

DETAILED ACTION

CLAIM INTERPRETATION

1. The following is a quotation of 35 U.S.C. 112(f): (FP **7.30.03**)

(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

2. The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and

(C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. (FP 7.30.05)

3. This application includes one or more claim limitations that do not use the word “means,” but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are: **force limiting mechanism for limiting** in claim 5.

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being

interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. (FP 7.30.06)

Claim Rejections – 35 USC § 112

4. The following is a quotation of 35 U.S.C. 112(b): (FP 7.30.02)

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of pre-AIA 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.

5. Claim 6 is rejected under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, 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. (FP 7.34.01)

Claim limitation “**means for vibrating the blade at a high frequency**” invokes 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for performing the entire claimed function and to clearly link the structure, material, or acts to the function. **The specification is devoid of adequate structure to perform the claimed function. In particular, the specification merely states the claimed function of vibrating the blade at a high frequency is performed “mechanically.” There is no disclosure of any particular structure, either explicitly or inherently, to perform the vibrating. The use of the term “mechanically” is not adequate structure for performing the vibrating function because it does not describe a particular structure for performing the function.** As would be recognized by those of ordinary skill in the art, there are many different ways to effect mechanical vibration. The specification does not provide sufficient details such that one of ordinary skill in the art would understand which

mechanical structures perform(s) the claimed function. Therefore, the claim is indefinite and is rejected under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph.

Applicant may:

- (a) Amend the claim so that the claim limitation will no longer be interpreted as a limitation under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph;
- (b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the entire claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (c) Amend the written description of the specification such that it clearly links the structure, material, or acts disclosed therein to the function recited in the claim, without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts and clearly links them to the function so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant should clarify the record by either:

- (a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or
- (b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181. (FP **7.34.23**)

6. The following is a quotation of 35 U.S.C. 112(a): (FP **7.30.01**)

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and

exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 6 is rejected under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. **As described above, the disclosure does not provide adequate structure to perform the claimed function of vibrating the blade at a high frequency. The specification does not demonstrate that applicant has made an invention that achieves the claimed function because the invention is not described with sufficient detail that one of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention.** (FP 7.31.01)

Claim Rejections – 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: (FP 7.07.aia)

A person shall be entitled to a patent unless—

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention. (FP 7.08.aia)

9. Claims 5 and 6 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by X. (FP 7.15.aia)

[NOTE: For the purposes of this training assume the X reference teaches each of the limitations as identified below.]

As per claim 5, X teaches ultrasonic surgical shears comprising:

- a) an ultrasonic surgical blade (Fig. 1, element 1);
- b) a clamping arm coupled to the blade and operable to open and close toward the blade (Fig. 1, element 2);
- c) a tissue pad attached to the clamping arm, the blade and tissue pad defining a clamping surface area (Fig. 1, element 3); and
- d) a force limiting mechanism for limiting an applied clamping force to a range of 60 psi to 210 psi at the clamping surface area. This element is interpreted under 35 U.S.C. 112(f) as a force limiter that is coupled to the clamping arm and engages the blade to accomplish the claimed function, and equivalents thereof. (X teaches a force limiter that is coupled to the clamping arm and abuts a portion of the blade handle to limit the user applied clamping force to a range of 100 psi to 150 psi, Fig. 1, element 4 and page 2, lines 15-30).

As per claim 6, X teaches (e) means for vibrating the blade at a high frequency. Because adequate structure has not been identified in the specification for performing the claimed function, the means limitation is interpreted for the purpose of applying prior art as any known mechanical structure that can perform the function of vibrating a blade at high frequency. (X teaches a power source for generating an electrical signal and a piezoceramic transducer in the hand-piece for converting the electrical signal into a longitudinal mechanical vibration to vibrate the blade at high frequency, page 3, lines 5-20).

INSTRUCTOR NOTES

112 Rejections

Claim 5

The first step in analyzing the claim is to perform claim construction to ascertain boundaries of protection sought by the applicant. See MPEP 2103(I)(C). Claims are given their “broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art.” See MPEP 2111. If the applicant invokes 35 U.S.C. § 112(f), the claim is construed to cover the structure, material, or acts described in the specification as performing the entire claimed function and equivalents to the disclosed structure, material or acts. See MPEP 2181.

Using the three-prong analysis in MPEP 2181, the claim limitation “(d) force limiting mechanism for limiting an applied clamping force to a range of 60 psi to 210 psi at the clamping surface area” invokes § 112(f):

- Prong A is met because: claim element (d) recites a “force limiting mechanism”, which is a generic placeholder for “means”. One of ordinary skill in the art would not recognize the term “mechanism” in this example as sufficiently definite meaning of structure and the phrase “force limiting” is simply a recitation of the function. No specific definition of the term “mechanism” is provided or recognized in the art.
- Prong B is met because: the generic placeholder (the “force limiting mechanism”) is modified by functional language (“for limiting an applied clamping force...”)
- Prong C is met because: claim element (d) is not further modified by sufficient structure or material for performing the claimed function.

Since § 112(f) has been invoked, the examiner should include a “Claim Interpretation” section in the Office action to address this on the record. The examiner should use form paragraphs 7.30.03.h (Claim Interpretation Header), 7.30.03 (Statement of Statutory Basis, 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph), new form paragraph 7.30.05 (Broadest Reasonable Interpretation under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, Sixth Paragraph: Use of “Means” (or “Step”) in Claim Drafting and Rebuttable Presumptions Raised) and new form paragraph 7.30.06 (35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, Sixth Paragraph, Invoked Despite Absence of “Means”). When using form paragraph 7.30.06, the examiner should identify the claim limitation that invokes § 112(f) in the first bracket (“force limiting mechanism for limiting”) and indicate in bracket 2 that this appears in claim 5.

Form paragraph 7.30.06 identifies proper applicant responses to a finding that the claim invokes § 112(f) (i.e., amendment or identifying how the claim does not invoke § 112(f) under the three prong analysis). It would not be sufficient for the applicant to respond by simply stating that they did not intend to invoke § 112(f). It is the claim language that determines whether § 112(f) has been invoked, not applicant’s intentions.

Note that claim 5 does not raise concerns under 35 U.S.C. § 112(b). Once it has been determined that the claim invokes § 112(f), the examiner must consult the specification to determine the corresponding structure that performs the claimed function. If the specification does not provide adequate structure for performing the entire claimed function and/or fails to clearly link the structure to the function, the claim must be rejected under § 112(b) as being indefinite. See MPEP 2181(II). In this case, the recited § 112(f) limitation is supported by adequate structure in the specification linked to the function. The specification discloses a “force limiter” for performing the function of limiting the applied clamping force to the specified range. In particular, the force limiter is described as coupled to the clamping arm, and as being designed in the same manner as conventional force limiting mechanisms, with the force limiter abutting a portion of the blade handle to limit the user applied clamping force. For these same reasons, the claim does not raise any concerns under 35 U.S.C. § 112(a).

Claim 6

Again, the first step in analyzing the claim is to perform claim construction to ascertain boundaries of protection sought by the applicant. Using the three-prong analysis in MPEP 2181, the claim limitation “(e) means for vibrating the blade at a high frequency” invokes § 112(f):

- Prong A is met because: claim element (e) recites “means”, which creates a presumption that § 112(f) is invoked.
- Prong B is met because: the “means” is modified by functional language (“vibrating...”)
- Prong C is met because: claim element (e) is not further modified by sufficient structure or material for performing the claimed function.

Note that form paragraphs 7.30.03.h, 7.30.03 and 7.30.05 only need to be in the Office action once. Since they have already been included to address the invocation of § 112(f) in claim 5, they do not need to be added again. Form paragraphs 7.30.06 and 7.30.07 (35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, Sixth Paragraph, Not Invoked Despite Presence of “Means” or “Step”) are not needed to address claim 6 because neither presumption has been overcome.

Claim 6 raises concerns under 35 U.S.C. § 112(b). Since the claim invokes § 112(f), the examiner must look to the specification to determine the structure or material that performs the claimed function. However, in this example, there is no disclosure of adequate structure to perform the claimed function of vibrating. Accordingly, the claim must be rejected as indefinite under 35 U.S.C. § 112(b). The examiner should use form paragraphs 7.30.02 (Statement of 112(b) Statutory Basis), 7.34.01 (Statement of Rejection for Indefiniteness), and new form paragraph 7.34.23 (Rejection Under 112(b) With 112(f) Interpretation). Note that form paragraph 7.34.23 lists potential options for applicants in responding to the rejection. This listing is provided as a best practice to advance prosecution.

Given that claim 6 is indefinite under § 112(b), the examiner should consider any potential deficiency under § 112(a). Because there is no disclosure of adequate structure to perform the claimed function, the specification does not convey with reasonable clarity to those skilled in the art that the applicant had possession of the claimed invention. A rejection under § 112(a) must be made for lacking an

adequate written description. See MPEP 2163.02. The examiner should use form paragraphs 7.30.01 and 7.31.01.

Note, questions regarding enablement may come up during the workshop. You should be familiar with the principles of enablement and the differences between written description and enablement in order to address any questions. However, for the purposes of this training assume in this example the disclosure provides enough information for one of ordinary skill in the art to make and use a “mechanical” device for vibrating the blade at a high frequency without undue experimentation. Therefore, a rejection under 35 U.S.C. § 112(a) for lacking an enabling disclosure should not be made in this instance.

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Claim 5

Previously, examiners would indicate in their claim interpretation under § 112(f), using form paragraph 7.34.21, the corresponding structure in the specification that performs the claimed function. However, form paragraph 7.34.21 has been deleted and should no longer be used. While the identification of corresponding structure is no longer required when establishing claim interpretation under § 112(f) using new form paragraph 7.30.05, it would be appropriate to do so when making a rejection.

The rejection under § 102(a)(1) provides a mapping of the elements of the claim and where that element is taught in the prior art reference “X.” The discussion in the specification regarding the “force limiting mechanism” includes an identification of the structure that corresponds to the claimed function. Thus, the corresponding structure is interpreted as a force limiter that is coupled to the clamping arm and engages the blade to accomplish the claimed function, and equivalents thereof. The rejection then goes on to explain how reference X anticipates this interpretation of the claim element.

Claim 6

Even though claim 6 is found to be indefinite, the examiner should practice compact prosecution and identify all applicable grounds of rejection in the Office action. Where the degree of uncertainty of the claim meaning is not great and at least one interpretation of the claim would render the claim unpatentable over the prior art, the examiner should enter a rejection over the prior art based upon this interpretation. See MPEP 2173.06. The examiner should state on the record how the claim term or phrase is being interpreted with respect to the prior art that is applied in the rejection. Here the examiner provides an interpretation for the indefinite limitation “means for vibrating the blade at high frequency” and describes how the prior art anticipates the claim based on this interpretation.