74 (Bd. App. 1961); and
- (E) "coke, brick, or **like** material". Ex parte Caldwell, 1906 C.D. 58 (Comm'r Pat.)

Rule(s)

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

MPEP 2173.05(d): Exemplary Claim Language [R-07.2015]

"Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences may lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower scope is a limitation, a rejection under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph should be made."

MPEP 2173.02(II): Threshold requirement of clarity and precision. [R-10.2019]

"If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, is appropriate."

Analysis using BRI

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

- The claim contains an instance of “exemplary claim language” where the claim recites a broad term, “pain reliever,” followed by terminology “such as.”
 - This seems to indicate that what follows is a narrower scope example of what is encompassed by the broad term, “aspirin”.
- In the analysis phase the examiner should first look to the specification to see if the narrower scope is intended to limit the preceding broader scope language.
 - Note that the mere use of the phrase “such as” or “for example” in a claim does not by itself render the claim indefinite because the analysis is fact specific and should not be applied as *per se* rules.

Analysis cont.

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

The specification teaches:

- [0018] The pain reliever component that can be used in the composition includes any over-the-counter (OTC) pain reliever including non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, naproxen, and ibuprofen, and the non-NSAIDs drug, acetaminophen. Prescription pain relievers that may also be used include drugs such as opioids and corticosteroids.

Analysis cont.

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

- What is the BRI of the phrase “a pain reliever such as aspirin?”
 - Based upon the specification, the phrase “pain reliever such as aspirin” could reasonably be interpreted that aspirin is a non-limiting example of a pain reliever.
 - Alternatively, the pain reliever could be limited to one having some unspecified characteristic that are the same as aspirin, OTC pain relievers, or perhaps just NSAID pain reliever of which aspirin is an example, or the pain reliever is intended to be limited to aspirin.
- Based on this analysis there is no indication of **a special definition**¹ in the specification that exemplification of a pain reliever in the claims is *intended* to be limiting.

¹See MPEP 2111.01 (IV) [R-10.2019] for special definition: “... To act as their own lexicographer, the applicant must clearly set forth a special definition of a claim term in the specification that differs from the plain and ordinary meaning it would otherwise possess.”

The conclusion:

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever **such as** aspirin.

- Based on the analysis what is the examiner's conclusion?
 - The claim, which recites "pain reliever such as aspirin" includes a broader term followed by exemplary language featuring a more narrow scope which may lead to confusion over the intended scope of the claim.
 - Accordingly, the metes and bounds of the claim containing that language are unclear.

What should be in the rejection?

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever such as aspirin.

- The examiner should avoid a conclusionary rejection.
 - A complete rejection should include:
 - The analysis of the claim element in view of MPEP/Rule
 - The conclusion of that analysis.
 - If appropriate a statement as to how to obviate the rejection

Writing the rejection

The form paragraph

The examiner should explain their conclusion

The detailed BRI analysis here provides a clear record of the systematic analysis of the claim limitation.

Suggestion on how to overcome the rejection.

1. A topical cream composition for treating skin irritation, comprising an alcoholic extract of *Aloe vera* and a pain reliever such as aspirin.

Claim 1 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112(pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

The phrase “pain reliever such as aspirin” includes a broader term followed by exemplary language featuring a more narrow scope which may lead to confusion over the intended scope of the claim because the metes and bounds of the claim containing that language are unclear rendering the claim indefinite.

Based on paragraph 0018 of the specification, the phrase “pain reliever such as aspirin” could reasonably be interpreted as aspirin is a non-limiting example of a pain reliever, the pain reliever is limited to one having some unspecified characteristic same as aspirin, OTC pain relievers, or perhaps just NSAID pain reliever of which aspirin is an example, or the pain reliever is intended to be limited to aspirin. There is no indication of a special definition in the specification that exemplification of a pain reliever in the claims is intended to be limiting.

Amending the claim by deleting the phrase “such as aspirin” would obviate the rejection.

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Thank You



