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From: LAVIN JR, LAWRENCE M [AG/1000] [mailto:lawrence.m.lavin.jr@monsanto.com]

Sent: Wednesday, May 03, 2006 1:58 PM

To: AB93Comments

Subject: Comments to Notice of Proposed Rulemaking

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

Attention: Robert W. Bahr

RE: Comments to Notice 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 1980 and practicing in the biotechnology field at Monsanto Company since 1992. I believe that the above-referenced proposed rules are detrimental to long-established and judicially-sanctioned patent practice and are especially prejudicial to applications directed to arts which have long development times from conception to commercialization such as the biotechnology arts. It is a fact of life that daily practice in the biotechnology field requires extensive and liberal continuation practice to deal with developing research results and the harsh 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.

In particular, I want to emphasize a few especially misguided 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 under the current paradigms of patent practice and protection of research results, it is improper and unfair to impose the rules retroactively.
- The proposed rules unlawfully result in the potential loss of rights to biotechnology patent owners who would not previously be harmed by a potential longer pendency.

- The proposed rules do not address the source of prolonged pendency and continuation practice, which is a restriction practice designed to facilitate PTO management rather than grant the full scope of applicant's invention. Especially onerous are restrictions to a single DNA sequence in a family of related genes that provide a common effect.
- The assumption that the filing of multiple continuation applications is an abuse of the system is unfounded, particularly when product development requires a decade or more of work, and continuations and continuations-in-part are a necessary and a legitimate business practice used in many industries. Eliminating the long-standing right to file continuing applications further restricts an already 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.

The proposed rules seem to be addressing a small number of cases where the patent applicant truly "games" the system by prolonging patent prosecution until a competitor commercializes a product that is covered by the patent application. In that rare case, rules should be crafted that remedy that unusual circumstance rather than indiscriminately punishes legitimate patent applicants. In the biotechnology sector, the need for multiple continuations is 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 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

Lawrence M. Lavin, Jr
Senior Patent Attorney
Monsanto Company