

From: Mircea Achiriloaie
Sent: Monday, April 21, 2008 9:34 PM
To: ab99.comments
Cc: Steven Bobzin; Joseph Cahill
Subject: Ceres Comments on Deposit Rules

Dear Ms. Kathleen Kahler Fonda:

Please see the attached letter regarding the *Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit*, 73 FR 34, 9254-9259 (February 20, 2008). For questions or concerns, please contact me directly via phone or email.

Best regards,
Mircea Achiriloaie

~~~~~  
Mircea Achiriloaie  
TPPA Department  
Ceres, Inc.  
1535 Rancho Conejo Blvd.  
Newbury Park, CA 91320-1440  
Tel: (805) 376-6516  
Fax: (805) 376-6537  
[www.ceres.net](http://www.ceres.net)



VIA EMAIL – AB99.Comments@uspto.gov

April 21, 2008

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

Re: Comments on Proposed Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit, 73 Fed. Reg. 34, 9254 (February 20, 2008)

Dear Under Secretary Dudas,

The undersigned thank the U.S. Patent and Trademark Office (“Office”) for the opportunity to comment on the Office’s Proposed Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit (“proposed revision”). While we support the Office’s goals of global harmonization of rules and insistence on full, enabling disclosures of inventions, the undersigned strongly oppose the proposed revision in its present form. The proposed revision would allow unrestricted public access to biological deposits as of the publication date of a patent application, rather than as of the issue date of a patent as is currently the case. The undersigned are concerned that the Office has failed to consider the unique and significant negative impact of the proposed revision on inventions involving plant materials, and on the inventors and businesses bringing new plant varieties to market.

Ceres, Inc. is the nation’s leading developer of dedicated energy crops like switchgrass for the emerging cellulosic biofuels industry. Ceres is concerned about the proposed revision and its effect on plant biotechnology and biofuels. Specifically, we are very concerned about the implications of the proposed revision for patents covering deposited plant materials. Such inventions are illustrated, for example, by US patents 7,351,887; 7,351,883; 7,348,473; 7,348,472; 7,345,228; 7,345,227; 7,345,226; 7,345,225; 7,345,224; 7,345,223; 7,342,151; 7,342,150; 7,342,149; 7,339,094; 7,339,093; 7,335,821; 7,335,820; and 7,335,819. Because of the nature of these type of inventions, the proposed revision would have a major negative impact on the entire plant breeding industry by allowing competitors early unrestricted access to the applicant’s invention – the seed to be patented. Uniquely, in the case of new plant varieties, the biological deposit required for a utility application (e.g. the seed) holds the essence of the invention. Given the breeding capacity of plants, the biological deposit itself can be used to engineer around the scope of the claims of the patent application. This undermines the spirit of the patent system itself; that is to provide the inventor with a period of exclusivity in exchange for a full, enabling disclosure of how the invention is made.

Full disclosure is an expectation that the undersigned fully supports, but in the unique case of plant varieties, this disclosure must be delayed in order to avoid destroying the inventor’s competitive advantage, something the patent system is intended to protect. We believe that for plant-related patents,



the biological deposit (e.g. the seed) should be required upon issue of the patent, not upon publication of the patent application. Notably, the proposed revisions place undue hardship on the inventors and businesses bringing new plant varieties to market for the following reasons.

*1) Unrestricted access to biological deposits has a disproportionately harmful impact on applicants for plant materials*

The Office justifies the proposed revision in part as trying to ensure uniform standards for public release of a patent disclosure. The nature of conventionally bred plant materials, however, is such that their public release could have significantly harsher consequence to applicants than publication of specifications of other inventions. Patent claims covering plant materials tend to be narrowly drawn to plants and materials closely related to the biological deposit. Under the proposed revision, anyone is given a period of time to obtain the biological deposit and use it for any purpose. Within this period, one could legitimately use the deposited material to make further selections, e.g. outcross the deposit's uniquely valuable genetic variability into distinct plant lines or cultivars. In doing so, a competitor could appropriate the value of an inventor's contribution to the art, while stepping outside the reach of the patent claims that could issue. A similar use of disclosures of patent specifications cannot be paralleled in other technologies. For example, claim terms can be chosen to encompass the essence of the contribution to the art illustrated by an electronic circuit diagram, without a need for a claim reference to anything resembling a specific ATCC accession number. Consequently, competitors cannot simply take the electronic circuit diagram and incorporate its valuable features into a non-infringing product, which would be analogous to what plant breeders could do with an ATCC seed deposit under the proposed revision.

*2) Provisional rights cannot adequately compensate for unrestricted release of plant materials*

Owners of patents covering conventionally bred plants do not typically allow use of their materials in breeding programs of competitors, or export of their materials to any jurisdiction. Yet, by providing a period of unrestricted access to deposited materials, the proposed revision would sometimes force patent applicants to allow such uses. Because the essence of breeding efforts can be easily incorporated into non-infringing varieties, as explained above, the provisional rights to a reasonable royalty provided by the AIPA cannot adequately compensate for such a use of the new plant materials.

*3) The proposed revision fails to harmonize the US practice with that of the European Patent Office*

The proposed revision is allegedly partly aimed at harmonizing the US rules with those of the EPO. But, EPC Rules 31-33 of the Implementing Regulations of the European Patent Convention provide safeguards for applicants. The EPC rules allow a patent applicant to limit biological material use to experimental purposes, limit material transfer to third parties, or limit availability to a designated expert. Thus, far from harmonizing the US practice with that of the European Patent Office, the proposed revision places US applicants at a significant disadvantage compared to applicants before the EPO. At the very least, the proposed revision should be modified to incorporate safeguards similar to those of EPC Rules 32 and 33.

*4) Other justifications for the proposed revision seem flawed*

Other troublesome rationalizations of the proposed revision include: (i) a selective reading of the GAO study, which was conducted when biological deposits were not available to requestors, and which contained explicit warnings of the potential risks of making these deposits available without restrictions,



and (ii) a disregard for the very purpose of a patent application, which is to secure patent rights to an applicant, and not necessarily to create enabling prior art to be used in Office rejections.

The uniqueness of the materials that makes a deposit necessary for satisfying the patent written description requirement of a plant variety, combined with the inappropriateness of reach-through claiming of further processed materials (*see* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, Fed. Cir. 2004), would make applicants vulnerable to irreparable harm under the proposed revision. In the case of new plant varieties, the required deposit not only teaches the public *how* to make the claimed invention, it *is* an embodiment of the invention. Combined with the self-replicating nature of plant seed, an early deposit significantly degrades the inventor's protection upon application, and reduces the incentive to apply for a patent. The subsequent loss in certainty of patent protection for new plant varieties for the emerging cellulosic biofuel industry may well reduce private funding for those companies developing such products, thus limiting the progress of this industry which promises to enhance the United States' energy security, rural economy, and carbon balance. The Office's failure to show a good reason for the proposed revision militates strongly against its adoption, and certainly to the extent it would apply to deposited plant materials.

Respectfully submitted,

Steven C. Bobzin, Ph.D.  
*Director of Technology Planning, Protection, and Acquisition*

Mircea Achiriloaie, J.D., Ph.D.  
*Patent Attorney*

Joseph Cahill, J.D., Ph.D.  
*Patent Agent*