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From: Peter Mascia
Sent: Tuesday, May 02, 2006 6:22 PM
To: AB93Comments
Cc: Clarke, Robert
Subject: Ceres, Inc. Comments on Proposed Rules Changes Concerning Continuation Practice and Claim Limitations

Dear Mr. Bahr,

Attached are the comments of Ceres, Inc. on the proposed rules changes to Practice for Continuing Applications, Requests for Continued Examination Practice and Applications Containing Patentably Indistinct Claims 71 Fed. Reg. 48-61

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S. Patent and Trademark Office.

Yours truly,

Peter Mascia, Ph.D.

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Comment of Ceres, Inc. on following pages

May 2, 2006

Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Attn: Robert W. Bahr, Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

Robert A. Clarke, Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Re: Comments on Notice of Proposed Rulemaking Entitled "Changes To Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (January 3, 2006)

Notice of Proposed Rulemaking Entitled "Changes To Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61 (January 3, 2006)

Dear Under Secretary Dudas, Mr. Bahr, and Mr. Clarke:

Ceres, Inc. appreciates the opportunity to comment on the proposed PTO rules.

Ceres is a biotechnology company based in Thousand Oaks, California, that employs about 130 people. Ceres focuses on break-through plants and plant-based products for a number of diverse industries, using state-of-the-art functional genomics and pathway engineering technologies. Ceres' integrated technology platforms have been recognized by industry leaders as a prime source of innovation in the industry and as a powerful engine for the generation of intellectual property. Through license-based collaborations and internal product development, Ceres is applying its proprietary plant genomic knowledge to a number of opportunities in the creation of enhanced plants, such as dedicated energy crops, fruits and vegetables, ornamentals, row crops, trees and turf, and plant-based products such as chemicals, enzymes, nutritional ingredients, personal care ingredients and pharmaceuticals. The genomics-based design of bioengineered plants addresses several urgent global needs: to provide more and better food for a growing world population; to discover new pharmaceuticals that address unmet medical needs; and to provide a large-scale, sustainable, carbon-neutral source of renewable energy.

Intellectual property protection via patents has been and continues to be critical to the agricultural biotechnology sector of the U.S. economy. The lifeblood of agricultural biotechnology companies is patent protection, which allows them to develop their products without fear of encroachment by others. Small agricultural biotechnology companies need strong, predictable patents on their innovations in order to attract investors, because the

investment community knows that commercial products need to be covered by patents. Hence, patents are critical to the success of small agricultural biotechnology companies such as Ceres.

In agricultural biotechnology, however, there is a long lead time from discovery to commercialization of a product, often taking 10 to 15 years to go from concept to product. The proposed new rules will wreak havoc on any company involved in agricultural biotechnology because the proposed rules will inhibit the ability to patent these "long lead time" products. Agricultural biotechnology companies will be unable to attract financing without patents for these products, meaning that the products will never be developed. Indeed, the proposed rules will wreak havoc in **any** technology area where there are long product development times.

Ceres recognizes that the PTO has to deal with workload and pendency issues. The need to address the growing patent application backlog at the USPTO is understood and acknowledged. The PTO's rationales for the proposed rules, however, are wrongheaded. Rather than reduce the backlog, they will **increase** the backlog, for reasons that have been discussed in the town hall meetings. Furthermore, the rationales do not justify the drastic nature of the proposed solutions, e.g., prosecution laches is a thing of the past with the new 20 year patent term, and is mostly a red herring. The PTO also implies that filing continuations and adding claims to cover competitors' products is an abuse of the system. The PTO is wrong. The practice of filing continuations to cover competitors' products has been endorsed by the courts and is a legitimate business practice. Trying to eliminate this practice is contrary to these court decisions and represents a fundamental shift from the settled expectations of the innovation community.

The proposed limitations on continuations may violate the Regulatory Flexibility Act because they will impact a substantial number of small entities. Small companies are part and parcel of the biotechnology industry, as shown by the membership of BIO, the Biotechnology Industry Organization. Over 600 of the 1,444 BIO company members as of 2004 fall into the small entity category as defined by the M.P.E.P. The proposed limits on continuations will affect a substantial number of these biotechnology companies because of the well known necessity for continuations in biotechnology. For example, based on a sampling of biotechnology patents in class 435 issued in January 2006, about 33% of the patents had at least one continuation. In contrast in a similar sampling of data processing class 716, only about 7% of the patents issued over the same period had a continuation in the lineage. This comparison indicates that the proposed limits on continuations will impact a substantial number of small biotechnology companies.

Notably, the Business Software Alliance is in favor of the proposed rules. The BSA includes companies such as Adobe, Apple, Cisco Systems, IBM, Intel, Microsoft and Symantec. BSA members are among the largest owners of patents in the U.S., and include 3 of the 4 largest recipients of U.S. patents issued in 2005 according to the PTO. The fact that large companies such as Microsoft are in favor of the proposed rules leads Ceres to question whether the proposed rules are truly neutral towards small companies. A PTO bias in favor of large companies and against such a substantial number of small entities may violate the Regulatory Flexibility Act.

Ceres believes that the limit of a single RCE in proposed § 1.114(f) may be contrary to statutory authority. 35 USC § 1323.

Ceres believes that the continuation limits set forth in proposed § 1.78(d)(1) may be contrary to the statutory authority permitting continuations. 35 USC §§ 120, 1212.

Ceres believes that the retroactive nature of the proposed rules may violate the requirements of the Administrative Procedures Act. 5 USC § 706. That is, they may be an arbitrary and capricious attempt to preempt Congress, which is considering patent reform legislation.

In summary, Ceres is strongly opposed to implementation of the proposed rules, and believes that the PTO should drop them in their entirety, because they are contrary to the PTO's mission to protect new product innovations for the benefit of society and will significantly dampen investment and innovation in key areas such has health, bio-energy and food security.

The PTO should allow Congress to consider and enact patent reform legislation before considering rules as draconian as the present proposed rules. For example, early draft bills such as H.R. 2795 § 123 proposed limits on continuations. However, later drafts (Coalition Draft) **removed** limitations on continuations. It would behoove the PTO to allow Congress to express its intent. If the PTO proceeds to implement these rules anyway, it is likely that the PTO will be sued to block their implementation, thus wasting PTO resources.

Why the PTO would implement rules that would discourage long term investment in technology is beyond comprehension. Ceres, however, is willing to engage in a constructive dialogue with the PTO and other members of the innovation community to consider rules that deal with the pendency and workload issues in an effective and rationale way.

Yours truly,

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