

From:

Sent: Thursday, August 12, 2010 4:05 PM

To: Restriction_Comments

Subject: PTO Request for Comments on Proposed Changes to Restriction Practice in Patent Applications

Director Kappos and Commissioner Stoll:

Please find below brief comments in response to the USPTO request for comments on proposed changes to restriction practice in patent applications (the "Request"). These represent my personal views and do not represent the views of Monsanto Company.

1. *What should be included in an Office action that sets forth a restriction requirement?*

The Request states that the "Office is considering revising restriction practice to improve the quality and consistency of restriction requirements". The Office should begin by setting out to make restriction practice as set out in the MPEP consistent with the patent laws and rules. The controlling statute states that "*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, emphases added) Similarly, the rules state that "*If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted [...].*" (37 CFR §1.142, emphasis added) Although the phrase "independent and distinct" appears multiple times in the Rules, the phrase "independent or distinct" does not, nor does it appear in the statutes. The Office should revise restriction practice to meet the "independent and distinct" standard.

The Request also refers to the 2005 Green Paper on Restriction Practice but does not revisit the proposals and options in that document, even though five years later some of these proposals may make even more sense than they did in 2005, for example in view of the ability to reduce inter-office search and examination "shared burden". The USPTO's Strategic Plan (p.17) lays out as a goal the improvement of pendency and quality by work sharing between patent offices. One option that should be reconsidered as an alternative to revising restriction practice to meet the "independent and distinct" standard is transitioning to a unity of invention standard as used in PCT examination, which would put US examination more in line with examination in those offices that participate in the Patent Prosecution Highway.

The Request further states that "the Office is considering explaining that in addition to the rationales currently set forth in the MPEP, a serious burden in support of a restriction requirement may be based on the rationale that the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. In this situation, a serious search burden and/or examination burden may exist where issues relevant to one invention are not relevant to the other invention."

This statement is troubling as it appears that procedural issues (*i. e.*, restriction practice) are being confused with examination issues (*e. g.*, 101 or 112 patentability issues). Further, burden alone is insufficient justification for requiring a restriction. Applicants are entitled to claim their invention as they view it, without the claim being divided into fragments, as instructed by the Federal Circuit in criticizing restriction practice in the case of *In re Weber*.

“We have decided in the past that § 112, second Paragraph [...] allows the inventor to claim the invention as he contemplates it. [...] If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. [...] Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.”

In re Weber, 580 F.2d 455 (Fed. Cir. 1978) (Emphases added.)

2. *What practice changes would result in more effective ways to seek higher level review of restriction requirements?*

Restriction practice is not uniform among the examining corps. There should be mandatory and regular training of the entire examination corps (including supervisors) to ensure uniform restriction practice. Quality of restriction practice by examiner and art unit should be evaluated by tracking meaningful metrics (*e. g.*, the number of successful petitions to withdraw a restriction requirement) aimed at improving examiners' use of restrictions.

Examiners should fully understand the invention as set out in a broad claim and not set forth a restriction by arbitrarily selecting embodiments especially when the restriction is presented as a choice of only a subset of the embodiments contemplated by the broad claim, thus artificially creating an alleged examination and search “burden”. A broadly claimed invention should not be arbitrarily assigned to different fields of art, *e. g.*, if a claim recites “eukaryote”, the examiner should not arbitrarily require a restriction between “plant” and “animal”.

Importantly, the petition process must be made timely! Delays in petition decisions force applicants to elect from among the sometimes limited or incomplete options set forth by the examiner, in order to avoid abandonment.

3. *How could the Office clarify requirements for restriction between related product inventions or related process inventions where the relationship is not specifically provided for in MPEP Chapter 800?*

4. *How could the Office modify Markush practice?*

Biological molecules (e. g., nucleotide sequences), whether or not presented as a formal Markush group, should be treated like any other invention. Treating biological molecules any differently from other inventions contravenes Article 27 of the TRIPS Agreement, which states that there should be no technology-specific rules: “*Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents 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.*” (Emphases added.)

Practitioners have seen examination arbitrarily limited to 10 nucleotide sequences, and experience shows that examiners routinely require limitation to a single sequence, typically justifying this by alleging that each sequence “constitutes an independent and patently distinct invention” even when applicants demonstrate that a group of sequences share both structural or sequence similarity and claimed functional similarity or equivalence.

5. *How could the Office improve rejoinder practice?*

The Request states that “The Office is considering whether to define “rejoinder” as the practice of withdrawing a restriction requirement as between some or all groupings of claims and reinstating certain claims previously withdrawn from consideration that occurs when the following conditions are met: (1) All claims to the elected invention are allowable; and (2) it is readily apparent that all claims to one or more nonelected inventions are allowable for the same reasons that the elected claims are allowable.”

This statement raises the question of what does “readily apparent” mean? How would an examiner know whether claims to non-elected inventions are patentable or not patentable if a search/examination has not been conducted? For example, claims with different species could conceivably have different effective filing dates and therefore be subject to different art. This questionable standard of “readily apparent” gives the examiner a way out so he/she does not have to rejoin/examine more claims.

6. *What other areas of restriction practice can the Office improve and how?*

Possibilities include initiating a flexible fee-adjustable searching system and improvement/modernization of the Office's IT systems. The USPTO Strategic Plan (p.11) admits that a "one size fits all" approach to examination does not work. Examination practice can be multi-tracked in aspects other than the timing of the start of substantive examination, for example through fee options to have more than a single invention searched and examined.

There is lack of transparency regarding the use of IT for searches, especially relating to biological sequences. It would be beneficial to disclose to the public the cost per search of a biological sequence, or alternatively to disclose that the cost to the Office is a blanket cost not dependent on the number of sequences searched. As practitioners we strongly presume that there is no significant cost burden based on our in-house experience.

Thank you for considering these comments.

Yours sincerely,

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