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Sent: Wednesday, May 03, 2006 4:08 PM
To: AB93Comments
Cc: BOLWELL, AGNES ADEL [AG/1000]
Subject: AB93 Comments

May 3, 2006

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 an attorney since 1999, as a registered patent attorney since 2000 and practicing in the biotechnology field at Monsanto Company since 2001. The above-referenced proposed rules seem arbitrary and are definitely detrimental to long-established and judicially-sanctioned patent practice in the field of biotechnology -- which has long development times from conception to commercialization. I also believe that the proposed rules on continuation practice will exacerbate, rather than correct current problems. I urge the Patent Office to carefully and seriously consider the thoughtful comments that have been presented by AIPLA and BIO substantiating these points.

Some of the proposed rules are especially egregious as they would apply to biotechnology innovation.

- It is improper and unfair to impose the rules retroactively because currently pending patent applications are directed to products that are years from commercialization.
- The rationale for the changes seems to be flawed, illogical and, arguably, unlawful. If these changes do go into effect, please note that biotechnology patent owners would prefer longer pendency over the impending loss of rights.
- This proposed ruling necessitates filing continuation applications if applicants hope to obtain 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.
- Because research and development in the biotechnology field typically covers a decade or more, the filing of multiple continuation applications is a legitimate business practice. 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.

- Rather than arbitrarily place these rules into effect, a better approach would be to initiate a pilot study 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, and encouraging applicant participation by minimizing the potential for fraud charges in subsequent litigation.
- I understand that the PTO is interested in addressing the small number of cases where applicants turn the system to their advantage by prolonging patent prosecution until a competitor commercializes a product that is covered by the patent application, but 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 should be recognized as such. Reform of current patent enforcement procedures would better address this issue.
- Additionally, it is my understanding 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.

Very truly yours

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