



# UNITED STATES PATENT AND TRADEMARK OFFICE

## **35 U.S.C. 112 2nd paragraph**

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# This talk follows

A recent DCPEP memo dated 9/2/08 posted

at <http://www.uspto.gov/web/patents/memorandum.htm>

Entitled:

“Indefiniteness Rejections under 35 USC 112, 2<sup>nd</sup> Paragraph”



## Also note

Another related DCPEP memo dated 9/2/08 posted  
at <http://www.uspto.gov/web/patents/memorandum.htm>

Entitled:

“Rejections under 35 U.S.C. 112, second paragraph, when  
examining means (or step) plus function claim limitations  
under 35 U.S.C. 112, sixth paragraph ”



# Importance of the Claims

“The claims must provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability.”

MPEP 2173



# Claim Interpretation

"[The] manner of claim interpretation that is used by courts in litigation is not the manner of claim interpretation that is applicable during prosecution of a pending application before the PTO."

MPEP 2106, citing *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989).



# Importance of Addressing Indefiniteness During Examination

“We [the CAFC] note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and *it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances* so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.”

*Halliburton Energy Servs. v. M-ILLC* 514 F.3d 1244, 1255  
(Fed. Cir. 2008) (Emphasis added per 9/2/08 Memo)



# Precise, Clear, Correct and Unambiguous

“An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”

MPEP 2106, quoting *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).



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

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”





## Primary Purpose of 35 U.S.C. 112, second paragraph

“The primary purpose of the definiteness requirement for claim language is to ensure that the scope of the claims is clear so that the public is informed of the boundaries of what constitutes infringement of the patent.”

From 9/2/08 Memo entitled “Indefiniteness Rejections under 35 USC 112, 2<sup>nd</sup> Paragraph”



## When a Claim is Subject to More than One Interpretation

“Where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, examiner should reject the claim as indefinite under 35 U.S.C. 112, second paragraph, and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable.”

From 9/2/08 Memo entitled “Indefiniteness Rejections under 35 USC 112, 2<sup>nd</sup> Paragraph”



## Two or More Plausible Constructions

USPTO gives claims the broadest reasonable construction in light of the specification and, if claim is amenable to two or more plausible constructions, applicant is required to amend claim to more precisely define metes and bounds of claimed invention or claim is indefinite under § 112, ¶ 2.

*Ex parte Miyazaki*, 89 USPQ2d 1207 (BPAI 2008) (expanded panel)



## Test for Definiteness at the USPTO

"The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether 'those skilled in the art would understand what is claimed when the claim is read in light of the specification.' "

MPEP 2173.02, quoting *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986).



## Two Separate Requirements under 35 U.S.C. 112, second paragraph

“...the claims must set forth the subject matter that applicants regard as their invention;

and

the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.”

MPEP 2171



## Analyzing Claims for Indefiniteness

“Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) the content of the particular application disclosure;
- (B) the teachings of the prior art; and
- (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

MPEP 2173.02



## Broadest Reasonable Interpretation

"USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure."

MPEP 2106, quoting *In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

"During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.

MPEP 2106, quoting *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).



## Importing Limitations from the Specification

"Limitations appearing in the specification but not recited in the claim should not be read into the claim. . . . Claims must be interpreted 'in view of the specification' without importing limitations from the specification into the claims unnecessarily."

MPEP 2106, citing *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003).





## Particularly Point Out and Distinctly Claim

"If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph."

MPEP 2171, citing *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989)



## Rejecting a Claim under 112 2<sup>nd</sup> Paragraph

"If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention."

MPEP 2171, citing *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).



## Reasons are Required

“If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is ‘vague and indefinite’ should be included in the Office action.”

MPEP 2173.02



## Consideration of Applicant's Arguments

“If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicant's arguments to be persuasive,

the examiner should indicate in the next Office communication that the previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner's position.”

MPEP 2173.02



## No *Per Se* Rules

“Office policy is not to employ *per se* rules to make technical rejections.

Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules.”

MPEP 2173.02



# Particular 35 U.S.C. 112 2<sup>nd</sup> Situations

Lack of Antecedent Basis	Example 1
“Use” Claims	Example 2
Preamble and Wherein clauses	Example 3
Exemplary Embodiments	Example 4
Derivatives and Derived From	Examples 5A, 5B, 5C and 6
Chemical Formula does not Define all variable	Example 7A
Variable for Chemical Formula Defined in Specification	Example 7B
Chemical Formula Includes Functional Limitation	Example 8
Reference to Another Claim	Example 9
Reference to A Cancelled Claim	Example 10
Reference to A Withdrawn Claim	Example 11
Dependent Claim does not Further Limit Independent Claim	Example 12
Punctuation and Typographical Errors	Examples 13, 14
Use of Trademarks	Example 15

See MPEP 2171 for other particular situations.



## Example 1: Lack of Antecedent Basis

Claim 1. An apparatus comprising a “translator controller” ... wherein “the linear translator”...

“The claim is ambiguous and a rejection under 35 U.S.C 112, second paragraph based upon a lack of proper antecedent basis is appropriate. In this case, it is unclear if the “linear translator” is a new element or is the previously introduced “translator controller.””

“[I]t is unclear whether the linear translator and the translator controller are the same element or different elements, and if different, how they relate to each other.”

A rejection for indefiniteness using FP 7.34.01 and 7.34.05 is warranted.

The quoted text is from Example 2 of the 9/2/08 Memo



## Product and/or Process Claims?

"A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph."

MPEP 2173.05(p), citing *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990).





## “Use” Claims

“Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph.”

MPEP 2173.05(q)



## Example 2: “Use” Claims

Claim 2. The use of a monoclonal antibody of claim 1 to isolate and purify human fibroblast interferon.

This claim “was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)”

“[R]eject a “use” claim under alternative grounds based on 35 U.S.C. 101 and under 35 U.S.C. 112”, using FPs 7.05, 7.05.01, 7.34.01 and 7.34.12 (essential steps missing).

Quoted text from MPEP 2173.05(q)



## Example 3: Effect of Preamble in Process Claim

Claim 1. A method of treating diabetes comprising administering compound X to a subject in need thereof.

This claim is considered complete with respect to 35 USC 112 2<sup>nd</sup> paragraph. There is no requirement that a preamble need to be repeated in a final “wherein” clause.



## Example 4: Exemplary Embodiments

Claim 1. A composition comprising Product X and a protease, for example, chymotrypsin.

Because protease (generic term) and chymotrypsin (a specific type of protease) are not identical in scope, the use of the phrase “for example” raises the question as to which term is required by the claim. A rejection under 35 U.S.C 112 2<sup>nd</sup> is warranted using FP 7.34.01 and 7.34.08 along with the following explanation.

Regarding claim 1, “the phrase “for example” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.”

MPEP 2173.05(d)



## Example 5A: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 or a derivative thereof and further comprising a pharmaceutically acceptable adjuvant.

Assume for this example that derivatives of SEQ ID NO: 1 are not clearly defined in specification or in the prior art.

Make a 2nd paragraph rejection using FP 7.34.01 along with any other appropriate rejections or objections.



## Example 5B: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 or a derivative thereof and a pharmaceutically acceptable adjuvant.

Assume for this example that derivatives of SEQ ID NO: 1 are not clearly defined in specification. However, SEQ ID NO: 1 and some variants thereof are well known in the prior art.

Make a 112 2nd paragraph rejection using FP 7.34.01 along with any other appropriate rejections or objections.



## Example 5C: Derivative

Claim 1. A vaccine comprising a protein having SEQ ID NO: 1 and a pharmaceutically acceptable adjuvant comprising BSA or a derivative of BSA.

Assume for this example that derivatives of BSA were well known in the prior art and/or are clearly defined in specification.

Do not make a rejection under 35 USC 112, 2<sup>nd</sup> paragraph over derivative.



## Example 6: “Derived From”

Claim 1. A composition comprising neural stem cells derived from a spinal cord.

The specification teaches that neural stem cells may be isolated from, i.e., derived from a spinal cord. Although this claim is broad, no issues are raised under 35 U.S.C. 112, 2<sup>nd</sup> paragraph with regard to the term “derived from” in this situation.





# Breadth

"Breadth of a claim is not to be equated with indefiniteness."

MPEP 2173.04, citing *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971).

"Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad."

MPEP 2173.04



## Claims to Chemical Formula

"A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented."

MPEP 2173.05(t), citing *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970)

"Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art."

MPEP 2173.05(t), citing *Martin v. Johnson*, 454 F.2d 746, 172 USPQ 391 (CCPA 1972)



## Claims to Chemical Formula (cont.)

"A compound of unknown structure may be claimed by a combination of physical and chemical characteristics. . . .

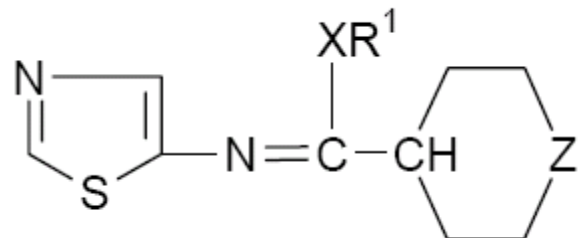
A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness."

MPEP 2173.05(t), citing *Ex parte Brian*, 118 USPQ 242 (Bd. App. 1958).



## Example 7A: Chemical Formula Does not Define All Variables

Claim 1. A compound having Formula 1



wherein R<sup>1</sup> is methyl or phenyl and X is selected from oxygen and sulfur.

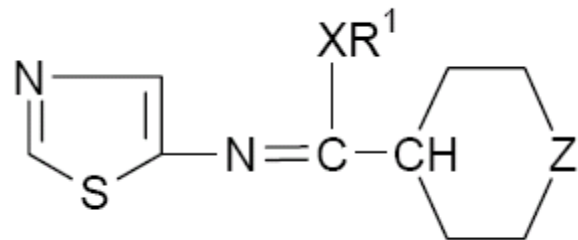
In this example, assume that the specification did not provide any definition for “Z”. Neither does the claim provide a definition for the variable “Z”.

Reject Claim 1 under 35 U.S.C 112 2<sup>nd</sup> paragraph using FP 7.34.01.



## Example 7B: Variable Recited in Chemical Formula is Defined in Specification

Claim 1. A compound having Formula 1



wherein  $\text{R}^1$  is methyl or phenyl and  $\text{X}$  is selected from oxygen and sulfur.

Claim 1 does not define variable “Z”. In this example, assume that the specification provides that “Z” is any appropriate linker for the two methylene moieties adjacent to Z.

In this example, no rejection under 35 U.S.C 112 2<sup>nd</sup> paragraph would be warranted.



# Functional Terms

"A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper."

MPEP 2173.05(g), citing *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).



## Functional Terms (cont.)

“When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area).”

*Halliburton Energy Servs. v. M-ILLC*, 514 F.3d 1244, 1255  
(Fed. Cir. 2008)



## Functional Terms for Chemical Compounds

"It was held that the limitation used to define a radical on a chemical compound as 'incapable of forming a dye with said oxidizing developing agent' although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought."

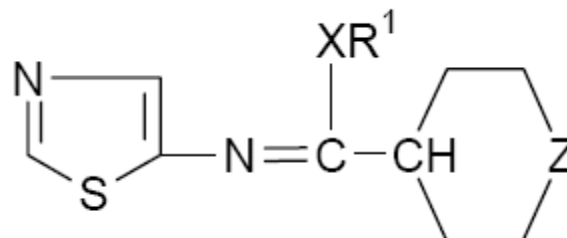
MPEP 2173.05(g), citing *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971).





## Example 8: Chemical Formula Which Includes a Functional Limitation

Claim 1. A compound having Formula 1



wherein X is oxygen, Z is sulfur and R1 is a leaving group.

The claim provides a functional limitation for the variable “R1”. The specification defines “leaving group” in a manner consistent with what is known in the art.

Although the claim is broad with respect to R1, no rejection under 35 U.S.C 112 2<sup>nd</sup> paragraph is warranted.



## Numerical Ranges and Amounts

“Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible.

Description of examples and preferences is properly set forth in the specification rather than in a single claim.”

MPEP 2173.05(c)



## Numerical Ranges and Amounts (cont.)

“A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).”

FP 7.34.04



## 1<sup>st</sup> and 2<sup>nd</sup> Paragraphs of 35 U.S.C. 112 are Separate and Distinct

“If a description or the enabling disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact alone does not render the claim imprecise or indefinite or otherwise not in compliance with 35 U.S.C. 112, second paragraph.”

MPEP 2174



## Relationship Between 112 2<sup>nd</sup> and Art Rejections

“When making a rejection over prior art in these circumstances, it is important for the examiner to point out how the claim is being interpreted.”

MPEP 2173.06



## Relationship Between 112 2<sup>nd</sup> and Art Rejections (cont.)

"[W]here the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections:

- (A) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph; and
- (B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable."

MPEP 2173.06, citing *Ex parte Ionescu*, 222 USPQ 537 (Bd.App. 1984).



## Relationship Between 112 2<sup>nd</sup> and Art Rejections (cont.)

"Where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art. . . . [A] rejection under 35 U.S.C. 103 should not be based on considerable speculation about the meaning of terms employed in a claim or assumptions that must be made as to the scope of the claims."

MPEP 2173.06, citing *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962).



# Clarity and Precision

“Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.”

MPEP 2173.02





## Amendments Must Not Introduce New Matter

35 U.S.C. 132(a) provides that “[n]o amendment shall introduce new matter into the disclosure of the invention.”



# Examiner's Suggestions

“If the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant.”

MPEP 2173.02



# Claim Objections

“If the form of the claim (as distinguished from its substance) is improper, an “objection” is made.

The practical difference between a rejection and an objection is that a rejection, involving the merits of the claim, is subject to review by the Board of Patent Appeals and Interferences, while an objection, if persisted, may be reviewed only by way of petition to the Director of the USPTO.”

MPEP 706.01



# Product by Process Claims

“A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper.”

MPEP 2173.05(p)



## Reference to Limitations in Another Claim

“A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph.”

MPEP 2173.05(f)



## Example 9: Reference to Another Claim

“For example, claims which read:

“The product produced by the method of claim 1.”

or

“A method of producing ethanol comprising contacting amylose with the culture\* of claim 1 under the following conditions.....”

are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim.”

\*assuming there is only one culture in claim 1.

MPEP 2173.05(f)



## Example 10: Reference to a Canceled Claim

Claim 1. Cancelled.

Claim 2. The product produced by the method of claim 1.

Claim 2 should be rejected under 35 USC 112 2<sup>nd</sup> using FP 7.34.01 and then examined under remaining statutes.



## Example 11: Reference to a Withdrawn Claim

Claim 1. (Withdrawn) A method of ....

Claim 2. The product produced by the method of claim 1.

Claim 2 should be objected to for depending upon a withdrawn claim using FP 7.29.01, as follows:

Claim 2 is objected to because of the following informalities: for depending upon a withdrawn claim . Appropriate correction is required.





## Example 12: Dependent Claim Fails to Further Limit Independent Claim

Claim 1. A DNA molecule comprising SEQ ID No 1.

Claim 2. The DNA of Claim 1 which consists of 100 or fewer nucleotides of SEQ ID No 1.

Assume for this example that SEQ ID NO 1 is 200 nucleotides in length.

Claim 2 should be objected to for not further limiting claim 1 using FP 7.36, as follows:

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The DNA molecule of claim 2 reads upon fragments of the DNA molecule of Claim 1. Because claim 2 does not require the entire SEQ ID No 1, Claim 2 is broader in scope than its independent claim 1.

MPEP 608.01(n)



## Example 13: Permitted Parentheses

Claim 1. A composition comprising Product X and a glycerol (glycerin).

Because glycerol equals glycerin, the use of parentheses is permitted.

“If one skilled in the art is able to ascertain in the example above, the meaning of the terms ... in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied.” No rejection is warranted under 35 USC 112. 2<sup>nd</sup> paragraph.

MPEP 2173.02



## Example 14: Problematic Parentheses

Claim 1. A composition comprising Product X and a protease (chymotrypsin).

Because protease (generic term) and chymotrypsin (a specific type of protease) are not identical in scope, the use of parentheses raises the question as to which term is required by the claim.

A rejection under 35 U.S.C 112 2<sup>nd</sup> is warranted using FP 7.34.01 and FP 7.34.04 (claim uses both narrow and broad limitations).



## Example 15: Use of Trademarks

Claim 1. A patch comprising Product A and a Velcro attachment.

VELCRO® is a Registered Trademark denoting a synthetic notion.

Use FP 7.34.01 and 7.35.01 to reject Claim 1. Use FP 6.20 to object to the use of the trademark.

“Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.”

MPEP 608.01(v) and 2173.05(u)



# UNITED STATES PATENT AND TRADEMARK OFFICE

## Questions?

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