

DEPARTMENT OF COMMERCE**Patent and Trademark Office****37 CFR Part 1**

[Docket No.: PTO-P-2006-0004]

RIN 0651-AC00

Examination of Patent Applications That Include Claims Containing Alternative Language**AGENCY:** United States Patent and Trademark Office, Commerce.**ACTION:** Notice of proposed rule making.

SUMMARY: The United States Patent and Trademark Office (Office) is proposing to revise the rules of practice pertaining to any claim using alternative language to claim one or more species. The search and examination of such claims often consume a disproportionate amount of Office resources as compared to other types of claims, because determining the patentability of these claims often requires a separate examination of each of the alternatives within the claims. The Office expects that requiring applicants who choose to draft claims that read on multiple species using alternative language to maintain a certain degree of relatedness among the alternatives will enable the Office to do a more thorough and more reliable examination of such claims.

COMMENT DEADLINE DATE: To be ensured of consideration, written comments must be received on or before October 9, 2007. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to markush.comments@uspto.gov. Comments may also be submitted by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, or by facsimile to (571) 273-7754, marked to the attention of Kathleen Kahler Fonda, Legal Advisor, Office of the Deputy Commissioner for Patent Examination Policy. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3 1/2-inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

The comments will be available for public inspection at the Office of the Commissioner for Patents, located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia, and will be available through anonymous file transfer protocol (ftp) via the Internet (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT:

Kathleen Kahler Fonda, Legal Advisor, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272-7754; by mail addressed to: Box Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; or by facsimile to (571) 273-7754, marked to the attention of Kathleen Kahler Fonda.

SUPPLEMENTARY INFORMATION:

I. Background Information. As part of its ongoing efforts to enhance patent quality and reduce pendency in accordance with the 21st Century Strategic Plan, the Office is proposing to revise its treatment of claims that recite alternatives, whether the claims use Markush or other forms of alternative language. While the origins of the Markush claim drafting technique lie in the chemical arts, claims that recite alternatives are now commonplace in all areas of technology. Applicants sometimes use Markush or other alternative formats to claim multiple inventions and/or to recite hundreds, if not thousands, of alternative embodiments of a single invention in one claim. Proper search of such complex claims, particularly those using Markush language, often consume a disproportionate amount of Office resources as compared to other types of claims. The prosecution of these complex claims likewise often requires separate examination and patentability determinations for each of the alternatives within the claim, e.g., if the alternatives raise separate prior art, enablement, or utility issues. Furthermore, the variety and frequency of alternatives recited in claims filed in applications pending before the Office, driven in part by trends in emerging technologies, have exacerbated problems with pendency.

In addition to comments on the proposed rules, the Office welcomes further suggestions for changes that would improve the examination of claims that recite Markush or other alternative language while appropriately balancing the interests of the Office with

those of applicants and the public. The Office expects that improving practices pertaining to claims that recite alternatives will enhance its ability to grant quality patents that effectively promote innovation in a timely manner.

A. Brief History of Office Treatment of Claims that Recite Alternatives. Claims that define species within the scope thereof by enumeration are now commonplace in all areas of technology. However, the Office had formerly deemed them unacceptable, apparently for failure to comply with the definiteness requirement of 35 U.S.C. 112. See Manuel C. Rosa, *Outline of Practice Relative to "Markush" Claims*, 34 J. Pat. Off. Soc'y 324, 324 (1952); *Manual of Patent Examining Procedure* (MPEP) section 706.03(d) (2nd Ed. 1953). In *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126, 128 (1924), the Office officially sanctioned a claim drafting technique, already in use for some time, wherein the phrase "selected from the group consisting of" is followed by a closed listing of specific members of the group. Claims including such language became known as "Markush claims." For example, if a claim to a chemical composition requires a particular alcohol, that alcohol could be defined via Markush language such as "an alcohol selected from the group consisting of methanol, ethanol, and isopropanol;" or "an alcohol of the formula R-OH, wherein R is selected from the group consisting of CH₃-, CH₃CH₂-, and (CH₃)₂CH-."

In addition to the indefiniteness issue, another factor giving rise to claims using Markush language was

the change from claims based on the central type of definition to those based on the peripheral definition. With the peripheral-type claims came the necessity of avoiding invalidity by reason of inoperative species which might be included within the metes and bounds of the claim. In mechanical cases, this problem is overcome by the use of elements defined as "means" but chemical claims do not lend themselves well to such a solution due to the fact that equivalence in chemical cases is difficult to establish. The Markush claim may be regarded as a partial solution to this problem, since it permits an applicant to claim a subgeneric group containing those materials which have been actually tested and known by applicant to be operable.

Richard L. Kelly, *et al.*, *Markush Claims*, 37 J. Pat. Off. Soc'y 164, 171 (1955). Thus, Markush practice arose from a need to address problems presented in claiming chemical compounds when an applicant could only define his or her invention by setting forth at least one set of alternatives from which a selection must be made. Most of the court decisions concerning claims that recite

alternatives involve Markush practice and reflect problems associated with claiming compounds by their chemical structure.

The Office has long wrestled with problems associated with Markush claiming. As noted in a 1935 review article:

[T]he extent to which the patent professional * * * made use of the Markush formula indicated that its application had gone far afield of the original intent. It was like a fire which had spread beyond control. It became the medium through which totally unrelated substances could be assembled under the guise of a genus. * * * If one member were found to be old or inoperative, that one was stricken from the group, and the diminished group reasserted with renewed vigor. In such a case the search required was for as many individual species as there were members recited in the group.

V.I. Richard, *Claims Under the Markush Formula*, 17 J. Pat. Off. Soc'y 179, 190 (1935).

By the 1950s, the Office generally viewed members of a proper Markush group as patentably indistinct from each other. See Manuel C. Rosa, U.S. Dep't of Commerce, *Training Manual for Patent Examiners: Outline of Practice Relative to "Markush" Claims* 11 (1958) ("These decisions uniformly hold that a reference for one of the members of the group is a reference for the entire group.") (citing *In re Ayres*, 83 F.2d 297, 29 USPQ 424 (CCPA 1936); *Ex parte Ellis*, 18 J. Pat. Off. Soc'y 731 (1936) (abstract only); *Ex parte Rutherford*, 63 USPQ 102 (Bd. Pat. App. 1943); *Ex parte Watt*, 63 USPQ 163 (Bd. Pat. App. 1942); *Ex parte Schroy*, 26 J. Pat. Off. Soc'y 498 (1944) (abstract only)). In 1958, the Court of Customs and Patent Appeals (CCPA), predecessor of the current Court of Appeals for the Federal Circuit (Federal Circuit), explained that Markush claims "were originally regarded as an exception to the previously acceptable claim terminology and were rigidly restricted to groups of substances belonging to some recognized class." *In re Ruff*, 256 F.2d 590, 598, 118 USPQ 340, 348 (CCPA 1958). However, Markush practice had been substantially liberalized in that "the original rigid, emergency-engendered restrictions have been progressively relaxed through the years to the point where it is no longer possible to indulge in a presumption that the members of a Markush group are recognized by anyone to be equivalents except as they 'possess at least one property in common which is mainly responsible for their function in the claimed relationship.'" *Ruff*, 256 F.2d at 599, 118 USPQ at 348 (quoting MPEP section 706.03(y) (2nd ed. 1953)).

The *Ruff* court concluded that in view of such liberalization, the mere fact that components were claimed as members of a Markush group could not be relied upon to establish the equivalency of these components. However, the *Ruff* court acknowledged that an applicant's expressed recognition of an art-recognized or obvious equivalent could be used as evidence that such equivalency does exist. See *Ruff*, 256 F.2d at 595, 118 USPQ at 345.

After the *Ruff* decision, the Office tried several approaches to rein in administrative problems arising from Markush claims. These included rejecting claims on the following bases: 35 U.S.C. 112, ¶ 2; 35 U.S.C. 121 (accompanied by a restriction requirement and withdrawal of the claim); and a "judicially created doctrine" of improper Markush grouping. See Edward C. Walterscheid, *Markush Practice Revisited*, 61 J. Pat. Off. Soc'y 270, 271 (1979). However, the CCPA clearly enunciated its view that these statute-based rejections were improper. In *In re Wolfrum*, the court held that it is improper to reject a Markush claim under 35 U.S.C. 112, ¶ 2, merely because more than one independent and distinct invention is encompassed by the claim. 486 F.2d 588, 591, 179 USPQ 620, 622 (CCPA 1973). In a later case, the court explained that 35 U.S.C. 121 "provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be 'independent and distinct.' It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis." *In re Weber*, 580 F.2d 455, 458, 198 USPQ 328, 331-32 (CCPA 1978) (emphases in original). Notably, although it determined that there was no statutory basis for rejecting a claim under 35 U.S.C. 121, the *Weber* court remanded the case to the Office for consideration of a doctrinally based "improper Markush claim" rejection. See also *In re Haas*, 486 F.2d 1053, 1054, 179 USPQ 623, 626 (CCPA 1973) (holding that following a restriction requirement, the withdrawal of a Markush claim from consideration not only in the application at issue but prospectively in any subsequent application on the basis of its content was effectively a rejection of that claim).

Shortly after *Weber* and *Haas*, the CCPA provided a detailed analysis of Markush practice in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). In that case, the Office rejected a claim drawn to coumarin compounds useful

as dyes based on a judicially created doctrine, gleaned by the Office Board of Appeals (Board) from a number of cited CCPA decisions, as reciting an improper Markush group. According to the Board, both final product dyes and intermediate compounds from which they could be synthesized were within the scope of the claim, and the claim failed for misjoinder because some species within its scope were not "functionally equivalent" to others. The court reversed the Board's decision, explaining that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter of the claim lacks "unity of invention." In tracing the history of "improper Markush" rejections, the court observed:

In the early years of the development of Markush practice, many of the cases involved the problem of clarity—avoiding the uncertainties of alternatives and the like. More recently, the cases have centered on problems of scope, which are related to enablement. Assuming enablement, however, there remains a body of Markush-practice law regarding Markush-type claims, particularly in the chemical field, concerned more with the concept of what might be better described as the concept of unity of invention. At least the term would be more descriptive and more intelligible internationally than is the more esoteric and provincial expression 'Markush practice.' It is with this unity of invention concept in mind that we approach the propriety of the appealed claims.

631 F.2d at 721, 206 USPQ at 305.

The *Harnisch* court then explained that the Office had a "perfect right" to rely on rules derived from case law "to determine whether the claims before it were or were not in proper form to be examined for patentability." 631 F.2d at 720, 206 USPQ at 304. The *Harnisch* court further suggested that the Office consider exercising its rule making powers to forestall procedural problems arising from Markush claims. 631 F.2d at 722 n.6, 206 USPQ at n.6. While it is clear from *Harnisch* that the CCPA was not hostile to the concept of "improper" Markush claims, the Office has not received further guidance from its reviewing courts as to the propriety of a Markush rejection since *Harnisch*.

The struggle to balance the needs of inventors for coverage of the full scope of their inventions with those of the Office for search and examination responsibilities commensurate in scope with resources is a long-standing one. The Office "must have some means for controlling such administrative matters as examiners' caseloads and the amount of searching done per filing fee." *Weber*, 580 F.2d at 458, 198 USPQ at 332. Controlling examiners' caseloads is a

much more significant concern in 2007 than it was in 1978. The volume and complexity of patent applications continue to outpace the examining corps' current capacity to examine them. The result is a pending—and growing—application backlog of historic proportions. Thus the Office does not believe that controlling the amount of searching per filing fee will, by itself, resolve the administrative issues raised by the use of Markush or alternative language.

For a more comprehensive review of the history of Markush claiming, see V.I. Richard, *Claims Under the Markush Formula*, 17 J. Pat. Off. Soc'y 179 (1935); Richard L. Kelly, et al., *Markush Claims*, 37 J. Pat. Off. Soc'y 164 (1955); Edward C. Walterscheid, *Markush Practice Revisited*, 61 J. Pat. Off. Soc'y 270 (1979); and *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980).

B. Claims Reciting Alternatives. Claims that use alternative language to define multiple species are often confusing and complex, and frequently border on being unmanageable. A single claim may continue for pages; even relatively short claims may encompass millions of species in the alternative. Claims that recite alternatives, especially in the chemical and biotechnological arts, often describe alternatives which themselves have multiple, nested points of variation or other complex variations, or set forth alternatives that lack either a shared utility or a common structure.

Markush formats and other forms of alternative language are generally used in two different contexts. First, a chemical compound or a portion thereof (either claimed as such, or as a component of a process or composition), may be defined using Markush language. In *Harnisch*, the court found that the claimed compounds, which were defined as members of a Markush group, had “unity of invention” because they shared a common function as dyes, and shared a substantial structural feature as coumarin compounds. 631 F.2d at 722, 206 USPQ at 305. Current Office practice, stemming from *Harnisch*, is that compounds that are defined by Markush language are directed to a single invention (*i.e.*, have “unity of invention”) when they “(1) share a common utility, and (2) share a substantial structural feature essential to that utility.” See MPEP 803.02 (8th Ed., Rev. 5, Aug. 2006). Second, entire process steps or components of a claimed invention, rather than a single compound or portion(s) thereof, may be defined using alternative language. According to current Office policy, Markush format is acceptable when

defining such process steps or components if all the members of the group possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. See MPEP 2173.05(h) (8th Ed., Rev. 5, Aug. 2006).

1. Example of Markush Format Alternative Language. Typical examples of apparently straightforward claims using the Markush format can be found in the PCT International Search and Preliminary Examination Guidelines (PCT Guidelines), Chapter 10 (available at <http://www.wipo.int/pct/en/texts/pdf/ispe.pdf>). Examples of such claims are set forth in paragraphs 10.38–10.45; paragraphs 10.52–10.59 therein address unity of invention issues specifically pertaining to biotechnological inventions.

Example 24 from the PCT Guidelines, reproduced below, is illustrative of an apparently straightforward claim which would actually be quite complex to search and examine.

10.44 Example 24

Claim 1: A pharmaceutical compound of the formula: A—B—C—D—E

Wherein:

A is selected from C₁–C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₅–C₇ heterocycle having 1–3 heteroatoms selected from O and N;

B is selected from C₁–C₆ alkyl or alkenyl or alkenyl, amino, sulfoxy, C₃–C₈ ether or thioether;

C is selected from C₅–C₈ saturated or unsaturated heterocycle having 1–4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C₄–C₈ carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

This claim reads on approximately 2.564×10^{23} possible species, there is no substantial feature shared by all species, and there is no indication that the species share a specific common utility. Claims in patent applications, especially those in the chemical and biotechnological arts, are often significantly more complex to search and examine than the apparently straightforward example above.

2. Examples of Other (Non-Markush) Alternative Language. Claims that recite alternatives usually define species that fall within the scope of a claim; however, such claims occasionally recite a list of species that are excluded from the scope of a claim. The most common forms of claims that set forth alternatives employ the phrase “selected from the group consisting” or the term

“or.” Other claim limitations written in an alternative form that do not use these phrases include, for example, the following:

(1) “A composition comprising any 10 molecules from Table 1” (wherein Table 1 includes 1000 chemical formulas);

(2) “A protein having SEQ ID NO: 1, wherein any polar residue may be substituted by a proline residue;” or “a protein having SEQ ID NO: 2” (where a review of SEQ ID NO: 2 of the sequence listing shows that at certain positions, specific alternative variations are permitted); and

(3) “A polypeptide consisting of a contiguous 10-mer fragment of SEQ ID NO: 3” (where a review of the sequence listing shows that fully defined SEQ ID NO: 3 is 200 residues long, and thus the claim reads upon plural fragments in the alternative: residues 1–10, residues 2–11, residues 3–12, etc.).

3. Example of Alternative Language in Process Claims. Although the above examples are directed to product claims, process claims also may be drafted in alternative language format. A process claim could, for example, recite a list of alternative active steps or achieve a list of alternative effects. Thus, a process claim employing alternative language could require the same product to achieve different effects, or require different products to achieve the same effect. Furthermore, such a process claim could recite two features which vary. A simple example of such a claim is:

“A process of administering product A, B, or C to treat disease D, E, or F.” Such a claim would read upon a matrix of nine species wherein the species do not all require either administering the same product or treating the same disease.

C. Current Practice With Respect to Claims Reciting a Markush Group. Current Office policy requires examination of all species of a claim that recites a Markush group when the alternatives are sufficiently few in number or so closely related that search and examination can be made without serious burden. See MPEP 803.02 (8th Ed., Rev. 5, Aug. 2006). Consistent with the *Harnisch* decision, the Office cannot refuse to examine what applicants regard as their invention unless the subject matter in a claim lacks unity of invention. As a result, even where the search and examination of a claim that has “unity of invention” would require serious burden, the examiner must determine the patentability of the claim. In such case, however, the examiner may require applicant to elect a single species under 37 CFR 1.146 for initial search and examination to facilitate examination on the merits. If the elected species is not allowable, examination of the Markush claim will be limited to the

elect species and any species not patentably distinct therefrom, and any separate claims to the elected species and any species not patentably distinct therefrom. See MPEP 803.02 (8th Ed., Rev. 5, Aug. 2006). Claims drawn to species patentably distinct from the elected species are held withdrawn from further consideration. If the elected species is allowable, then the search and examination of the Markush claim will be extended to non-elected species to the extent necessary to determine patentability of the claim. This may require a separate search and examination of each alternative claimed, *i.e.*, a separate patentability determination of each non-elected species.

The *Harnisch* court did not set forth a generally applicable test for the Office to follow in determining whether, in an application filed under 35 U.S.C. 111(a), alternatives within a claim have “unity of invention,” nor did it suggest a specific mechanism by which the Office could refuse to examine a claim that lacks “unity of invention.” The procedure described in the paragraph above applies when the alternatives within a claim have “unity of invention.” However, to date, the Office has not established official procedures for examiners to follow when examining a claim that recites alternatives wherein the alternatives lack “unity of invention” or for restricting an application to one invention where multiple independent and distinct inventions are recited as alternatives in a single claim. The Office is proposing to revise the rules of practice to provide such procedures.

D. Proposed Treatment of Claims that Recite Alternatives. In a separate rule making, the Office proposed to revise the rules of practice relating to the examination of claims in patent applications to focus its initial examination on a limited number of claims. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR 61 (Jan. 3, 2006), 1302 *Off. Gaz. Patent Office* 1329 (Jan. 24, 2006) (proposed rule). Applicants should not be permitted to circumvent the proposed claims rules by presenting a single claim that sets forth multiple independent and distinct inventions in the alternative. Although comments were requested regarding how claims that read on multiple species using alternative language should be counted for purposes of proposed 37 CFR 1.75(b)(1), the Office did not propose a specific rule change to address the issue. Furthermore, the comments received from the public did not address the issue of how to treat a single claim

that encompasses more than one independent and distinct invention.

Regardless of whether the proposed rules pertaining to the number of claims are promulgated, the Office needs to address the challenges created by claims that employ alternative language, particularly Markush language, for the reasons discussed above. As noted above, applicants in all areas of technology have been filing increasing numbers of claims that employ alternative language; the complexity and variety of the format of those claims are also on the rise. To enable the Office to do a better, more thorough and reliable examination of such claims, the Office is proposing rules to limit each claim to a single invention and to define acceptable formats for claims that set forth alternatives. These proposed rules are not intended to change current restriction practice with regard to multiple independent and distinct inventions claimed in separate claims of an application. Rather, they are intended to provide a mechanism by which the Office can require a single claim to be limited to a single invention.

1. *Each claim must be limited to a single invention.* A claim that is directed to multiple independent and distinct inventions would meet the statutory eligibility requirement for restriction set forth in 35 U.S.C. 121:

If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. * * *

35 U.S.C. 121.

Through the use of the word “may,” the statute is permissive, not mandatory, and gives the Director discretion to require restriction. Thus, the Office proposes that if a single claim defines multiple independent and distinct inventions, the examiner may apply a restriction requirement before examination. In determining whether a claim is limited to a single invention, the claim as a whole must be considered; the discrete components of the claim are not to be analyzed in isolation. See, *e.g.*, *Diamond v. Diehr*, 450 U.S. 175, 188–89, 209 USPQ 1, 9 (1981); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983).

As a general principle, a claim that encompasses more than one species, but does not list alternatives, defines one generic invention. If such a claim were restricted, the generic invention might never be examined as a whole if the claim were divided into parts. *Weber*, 580 F.2d at 458, 198 USPQ at 330 (“The totality of the resulting fragmentary claims would not necessarily be the

equivalent of the original claim.”). Although dividing one generic claim by restriction may not be appropriate under *Weber*, making a requirement for an election of species for initial search and examination purposes would be permissible under § 1.146. This procedure provides a practical way to examine a large genus:

Restriction of the members which applicants are permitted to combine in the Markush group evolved from the administrative principle promulgated by the Patent Office that only a single invention can be claimed in a single application. The reason for such a rule is based upon the very real necessity of avoiding multiple searches for a single fee. Consequently, the problem of proper grouping is simply one of administration, and restriction of members which properly may be combined in a Markush group is solely based on the premise that only one invention may be claimed in any one application.

Kelly, 37 J. Pat. Off. Soc’y at 171–172. See also the Office commentary quoted by the court in *In re Feight*, 181 F.2d 206, 209, 85 USPQ 274, 277 (CCPA 1950):

The appellant’s position, therefore, amounts to this: that an applicant may include claims to a number of independent inventions in a single application and, by also including one or more claims, however improper, which recite all of these inventions, may compel the Patent Office to act upon the merits of all his claims. The mere statement of this proposition seems sufficient to show its unsoundness since, if accepted, it would be possible for an applicant to obtain an examination of an unlimited number of independent inventions for a single fee, by including in his application a claim which catalogued all of them.

If any portion of a claim requires selection from a list of alternatives, then the claim as a whole should be treated as a claim that reads on multiple species using alternative language, and would be subject to the provisions of proposed §§ 1.75(j) and 1.140. For example, the following claims define the same subject matter:

1. A composition comprising component 1 selected from the group consisting of A, B, and C and component 2 selected from the group consisting of D, E, and F.

2. A composition comprising AD, AE, AF, BD, BE, BF, CD, CE, or CF.

In the above example, AD, AE, AF, etc., each represent individual alternative species. Determining whether the claimed subject matter is limited to a single invention does not depend on there being a community of properties among the variable members of the Markush expressions themselves (A, B, C, etc.), but rather depends on

whether the individual species (AD, AE, AF, etc.) within the scope of the claim define a single invention. This is not always a straightforward task, especially when claims employ complex alternative language.

In the 1950s, as a general rule, members of a proper Markush group were not considered to be patentably distinct from each other. *Training Manual for Patent Examiners: Outline of Practice Relative to "Markush" Claims* at 11. That practice ended when the court in *Ruff*, quoting MPEP 706.03(y) (2nd ed. 1953), indicated that Markush practice had been liberalized to such an extent that the mere fact that components were claimed as members of a Markush group could not be relied upon to establish the equivalency of these components. 256 F.2d at 599, 118 USPQ at 348. However, the court also observed that an applicant's expressed recognition of an art-recognized or obvious equivalent may be used as evidence that such equivalency does exist. 256 F.2d at 595, 118 USPQ at 345. Similarly, in a later case, the Commissioner of Patents determined that if there is an express admission that claimed species would have been obvious over each other within the meaning of 35 U.S.C. 103, an examiner should not require restriction. *See In re Lee*, 199 USPQ 108, 109 (Comm'r Pat. 1978).

In addition to proposing a requirement limiting a claim to a single invention, the Office is proposing to specify that when subject matter that reads on multiple species is defined in a single claim using alternative language, the claim is limited to a single invention when at least one of the following two conditions is met: (1) All of the species encompassed by the claim share a substantial feature essential for a common utility, or (2) all of the species are *prima facie* obvious over each other. The first definition is based on the guidance provided by the CCPA in *In re Harnisch*. The second definition codifies the long-standing principle that it is improper to restrict between species that are *prima facie* obvious over each other.

The Office proposes to encourage applicants, when filing a claim that employs alternative language, to provide an explanation as to why the claim is directed to a single invention. Applicant may explain, for example, that the species share a substantial feature essential for a common utility. The feature could be a common structure, material, or act necessary for at least one shared specific, substantial, and credible utility (*i.e.*, 35 U.S.C. 101 utility). Alternatively, applicant may

explain that the species are *prima facie* obvious over each other.

When applicant submits an explanation in a timely manner, the examiner will fully consider it. If convincing, the examiner will not object to the claim as being directed to more than one invention, nor will restriction be required under proposed § 1.140. Where the examiner disagrees with an applicant's statement under proposed § 1.140(b), the examiner must provide an explanation why applicant's statement is not convincing and why the claim is not limited to a single invention. The Office is of the opinion that providing applicants with the opportunity to explain upon filing why a claim that reads on multiple species using alternative language complies with the proposed rule ultimately will reduce the number of restriction requirements and shorten the overall time to a first Office action on the merits of the claims.

As noted above, the Office proposal defines two ways in which a claim that employs alternative language would meet the requirement of being limited to a single invention. However, a claim that encompasses more than one embodiment by using generic terminology (*i.e.*, without requiring selection from of a list of alternatives) would not be subject to the provisions of § 1.140. For example, a claim reciting the generic limitation "a means for attaching," in the context of a specification that discloses staples, tape, and glue as suitable means would encompass several species. However, the "means for attaching" limitation would not subject the claim to the provisions of § 1.75(j) or (k) or § 1.140 because the claimed invention does not require, and is not limited to, the means specifically disclosed in the specification. By contrast, a claim reciting the limitation "an attachment means selected from the group consisting of staples, glue, or tape" would be subject to the provisions of proposed § 1.75(j) and (k) and § 1.140.

The Office also proposes that if an application seeks the benefit under title 35, United States Code, of a prior-filed application and discloses subject matter that was not disclosed in the prior-filed application, the applicant must identify which claim or claims in the application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application. This proposal would reduce examination complexities and identify situations wherein a prior art reference that anticipates or renders *prima facie* obvious at least one species within the scope of a claim would not be available

as prior art against another species if that species was set forth in a separate claim.

2. Format Requirements for a Claim With Species Presented as a Set of Alternatives. Under current practice, a claim that sets forth multiple independent and distinct inventions in the alternative via Markush format is examined in accordance with MPEP 803.02. Applicants frequently present claims that define alternative species in a complex manner, *e.g.*, defining alternatives by reference to a set of additional alternatives, setting forth alternatives that encompass the same species, and listing components that are not interchangeable as alternatives. Given the administrative difficulties that arise during the search and examination of claims that present species using alternative language and the proposal to require each claim to be limited to a single invention, the Office proposes to require a simplified format for the presentation of such claims and to set forth conditions that must be met by any claim that uses alternative language. It is generally understood that "members of [a] Markush group are * * * alternatively usable for the purposes of the invention." *In re Driscoll*, 562 F.2d 1245, 1249, 195 USPQ 434, 436 (CCPA 1977). Similarly, with regard to international applications, the PCT Guidelines (paragraph 5.18) specifies that a claim can contain alternatives "provided those alternatives are of a similar nature and can fairly be substituted one for another, and provided also that the number and presentation of alternatives is a single claim does not make the claim obscure or difficult to construe." The Office proposes to adopt language similar to that in the PCT Guidelines, specifically requiring that the number and presentation of alternatives in the claim not make the claim difficult to construe, and requiring that each alternative within a list of alternatives must be substitutable one for another. In addition, to reduce the complexity of determining whether a claim is directed to a single invention, the Office proposes to specify that no alternative may itself be defined as a set of further alternatives. Finally, the Office proposes to specify that no alternative may be encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention. When alternatives partially overlap in scope, it is more difficult to determine whether a single claim encompasses more than one invention. Thus, a single claim that includes alternatives that either fully overlap

(e.g., “selected from the group consisting of an adhesive agent, tape, and glue”) or partially overlap (e.g., “selected from the group consisting of citrus fruits and tropical fruits”) in scope may be subject to an objection. Applicants should file a series of individual claims from the broadest scope that they feel they are entitled to the narrowest scope they are willing to accept. Put differently, applicant should narrow the scope of protection sought via separate claims and not via nested sets of overlapping alternatives.

Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is proposed to be amended as follows:

Section 1.75: Section 1.75(a) is proposed to be amended by adding the proviso that a claim must be limited to a single invention. While it has long been Office policy to exercise the discretionary authority granted in 35 U.S.C. 121 to restrict an application to a single invention, the Office has not yet established mechanisms for objecting to the format of a single claim that is directed to multiple independent and distinct inventions, or restricting a single claim to a single invention. Proposed § 1.75(a) would provide the basis for objecting to the format of a claim that is directed to two or more independent and distinct inventions. See also the proposed addition of § 1.140, which provides for the restriction of a claim to a single invention, and the proposed amendment to § 1.142(b), which provides that the propriety of a requirement for restriction will be determined without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim.

Section 1.75(d)(2) is proposed to be amended by deleting the reference to § 1.141 to § 1.146 as unnecessary in view of proposed changes to those rules. Paragraph (d)(2) is also proposed to be amended by adding the proviso that if an application seeks the benefit under title 35, United States Code, of a prior-filed application and discloses subject matter that was not disclosed in the prior-filed application, the applicant must identify which claim or claims in the application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application.

Section 1.75(e) is proposed to be amended to replace “the nature of the case admits, as in the case of” with “the application describes a claimed invention as” to use more current terminology. Paragraphs (e)(1) and (e)(3)

are proposed to be amended to replace the word “combination” with “invention” to clarify that this provision is applicable to any claimed invention, not just one considered to be a combination.

Section 1.75(j) is proposed to be added to set forth the required format for a claim that reads on multiple species using alternative language. A claim that does not comply with the provisions of this section would be subject to an objection. The Office proposes to add paragraph (j)(1) to specify that the number and presentation of alternatives in a claim must not make the claim difficult to construe. The proposed rule language is consistent with that of the PCT Guidelines (paragraph 5.18). 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.

Section 1.75(j)(4) is proposed to be added to require each alternative within a list of alternatives to be substitutable one for another. The proposed rule is consistent with paragraph 5.18 of the PCT Guidelines and current Office practice (see MPEP 2173.05(h)). Thus a claim that employs alternative language would not be in a proper format unless all of the alternatives are interchangeable, and substitution of one for another would result in the same invention.

Section 1.75(k) is proposed to be added to specify that a claim must be self-contained, without incorporating 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 defines a set of alternatives, the claim must comply with, and is subject to the provisions of, paragraph (j) of this section and § 1.140. This section is proposed to be added to ensure that a claim would receive the same treatment whether defined by alternative language explicitly set forth in the claim or defined by alternative language that is incorporated by reference to another portion of the specification.

Section 1.140: Section 1.140 is proposed to be added to require a claim to be limited to a single invention in applications filed under 35 U.S.C. 111(a). Paragraph (a) is proposed to be added to specify that a claim presenting alternatives must be limited to a single

invention, and to specify that a claim would be considered as limited to a single invention where all the species encompassed by the claim meet at least one of the following two conditions: (i) Share a substantial feature essential for a common utility, or (ii) are *prima facie* obvious over each other.

Alternatives share a substantial feature necessary for a common utility when they share a utility that complies with the requirements of 35 U.S.C. 101. A substantial feature in this context is a feature, such as a particular structure, material, or act, without which the claimed alternatives would not retain the shared utility.

Paragraph (b) is proposed to be added to indicate that the presentation of a claim that reads on multiple species using alternative language may be accompanied by a statement explaining why the claim is limited to a single invention. This would provide the applicant with the opportunity to present an explanation as to why a claim is limited to a single invention before the Office determines whether an objection under proposed § 1.75(a) or a restriction requirement under proposed § 1.142 would be proper.

Section 1.141: Section 1.141(a) is proposed to be revised by replacing “may not” with the more permissive term “should not” in the context of claiming two or more independent and distinct inventions in one application. The proposed revision is consistent with current practice as the Director has not made restriction mandatory. Furthermore, the “exception” language in paragraph (a), i.e., that different species may be specifically claimed in different claims provided the application also includes an allowable claim generic thereto, is proposed to be deleted. If the application includes an allowable generic claim, restriction would be improper and the generic claim would define a single invention.

Section 1.141(b) is proposed to be revised to clarify when restriction would be appropriate where an application claims a product, a process of making that product, and a process of using that product. The proposed revision clarifies that a three-way restriction requirement can be made only where the process of making the product is distinct from the product, the process of using the product is distinct from the product, and the processes of making and using the product are distinct from each other.

Section 1.142: Section 1.142(a) is proposed to be revised to specify that the provisions therein authorize restriction requirements in applications filed under 35 U.S.C. 111(a).

The content of current paragraph (b) of § 1.142 is proposed to be moved to paragraph (d) and further modified. Section 1.142(b) as proposed recites that the propriety of a restriction requirement will be determined without regard to whether plural inventions are recited in separate claims or as alternatives within a single claim. This proposal, which substantively corresponds to § 1.475(e) (pertaining to unity of invention determinations in National Stage applications filed under 35 U.S.C. 371), provides support for an intra-claim restriction requirement, *i.e.*, a requirement to limit a single claim to a single invention.

Section 1.142(c) is proposed to be added to incorporate subject matter from current paragraph (b) and indicate that any claim limited solely to a non-elected invention, if not cancelled, is withdrawn from further consideration, although it is subject to reinstatement in the event the restriction requirement is withdrawn.

Section 1.142(d) is proposed to be added to provide that any claim that recites both an elected invention and a non-elected invention will be objected to as failing to comply with § 1.75(a), which requires each claim to be limited to a single invention. Section 1.142(d) as proposed would also provide that any non-elected invention must be canceled before a claim that recites both an elected invention and a non-elected invention would be allowed (subject to reconsideration and review as provided in §§ 1.143, 1.144, and 1.181).

Section 1.143: Section 1.143 is proposed to be revised to add a new paragraph (a), and to move the current paragraph, with clarifying revisions, to new paragraph (b). Paragraph (a) is proposed to be added to specify that the election of an invention or species may be made with or without traverse, although traversal is necessary to preserve the right to petition. Paragraph (b) is proposed to be revised to indicate that the applicant must indicate an election of one invention or species for prosecution, and that any request for reconsideration of the requirement must distinctly and specifically point out supposed errors in the requirement.

Section 1.144: Section 1.144 is proposed to be revised to clarify when an applicant may petition the Director to review the requirement for restriction. Paragraph (a) as proposed requires a timely request for reconsideration of the requirement. Paragraph (b) as proposed provides that a petition may be filed after a restriction requirement is made final or a second requirement for restriction is made, even if the second requirement is not

made final, whereas the present rule requires a final restriction requirement before petitioning. Proposed paragraph (b) also sets forth when a petition must be filed, *i.e.*, within the earlier of two months of the mailing date of the final requirement for restriction from which relief is requested or the filing of a Notice of Appeal. Paragraph (c) is proposed to be added to specify that a petition before the second requirement will be dismissed as premature, and that filing a petition does not obviate applicant's obligation to timely reply to the remainder of the action. Paragraph (d) is proposed to be added to specify that the two-month period for filing the petition is not extendable and that late filed petitions may be dismissed as untimely.

Section 1.145: Section 1.145 is proposed to be revised by specifying that after an Office action on an application, if the applicant presents by amendment one or more claims directed to an invention distinct from and independent of the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181. The current rule indicates applicant "will" be required to restrict, and does not reference § 1.181.

Section 1.146: Section 1.146 is proposed to be revised to permit an examiner, in the course of examining a claim directed to a single invention that encompasses multiple patentably distinct species, to require an election of one disclosed species of the claim for initial search and examination purposes.

Section 1.146(b) is proposed to be added to specify that the examiner may require the applicant to restrict a claim that was subject to an election requirement under paragraph (a) of this section to the one or more species that were searched and examined if any species encompassed by the claim is not patentable.

Under current practice, before searching the prior art for the claimed invention, an examiner makes an initial determination as to whether the claims presented are directed to a single invention or multiple independent and distinct inventions. If a single claim encompasses multiple species, the examiner may require a provisional election of a single species. *See* MPEP 803.02 and 809.

Under the proposed rule, when a claim encompasses multiple species, an examiner may continue to require a provisional election of a single disclosed species, even if a claim is

limited to a single invention. For example, if a specification discloses staples, tape, and glue as exemplary "means for attaching," an applicant may present one claim reciting the limitation "a means for attaching" (which clearly includes within its scope multiple species) and in addition present one or more claims that specify the particular means. If each species that employs a specific means is patentably distinct from the other species, the "means for attaching" claim would be a claim that links together otherwise restrictable inventions. If an applicant elects a particular means in reply to a requirement for a provisional election of a single disclosed species and the examiner determines that species is allowable, the examiner would be required, consistent with current practice, to continue to examine the "means for attaching" claim until a determination on the patentability of the claim is reached. If the "means for attaching" claim is allowable, then any claim that depends from or otherwise requires all the limitations of the allowable claim would be examined for patentability and the provisional election would no longer be effective.

In addition to being applicable to a claim that defines multiple species using generic terminology, *i.e.*, without requiring selection of an alternative, the proposed provision would also apply to a claim that uses alternative language. Evidence that supports a finding that one species does not comply with the requirements of 35 U.S.C. 101 or 112 would not necessarily support a finding of lack of utility, enablement, or adequate written description with regard to any other species. Thus, where the elected species is patentable but the claims are not enabled or adequately described over their entire scope, the proposed rule would permit an examiner to require restriction of the claims to the elected species (and allowable obvious variants thereof).

Section 1.499: This section is proposed to be revised by designating the currently undesignated paragraph as paragraph (a) and adding new paragraphs (b), (c), and (d).

Paragraph (b) is proposed to be added to address treatment of a claim limited solely to a non-elected invention in a national stage application. The language corresponds to that in proposed § 1.142(c). Paragraph (c) is proposed to be added to indicate that any claim in a national stage application that recites in the alternative both an elected and a non-elected invention will be objected to as failing to comply with § 1.475. The language is analogous to that in proposed § 1.142(d). Paragraph (d) is

proposed to be added to set forth that if, after an Office action in a national stage application, the applicant presents by amendment one or more claims directed to an invention that lacks unity of invention (§ 1.475) with the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181. The language is analogous to that it proposed § 1.145.

Rule Making Considerations

Administrative Procedure Act: As discussed previously, the court in *Harnisch* invited the Office to exercise its rule making authority under former 35 U.S.C. 6(a) to anticipate and forestall the “procedural problems” surrounding Markush claims. 631 F.2d at 722 n.7, 206 USPQ at 306 n.7. Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure. See *Bachow Communs., Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are “rules of agency organization, procedure, or practice” and exempt from the Administrative Procedure Act’s notice and comment requirement); see also *Fressola v. Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) (“it is extremely doubtful whether any of the rules formulated to govern patent or trade-mark practice are other than ‘interpretive rules, general statements of policy, * * * procedure, or practice.’”) (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Rep. 149, 153 (1948)). Therefore, the changes being proposed in this notice involve interpretive rules, or rules of agency practice and procedure. Accordingly, prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law). Nevertheless, the Office is seeking public comment on proposed changes to obtain the benefit of such input prior to adopting changes to the rules of practice on these issues.

Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are required. See 5 U.S.C. 603.

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism

Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

Paperwork Reduction Act: This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information involved in this notice have been reviewed and previously approved by OMB under OMB control numbers: 0651–0031, and 0651–0032. The United States Patent and Trademark Office is not resubmitting the other information collections listed above to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with the information collections under these OMB control numbers. The principal impacts of the changes in this proposed rule are to: (1) Expressly require that a claim be limited to a single invention; and (2) specify the conditions under which a claim that reads on multiple species by using alternative language to list species) will be treated as limited to a single invention.

Interested persons are requested to send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office; and (2) Robert A. Clarke, Deputy Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Inventions and patents, Lawyers.

For the reasons set forth in the preamble, 37 CFR part 1 is proposed to be amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

2. Section 1.75 is amended by revising paragraphs (a), (d)(2), and (e), and adding paragraphs (j) and (k) to read as follows:

§ 1.75 Claims.

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his or her invention or discovery. A claim must be limited to a single invention.

* * * * *

(d) * * *

(2) If an application seeks the benefit under title 35, United States Code, of a prior-filed application and discloses subject matter that was not disclosed in the prior-filed application, the applicant must identify which claim or claims in the application are disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application.

(e) Where the application describes a claimed invention as an improvement, any independent claim should contain in the following order:

(1) A preamble comprising a general description of all the elements or steps of the claimed invention which are conventional or known;

(2) A phrase such as “wherein the improvement comprises”; and

(3) Those elements, steps, and/or relationships which constitute that portion of the claimed invention which the applicant considers as the new or improved portion.

* * * * *

(j) A claim that reads on multiple species by using alternative language must meet the following conditions:

(1) The number and presentation of alternatives in the claim does not make the claim difficult to construe;

(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.

(k) 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.

3. Section 1.140 is added after the undesignated center heading "Joinder of Inventions in One Application; Restriction" to read as follows:

§ 1.140 Requirement for a claim to be limited to a single invention in an application filed under 35 U.S.C. 111(a).

(a) Two 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) The species are *prima facie* obvious over each other.

(b) The presentation of a claim that reads on multiple species using alternative language (§ 1.75(j)) may be accompanied by a statement explaining why the claim is limited to a single invention. Such a statement shall be considered by the Office if filed by the applicant at the same time as the presentation of such a claim and may be considered by the Office if filed by the applicant after the presentation of such a claim but before the mailing date of any restriction requirement or action on the merits.

4. Section 1.141 is revised to read as follows:

§ 1.141 Different inventions in one application filed under 35 U.S.C. 111(a).

(a) Two or more independent and distinct inventions should not be claimed in one application.

(b) Where claims to a product, process of making the product, and process of using the product are included in an application, a three-way requirement for restriction can be made only where the process of making the product is distinct from the product, the process of using the product is distinct from the product, and the processes of making and using the product are distinct from each other.

5. Section 1.142 is revised to read as follows:

§ 1.142 Requirement for restriction to a single invention in an application filed under 35 U.S.C. 111(a).

(a) If two or more independent and distinct inventions are claimed in a single application filed under 35 U.S.C. 111(a), the examiner in an Office action

may require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction. Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

(b) The propriety of a requirement for restriction shall be determined without regard to whether the plural inventions are recited in separate claims or as alternatives within a single claim.

(c) Any claim limited solely to a non-elected invention, if not canceled, is withdrawn from further consideration. Any claim withdrawn from further consideration as a result of a restriction requirement and election is subject to reinstatement in the event the restriction requirement is withdrawn or overruled.

(d) 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.

6. Section 1.143 is revised to read as follows:

§ 1.143 Reconsideration of requirement for restriction.

(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.

(b) 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.

7. Section 1.144 is revised to read as follows:

§ 1.144 Petition from requirement for restriction.

(a) Applicant may petition the Director to review the requirement for restriction. A petition will not be considered unless reconsideration of the requirement was timely requested (see § 1.143).

(b) A petition may be filed after the requirement for restriction is made final

or a second requirement for restriction is made, even if the second requirement is not final. The petition must be filed within the earlier of:

(1) Two months of the mailing date of the final requirement for restriction from which relief is requested; or

(2) The filing of a Notice of Appeal.

(c) A petition filed before the earlier of a final restriction requirement or a second requirement for restriction will be dismissed as premature. Filing a petition does not obviate applicant's obligation to timely reply to the remainder of the action.

(d) The two-month period for filing a petition is not extendable. Late filed petitions may be dismissed as untimely (see § 1.181).

8. Section 1.145 is revised to read as follows:

§ 1.145 Subsequent presentation of claims for a different invention in an application filed under 35 U.S.C. 111(a).

If, after an Office action on an application, the applicant presents by amendment one or more claims directed to an invention distinct from and independent of the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181.

9. Section 1.146 is revised to read as follows:

§ 1.146 Requirement for an election of a single species in an application filed under 35 U.S.C. 111(a).

(a) If one or more claims are directed to a single invention but encompass multiple disclosed and patentably distinct species, regardless of whether the claim uses alternative language, the examiner may require the applicant to elect one species that is disclosed in the application as filed for initial search and examination.

(b) The examiner may require the applicant to restrict any claim that was subject to an election requirement under paragraph (a) of this section to the one or more species that were searched and examined if any species encompassed by the claim is not patentable.

10. Section 1.499 is revised to designate the current paragraph as paragraph (a) and to add paragraphs (b), (c), and (d) to read as follows:

§ 1.499 Unity of invention during the national stage.

* * * * *

(b) Any claim limited solely to a non-elected invention, if not canceled, will be withdrawn from further consideration. Any claim withdrawn

from further consideration is subject to reinstatement in the event the restriction requirement is withdrawn or overruled.

(c) Any claim that recites in the alternative both an elected and a non-elected invention will be objected to as failing to comply with § 1.475. Any non-elected invention must be canceled before the claim will be allowed, unless the restriction requirement is withdrawn or overruled.

(d) If, after an Office action on an application, the applicant presents by amendment one or more claims directed to an invention that lacks unity of invention (§ 1.475) with the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181.

Dated: August 2, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E7-15591 Filed 8-9-07; 8:45 am]

BILLING CODE 3510-16-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA-R04-RCRA-2007-0016; FRL-8451-7]

Florida: Proposed Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Florida has applied to EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Florida. In the "Rules and Regulations" section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble of the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further

action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment.

DATES: Comments must be received on or before September 10, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-RCRA-2007-0016 by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *E-mail:* johnson.otis@epa.gov.

- *Fax:* (404) 562-9964 (prior to faxing, please notify the EPA contact listed below).

- *Mail:* Send written comments to Otis Johnson, Permit and State Programs Section, RCRA Programs/Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

- *Hand Delivery:* Otis Johnson, Permit and State Programs Section, RCRA Programs/Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R04-RCRA-2007-0016. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the

public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. (For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>).

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy. You may view and copy Florida's application at The EPA, Region 4, The Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303 from 8 a.m. to 4 p.m. Monday through Friday, excluding legal holidays. The office telephone number is (404) 562-8041.

You may also view and copy Florida's application from 8 a.m. to 5 p.m. at The Florida Department of Environmental Protection, Twin Towers Building, 2600 Blair Stone Road, MS 4560, Tallahassee, Florida 32399-2400.

FOR FURTHER INFORMATION CONTACT: Otis Johnson, Permits and State Programs Section, RCRA Programs/Materials Management Branch, RCRA Division, U.S. Environmental Protection Agency, The Sam Nunn Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303; (404) 562-8481; fax number: (404) 562-9964; email address: johnson.otis@epa.gov.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the "Rules and Regulations" section of this **Federal Register**.

Dated: July 13, 2007.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

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