

-----Original Message-----

**From:** Michael K Kirk

**Sent:** Monday, October 15, 2007 11:57 PM

**To:** Markush.Comments

**Subject:** Comments on Claims Containing Alternative Language

Kathleen Kahler Fonda

Legal Advisor

Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Fonda,

I am pleased to submit the comments of the American Intellectual Property Law Association on the proposed revision of the rules of practice pertaining to claims using alternative language.

I would greatly appreciate an acknowledgment of receipt of these comments.

Thank you,

Mike Kirk

Executive Director

AIPLA





is stated that “[t]he proposed rule language is consistent with that of the PCT Guidelines (paragraph 5.18)” (72 Fed. Reg. at 44997).

The PTO should continue to rely on 35 U.S.C. § 112, second paragraph, to determine whether a claim is “difficult to construe,” or is otherwise unclear. The proposed language would not provide any guidance for either examiners or applicants and is capable of many interpretations. Applicants should be held to the statutory standard for clarity, but should not be held to any further nebulous standard that will only detract attention away from the objective of determining patentability. Accordingly, we request that the proposed requirements in paragraph (j)(1), if retained, be clarified and modified to require compliance only where the failure to comply with the limitations proposed in these paragraphs leads to a lack of clarity in violation of 35 U.S.C. § 112, second paragraph.

### **37 C.F.R. § 1.75(j)(2-4)**

This proposed section would require that “[a] claim that reads on multiple species by using alternative language must meet the conditions: ... (2) No alternative is defined as a set of further alternatives within the claim; and (3) No alternative is encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention. (4) Each alternative within a list of alternatives must be substitutable one for another.” In the commentary related to these subsections, it is stated that paragraphs (j)(2) and (j)(3) are proposed to be added to specify that no alternative can itself be defined as a set of further alternatives within a claim and that no alternative can be encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention. Further, the commentary indicates that proposed rule j(4) is added to require each alternative within a list of alternatives to be substitutable one for another.

Examiners have the flexibility to deal with clarity issues under 35 U.S.C. § 112, second paragraph. The proposed language of § 1.75(j)(2) is unclear and overly restrictive, as there are many claims that recite nested alternatives that are not unduly burdensome to search and that are not unclear. It is not clear whether an alternative can be defined as a set of further alternatives in a dependent claim. Clarification is requested. We suggest that this limitation of paragraph (j)(2) may be appropriate where the nested alternatives result in a lack of clarity in violation of the provisions of 35 U.S.C. § 112, second paragraph.

The proposed language of § 1.75(j)(4) is unclear as the PTO has not defined what is required in order to make an alternative “substitutable” for another alternative. Does this mean that each alternative must possess some functionality that makes it useful in the context of the claimed invention, or does it mean that each alternative must possess the identical properties and characteristics of each other alternative? Clarification is requested. The proposed language of § 1.75(j)(4) also is overly restrictive, particularly in the context of claims directed to combinations/subcombinations. For example, combination/subcombination claims comprising nucleic acids or proteins potentially may not be patentable simply because the invention in these cases may constitute a collection, library, or array of molecules, each of which may not be substitutable for the other. Proposed § 1.75(j)(4) would unduly discriminate against these inventions.

As with paragraph (j)(1), we request that the proposed requirements in paragraphs (j)(2-4), if retained, be clarified and modified to require compliance only where the failure to comply with the limitations proposed in these paragraphs leads to a lack of clarity in violation of 35 U.S.C. § 112, second paragraph.

### **37 C.F.R. § 1.75(k)**

The proposed section would require that “[a] claim may not incorporate another part of the specification or drawings by reference, unless there is no other practical way to define the invention. If a claim incorporates another part of the specification or drawings by reference, and that portion of the specification or drawings sets forth alternatives, the claim must comply with, and is subject to the provisions of, paragraph (j) of this section and § 1.140.”

According to the commentary at 72 Fed. Reg. 44997, this section is proposed to be added to ensure that a claim would receive the same treatment whether defined by alternative language specifically

set forth in the claim or defined by alternative language that is incorporated by reference to another portion of the specification. However, it is not clear whether the use of a generic limitation or a means plus function limitation, where the alternatives associated with these limitations are described in the specification, are considered an exception to this proposed provision or somehow not covered by this proposal. The PTO has indicated at 72 Fed Reg. 44996, that these types of generic expressions in the claims supported by alternatives in the specification are not subject to the provisions of proposed § 1.75(k). Clarification is requested. The policy underlying the proposed limitation appears to suggest that the Office is encouraging the use of limitations where the claimed invention does not require, and is not limited to, the means specifically disclosed in the specification, but would find fault with the limitation where the claim would require, and would be limited to, at least one of the alternatives specifically recited in the claim. Finally, we request that the PTO adopt the policy that if an examiner objects to a claim that is not complying with this proposed section, the examiner be required to suggest an alternative practical way to define the invention.

### **37 C.F.R. § 1.140(a)(1)**

The proposed section pertains to the requirements for a claim to be limited to a single invention in an application filed under 35 U.S.C. § 111(a). In particular, it requires that “[t]wo or more independent and distinct inventions may not be claimed in a single claim. See § 1.75(a). A claim that reads on multiple species using alternative language is limited to a single invention when all the species encompassed by the claim meet at least one of the following two conditions: (1) The species share a substantial feature essential for a common utility, or (2) are prima facie obvious over each other.”

The proposed language in this section is troubling from several viewpoints. First, this section proposes to require a claim to be limited to a single invention in applications filed under 35 U.S.C. § 111(a), rather than adopting the more permissive approach of § 121 that permits, but does not require, that an application be restricted when multiple inventions that are independent and distinct are presented in a patent application. Even if the PTO wanted to adopt a limitation that a claim be limited to a single invention, that requirement should be optional and depend on whether the search and examination of the multiple inventions within a single claim would cause an unnecessary burden to the PTO. In addition, the adoption of a requirement that a claim be limited to a single invention would suggest that the validity of a claim that did not satisfy this requirement could be attacked. There is no justification in policy or practice for adopting such a rigid position, and unnecessarily place patent owners at risk that claims would be rendered invalid based on a technicality that did not adversely affect the search or examination of the claimed invention.

As pointed out in the proposed amendment of § 1.141(a) that would state that “two or more independent and distinct inventions should not be claimed in one application,” the PTO is proposing to adopt flexibility inherent in 35 U.S.C. § 121 because the Director has not made restriction mandatory. If the PTO addresses the requirements for a single claim, it should adopt a position similar to that for proposed § 1.141(a) and suggest only that a claim should be directed to a single invention.

Second, the suggestion that a claim would be considered as limited to a single invention where all the species encompassed by the claim need to meet at least one of two specified conditions is of particular concern. The first condition that the species share a substantial feature essential for a common utility, is described as a feature, such as a particular structure, material, or act, without which the claimed alternatives would not retain the shared utility. 72 Fed. Reg. at 44997. As we understand this requirement, this would require that applicants prove that there is no other structure, material or act that could provide the shared utility. This is not only unacceptable, but clearly inconsistent with the relevant case law that only requires that the species share a single structural similarity. *In re Harnisch*, 631 F.2d 716, 722, 206 USPQ 300, 305 (CCPA 1980). As recognized in this decision in determining the propriety of a Markush grouping, the compounds must be considered as wholes and not broken down into elements or other components, and there is certainly no suggestion that applicants have a burden to eliminate any possibility that other structures would possess the utility shared by the claimed grouping of compounds.

The alternative condition for considering species to be limited to a single invention is that they are prima facie obvious over each other. This proposed condition is neither clear nor appropriate for determining whether a single invention is claimed. It is not clear whether the PTO would base this determination on a one-way test or a two-way test for obviousness, nor is it clear what assumptions should

be made about the state of the prior art in making this determination. Further, it is not clear whether the species should be considered prima facie obvious over each other in any context, or only in the context of the claimed invention. If these conditions are to be retained, clarification is requested. Merely because applicants have determined that there are alternative embodiments of a particular structure, process, or material that are alternatively useful in the context of the claimed invention, does not mean that each alternative is prima facie obvious over any other alternatives. It would be improper for the PTO to make such an assumption as it would use applicants own disclosure against the claims.

Finally, the practical operation of proposed § 1.140 is likely to violate the basic premise of a claim that must set forth what applicants regard as their invention. 35 U.S.C. § 112, second paragraph. Any proposed regulation that places the determination of what applicants regard as their invention in the hands of a patent examiner who will be guided primarily by what the examiner considers to be an appropriate field of search is clearly inappropriate. Such an artificial constraint on applicants' ability to claim what they regard as their invention is arguably improper for the same reasons discussed in the *Weber* and *Haas* decisions discussed in the Notice. If the proposed approach is adopted by the PTO, it should only apply to new applications filed on or after the effective date of the rules so that applicants have a fair opportunity to draft both applications and claims in a manner that will minimize the loss of opportunities to protect their inventions.

### **37 C.F.R. § 1.142(d)**

This proposed section pertains to the requirements for restriction to a single invention in an application filed under 35 U.S.C. § 111(a). The proposal would require that any claim that recites both an elected and a non-elected invention in the alternative will be objected to as failing to comply with § 1.75(a). Any non-elected invention must be canceled before the claim will be allowed, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181.

This proposed section is problematic for the same reasons advanced above with regard to the rights of applicants to claim what they regard as their invention. Any requirement to artificially limit the scope of a claim to only that subject matter that the examiner has searched and examined may be appropriate in some extreme cases, but is considered to be otherwise inappropriate as a general principle. In addition, the proposed section as drafted would appear to be too broad if it would apply to a case where an independent claim is generic and allowable, and a dependent claim recites an elected and a non-elected invention in the alternative. Presumably the allowance of the independent generic claim would indicate that the examiner searched broadly enough to consider both inventions. At the very least, this proposed section should be clarified.

### **37 C.F.R. § 1.143**

The proposed rule would require that (a) the election of an invention or species may be made with or without traverse. To preserve a right to seek reconsideration or petition for review of a requirement for restriction, the election must be with traverse. In addition, subsection (b) of the rule requires that if the applicant traverses a requirement for restriction, he or she may request reconsideration of the requirement, including withdrawal or modification, distinctly and specifically pointing out supposed errors in the requirement. In requesting reconsideration, the applicant must indicate an election of one invention or species for prosecution, which invention or species shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request.

The petition procedure at present takes an inordinately long time, is cumbersome, and costly. Accordingly, we suggest that in addition to the proposed rules regarding requirement for restriction, a further procedure should be provided (similar to the pre-Appeal Brief procedure) in which the applicant may have the matter considered by a quality assurance specialist (QAS). Additionally, prosecution should be suspended until the QAS review is completed and communicated to applicants. It is important that the examiner get it right before search and examination begins to avoid the waste of resources.

### **37 C.F.R. § 1.144**

Proposed § 1.144 pertains to petitions from requirements for restriction.

