-----Original Message-----
From: Lathrop, Brian K.
Sent: Tuesday, October 09, 2007 9:15 AM
To: Markush.Comments
Subject: Comments in response to the notice of proposed rule making

Dear Sir:

Please see the attached comments in response to the notice of proposed rule making at 72 Fed. Reg. 44992 (August 10, 2007).

<<#615862 v1 - Comments on the Proposed Rules.doc>>
Sincerely,

Brian Lathrop

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October 8, 2007

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Comments on Examination of Patent Applications That Include Claims Containing Alternative Language, 72 Fed. Reg. 44992-45001 (proposed Aug. 10, 2007) (to be codified at 37 C.F.R. pt. 1) (hereinafter "Proposed Rules").

Dear Under Secretary Dudas:

The following commentator is providing comments on the Proposed Rules in his individual capacity. The commentator is:

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The commentator is a member of the Virginia Bar and is licensed to practice before the United States Patent and Trademark Office (USPTO). The commentator was an Examiner in the biotechnology arts from 1996-1998. The commentator's views are his own and do not necessarily reflect the views of Drinker, Biddle & Reath LLP, any client thereof, or any organization with which the commentator is or has been affiliated.

Introduction

To improve the quality and efficiency of examination, the USPTO proposes changes to 37 C.F.R. pt. 1, particularly with respect to the examination of claims that recite elements of the invention in the alternative. The USPTO seeks public comments on the Proposed Rules on or before October 9, 2007, and welcomes alternative suggestions from commentators. The commentator agrees that changes to 37 C.F.R. pt. 1 may improve the quality and efficiency of examination; however, the Proposed Rules discriminate against certain inventions directed to combinations or ensembles of DNA and protein sequences (hereafter "biomolecules"). Accordingly, the USPTO should modify or strike altogether some of the Proposed Rules.

Comments

1. **The USPTO should clarify 37 C.F.R. § 1.75(a) (proposed) to indicate that a claim must be limited to a single *independent and distinct* invention, consistent with 35 U.S.C. § 121 and 37 C.F.R. § 1.140(a) (proposed).**

   The text of Rule 75(a) should be revised to state:

   (a) . . . A claim must be limited to a single <u>*independent and distinct*</u> invention.

As proposed, Rule 75(a) states that a "claim must be limited to a single invention." Rule 140(a), however, states *inter alia* that two or more "*independent and distinct* inventions may not be claimed in a single claim," with an internal reference to Rule 75(a). If the intent of the USPTO is for Rule 75(a) to require a claim to be limited to a single *independent and distinct* invention, the USPTO should use appropriate language in Rule 75(a). *See* 72 Fed. Reg. at 44997 (discussing Rule 75(a) in the context of objecting to "a single claim that is directed to multiple independent and distinct inventions").

Such a revision would clarify that Rule 75(a) must be applied consistently with 35 U.S.C. § 121 and with binding legal precedent. Further, the language would clarify that the USPTO does not intend to change significantly the procedures set forth in the Manual of Patent Examining Procedure, 8th ed, revised August 2006 (MPEP) § 800, *et seq*.

2. **Restriction between nucleic acid or protein sequences in the context of 37 C.F.R. § 1.75(a) (proposed), irrespective of whether multiple sequences are part of a single invention, prejudices inventions directed to ensembles or combinations of biomolecular species.**

The USPTO should exercise its rulemaking authority or otherwise provide guidance or training to Examiners to apply Rule 75(a) correctly in the context of biomolecules. The USPTO frequently restricts DNA or protein sequences on the basis that they are *per se* independent and distinct inventions, without considering whether the biomolecules in combination constitute a single independent and distinct invention. A *per se* approach is contrary to binding precedent that requires the USPTO to consider the claimed invention as a whole for the purpose of 35 U.S.C. § 121. *See In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978).

Some inventions require combinations of biomolecules. DNA arrays, for example, may require multiple, distinct DNA sequences to discriminate target sequences by differential hybridization. Biomarker panels for diagnosis of disease states, for example, may require multiple, distinct biomarkers to provide a statistically significant diagnostic pattern. In many cases, these biomarkers are proteins that may have totally different amino acid sequences and functions. The invention in these cases often is a specific ensemble of biomolecular species, not the sequences themselves.

Current procedures permit applicants to claim ensembles of biomolecular species as linking claims or as combination/subcombination claims. *See* MPEP §§ 809, *et seq.*, and 806.05(a), *et seq*. To the extent that the USPTO continues to consider biomolecular species as *per se* independent and distinct inventions, however, Rule 75(a) eliminates the use of linking claims or combination/subcombinations to claim multiple biomolecular species in a single invention. The USPTO should offer appropriate comments, training, or other guidance to

Examiners that nucleic acid and protein sequences cannot be considered *per se* independent and distinct inventions.

Further, to the extent that the USPTO continues its *per se* approach to protein and nucleic acid sequences, the misapplication of Rule 75(a) would cause the USPTO to derogate international obligations of the United States. The United States may not legally discriminate the availability and enjoyment of patents rights as to a field of technology. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Part II—Standards Concerning the Availability, Scope and Use of Intellectual Property Rights, Art. 27, "Patentable Subject Matter." ("[P]atents shall be available and patent rights enjoyable ***without discrimination as to*** the place of invention, ***the field of technology*** and whether products are imported or locally produced.") (emphasis added). For the reasons set forth above, Rule 75(a), applied in combination with a *per se* approach to restriction between DNA and protein sequences, would discriminate against technologies directed to ensembles of biomolecules, e.g., DNA arrays, biomolecular libraries, and biomarker panels.

3. 37 C.F.R. § 1.75(j)(1) (proposed) is arbitrary and capricious because (1) it improperly limits the number of alternatives an inventor can claim, and (2) it requires a subjective standard for determining proper claim format.

Rule 75(j)(1) allows an Examiner to object to the form of an otherwise allowable claim, where the claim "reads on multiple species by using alternative language," and where "[t]he number and presentation of alternatives in the claim" makes the claim "difficult to construe." *See* 72 Fed. Reg. at 44997.

The commentator agrees that the USPTO has authority to regulate the presentation of claims. *See In re Harnisch*, 631 F.2d 716, 720, 206 U.S.P.Q. 300, 304 (C.C.P.A. 1980). The USPTO recently has clarified and exemplified language that it considers "difficult to construe." *See* John LeGuyader, Director, TC600, "Proposed Rule Changes—Search and Examination of Alternative (Markush) Claims," Biotechnology/Chemical/ Pharmaceutical Customer Partnership Conference, September 12, 2007, *available at* http://www.uspto.gov/web/patents/biochem-pharm/bcpcp091207.htm. The USPTO may wish to regulate the presentation of claims similar to those discussed by Mr. LeGuyader. *Cf.* 37 C.F.R. § 1.75(k) (proposed) (addressing claim presentation issues related to those discussed by Mr. LaGuyader).

The USPTO, however, has no authority whatsoever to regulate the ***number*** of species claimed using alternative language. An inventor by law may claim the subject matter that applicant regards as the invention. 35 U.S.C. § 112, second paragraph. If that invention is directed to multiple alternative species, the USPTO must examine that invention. A USPTO rule to the contrary must be set aside as arbitrary and capricious and not in accord with the law. The USPTO otherwise makes the same "improper *Markush* claim" rejection prohibited by *Weber* and *Haas*. *See* 72 Fed. Reg. at 44993 (discussing *In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978) and *In re Hass*, 486 F.2d 1053, 1054, 179 U.S.P.Q. 623, 626 (C.C.P.A. 1973)).

The USPTO seeks authority for Rule 75(j)(1) only with reference to World Intellectual Property Organization, Patent Cooperation Treaty, PCT International Search and Preliminary Examination Guidelines (March 25, 2004) ("Guidelines") ¶ 5.18, *available at* http://www.wipo.int/pct/en/texts/pdf/ispe.pdf. *See* 72 Fed. Reg. at 44997. The USPTO, however, ignores ¶ 10.17

of the same Guidelines, which directly relates to restriction practice regarding Markush claims. This portion of the Guidelines does not use, explain, or otherwise support adoption of a "difficult to construe" standard. In any event, to whatever extent the USPTO seeks legal justification of its rules from the PCT Guidelines, the Guidelines "may be used *mutatis mutandis* by national Offices in dealing with national applications ***if the national law so permits***." Guidelines, ¶ 1.02 (emphasis added). Further, "the Guidelines do not have the binding authority of a legal text." Guidelines, ¶ 1.04.

4. 37 C.F.R. § 1.75(j)(4) (proposed) (A) does not reflecting binding precedent for determining whether claims properly use alternative language, (B) does not reflect the approach taken under the PCT, and (C) inconsistent with 37 C.F.R. § 1.140(a)(1) (proposed).

Rule 75(j)(4) prohibits the recitation of species in the alternative form in a claim, unless the species are "substitutable, one for the other." The species of DNA or protein sequences within the ensembles of biomolecules discussed above may not substitutable one for another. In many cases, the diversity of members within the ensemble is required for the invention to work. Rule 75(j)(4) essentially would prohibit by regulatory fiat inventions directed to ensembles of biomolecules. The USPTO thus should strike Rule 75(j)(4).

A. Under *Harnisch*, alternatively claimed species within a generic claim may not be restricted if the species [1] share a common function and [2] share a substantial structural feature.

The USPTO acknowledges that claims must be considered as a whole to determine whether restriction of a generic claim to multiple independent and distinct inventions. *See* 72 Fed. Reg. at 44995 (quoting *In re Weber*, 580 F.2d 455, 458, 198 USPQ 332, 328 (C.C.P.A. 1978) ("The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim.")). The USPTO further acknowledges that *In re Harnisch*, 631 F.2d 716, 206 U.S.P.Q. 300 (C.C.P.A. 1980) states the binding legal standard for determining whether a claim that recites alternative species is directed to multiple independent and distinct inventions. 72 Fed. Reg. at 44993. The USPTO states:

> In *Harnisch*, the court found that the claimed compounds, which were defined as members of a Markush group, had 'unity of invention' because [1] they shared a common function as dyes, and [2] shared a substantial structural feature as coumarin compounds. [*Harnisch*,] 631 F.2d at 722, 206 U.S.P.Q. at 305." 72 Fed. Reg. at 44993-94 (emphasis added).

The *Harnisch* court did not hold that species must be substitutable one for another. Indeed, the USPTO cannot point to binding legal precedent for Rule 75(j)(4).[1]

[1] The USPTO cites *In re Driscoll*, 562 F.2d 1245, 1249, 195 U.S.P.Q. 434, 436 (C.C.P.A. 1977) for the proposition that species must be "alternatively useful." 72 Fed. Reg. at 44996. *Driscoll* turned on whether a priority document adequately described a claimed invention pursuant to 35 U.S.C. § 112, first paragraph. The general comments on *Markush* claims in *Driscoll* are dicta and cannot be used to overturn *Harnisch*. Further, the C.C.P.A. decided *Driscoll* before it decided *Harnisch*, so *Driscoll* in any event cannot supersede *Harnisch* or set an alternative legal standard to *Harnisch*.

B. Rule 75(j)(4) does not reflect the approach to *Markush* claims used in international practice.

The *Harnisch* court deliberately adopted a "unity of invention" standard to be "intelligible internationally." *Harnisch*, 631 F.2d at 721, 206 U.S.P.Q. at 305. The current international approach for determining unity of invention for *Markush* type claims is set forth at Manual of Patent Examining Practice, 8th ed., revised Aug. 2006 (MPEP), Appendix AI, "Administrative Instructions Under the PCT," Annex B "Unity of Invention," (f) "Markush Practice" (emphasis added):

> (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
>
> (A) all alternatives have a common property or activity, and
>
> (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
>
> (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The Administrative Instructions state that "a recognized class of chemical compounds" in (B)(2) means that the species can be "substituted one for the other, with the expectation that the same intended result would be achieved." *See* MPEP, Appendix AI, Annex B, (f)(iii). The international approach provides two alternatives to determine whether a *Markush* claim possesses unity of invention, (1) all the alternatives have a common property or activity, and a common structure is present, or (2) all the alternatives have a common property or activity, and the alternatives are substitutable one for another. Rule 75(j)(4), on the other hand, requires that the alternatives be substitutable one for another, regardless of whether the claim otherwise possesses unity of invention. Accordingly, Rule 75(j)(4) is inconsistent with the PCT, as well.

C. 37 C.F.R. § 1.75(j)(4) (proposed) sets a standard inconsistent with 37 C.F.R. § 1.140(a)(1) (proposed).

Rule 140(a)(1) sets one standard for claims reading on multiple species using alternative language, Rule 75(j)(4) sets another. Rule 140(a)(1) states *inter alia*:

> 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 common utility. . . .

Rule 75(j)(4) by contrast requires that alternatively claimed species be substitutable one for another. The two Rules are inconsistent. This inconsistency can be remedied by striking Rule 75(j)(4).

Conclusion

The USPTO should modify significantly or strike certain provisions of the Proposed Rules, including Rule 75(j)(1) and (4). The USPTO otherwise will discriminate against certain inventions directed to combinations or ensembles of biomolecules.