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From: UNSON, MIA D [AG/2551] [mailto:mia.d.unson@monsanto.com]
Sent: Wednesday, May 03, 2006 2:13 PM
To: AB93Comments
Subject: Comments on proposed changes to practice for examination of claims and continuing applications

AB93Comments@uspto.gov
Mail Stop Comments - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr

The following are my personal comments (and not necessarily those of my employer Monsanto Company) to Notices of Proposed Rulemaking: Changes to Practice for the Examination of Claims In Patent Applications (Fed Reg. Vol 71 No. 1 page 61, Jan. 3, 2006), and Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims, (Fed Reg Vol 71 No. 1 Page 48, Jan. 3, 2006).

I have been practicing as a registered patent agent since 2002 and practicing in the biotechnology field at Monsanto Company since 2004. I believe that the above-referenced proposed rules would be detrimental to long-established and judicially-sanctioned patent practice especially in biotechnology and other unpredictable arts, which have long development times from conception to commercialization. Applicants in the biotechnology field require extensive and liberal continuation practice to deal with the Office's current restriction practice, for which an applicant generally has no practical recourse or alternative. I also believe that the proposed rules on continuation practice will exacerbate, rather than correct, quality and pendency problems at the Patent Office. I urge the Office to carefully and seriously consider the thoughtful comments that have been presented by AIPLA and BIO substantiating these points. The Office must not disregard the detrimental effects the proposed rules would have on biotechnology, which is an important sector of the US economy and fundamental to the country's leadership in the medical and agricultural fields.

Please especially note the following aspects of the proposed rules as they would apply to biotechnology innovation.

* Since currently pending patent applications are directed to products that are years from commercialization and are filed on the current paradigms of research funding influenced by patent practice, it is improper and unfair to impose the rules retroactively.

* The rationale for the changes is flawed, illogical and, arguably, unlawful; even if valid, biotechnology patent owners would prefer longer pendency over the impending loss of rights.

* A real problem, as I see it, is restriction practice which is a methodology evolved by collaboration of Patent Office officials and the Examiners' union, to facilitate PTO management by mincing patent claims into pieces that are calculated to be readily examined in a common unit of time. This inherently creates continuation applications if applicants hope to get patents on the full scope of their inventions. It is not uncommon for applicants to be required to elect a single sub group of claims that are divided into 20, 50 and sometimes 100 or more subgroups of allegedly "independent and distinct" inventions by examiners. Especially onerous are restrictions to a single DNA sequence in a family of related genes that provide a common effect.

* The filing of multiple continuation applications is simply not an abuse of the system, but is a legitimate business practice in many industries when research and development typically covers a decade or more. As a result patent term is already about one-half of the statutory term enjoyed by the fast-development and regulatory-free industries. Restricting the long-standing right to file continuing applications would further reduce the opportunity for the currently-limited patent term.

* A pilot study should be conducted in patent examining groups that serve industries that favor the proposed rules.

* If the Director is seriously interested in reducing pendency, alternatives that could benefit applicants should be investigated, e.g. outsourcing searches at cost to the applicant, formalizing deferred examination, encouraging applicant participation by minimizing the potential for fraud charges in subsequent litigation, radically changing restriction practice, and taking back control of Patent Office operations from the examiner's union.

* If the PTO is interested in addressing the small number of cases where applicants "game" the system by prolonging patent prosecution until a competitor commercializes a product that is covered by the patent application, the PTO should find a remedy that does not punish legitimate patent applicants. In the biotechnology sector the need for multiple continuations is a legitimate business practice and is not a "bad actor" issue. More rational remedies can be addressed by Congress by reforming patent enforcement procedures and remedies.

* I also understand that the proposed rules would limit a priority claim back to a single preceding application which could cause a publication from an earlier application (from which priority cannot be claimed) to be Section 102(b) prior art. Such a situation would effectively negate patentability for unpatented inventions subject to continuing restriction. Preservation of patent rights in applications subject to restriction to hundreds of "independent and distinct" inventions may require filing thousands of divisional applications on inventions in a research and development pipeline that would otherwise be abandoned under current practice.

I urge the Director and Commissioner to study the detailed comments submitted by BIO and AIPLA and reconsider implementation of these proposed rules.

Yours sincerely,
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