From: Leslie Meyer-Leon
Sent: Monday, April 21, 2008 3:23 PM
To: ab99.comments
Cc: board@bpla.org
Subject: Letter to Ms. Fonda re: Comments on Proposed Rule Changes, "Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit," 73 Fed. Reg. 9254 (Feb. 20, 2008)

Please find attached a letter from the Boston Patent Law Association, in response to the request for comments on the Proposed Rule Changes, "Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit," 73 Fed. Reg. 9254 (Feb. 20, 2008).
Best regards,
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April 21, 2008

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

Dear Ms. Fonda:

The Boston Patent Law Association (BPLA) is an association of intellectual property professionals, providing educational programs and a forum for the interchange of ideas and information concerning patent, trademark, and copyright laws in the Boston area. These comments were prepared with the assistance of both the Patent Office Practice Committee and the Biotechnology Committee of the BPLA.

The Notice proposed changes to the rules of practice governing the deposit of biological materials to require that (1) a deposit be made before the publication of the patent application in which it is referenced and (2) all restrictions on access to the deposited material be removed upon publication. Presently, not until the issue date of the patent must deposits be made, and restrictions on access removed. The notice states that the changes are necessary for the public to have access to the biological materials referenced in the published specification to the same extent that it has access to the rest of the disclosure and for the claims to be fully enabled.

Proposed Rules Not Required by AIPA

The Office argues that the rule changes are required by the American Inventors Protection Act of 1999, as amended by the Intellectual Property and High Technology Technical Amendments Act of 2002 ("AIPA"). (P.L. 106-113, 113 Stat. 1501 (1999); P. L. 107-273, 116 Stat. 1757 (2002)) The AIPA amended 35 U.S.C. § 122 to require that, in most cases, pending applications be published 18 months after the claimed priority date. It also provided for provisional royalty rights for the period between publication and issuance in Section 154(d).

According to the Office, requiring the deposit to be made before publication and any restrictions to be removed by publication ensures that the specification will provide an enabling disclosure as of the publication date.

The PTO's arguments in favor of this proposed rule change are flawed. Contrary to the PTO's assertion, the AIPA does not require the proposed rule changes. There is nothing in the Act that requires unrestricted deposit prior to publication. Congress actually considered such a change, was well aware of the risks involved, and mandated that the Comptroller General (in consultation with the Office) conduct a study of the risks and the legal issues involved. See P.L. 106-113, § 4805 (1999). The resulting GAO report, cited in the Notice, concluded that "the statute does not require an associated release of a biological deposit concurrent with 18-month publication…." *Deposits of Biological Materials in Support of Certain Patent Applications*, GAO-01-49 (Oct. 2000) at 5.

For provisional rights to be available, the invention claimed in the patent must be "substantially identical" to the invention claimed in the published application.
35 U.S.C. § 154(d)(2). In the biotechnology area, the invention claimed in the patent is unlikely to be substantially identical to that claimed in the published application because the claims are often narrowed during prosecution and restriction requirements are common. For example, a published application may claim a genus, while the issued patent will often be limited to a narrow specie or species. In such cases, provisional rights may not be available, or may be very limited, while access to the deposits will be broadly given.

Alternatively, if these proposed rules are believed necessary to provide provisional rights under 35 U.S.C. 154(d), a compromise position would be to allow an applicant the choice between having provisional rights available by making deposits and access available upon publication, and not having provisional rights available and making deposits and access available upon issuance.

Nor should the rules governing deposit be changed so that the invention will be fully enabled. The proposed rule changes, however, will provide the public the right and means to practice what is disclosed in a published patent application, without any protection to the patentee. And also without the applicant be given any indication of what will be patented. Due to the U.S. restriction practice, for example, what is claimed in the published application may be vastly different from what is ultimately patented.

A deposit may be required for enablement, but it goes well beyond the usual degree of enablement provided by a written specification. For an invention that does not require a deposit, a specification that meets the enablement requirement of Section 112, first paragraph, tells the competitor how to make and use the claimed invention. By contrast, with the biological deposit, the competitor is given the invention in whole and the complete means to reproduce the invention. This is given with no *quid pro quo* as no patent is guaranteed to be obtained directed to the deposited material

Proposed Rules Not Necessary for Equality

The rule changes are also stated to be necessary to provide equivalent treatment between the biological arts and other technologies. The Office states that, with a few exceptions, the patent statute does not distinguish among different areas of technology.

This argument is also flawed. The rule changes are not necessary for equivalent treatment of inventions. The release of deposited biological material at publication will likely have a serious adverse impact on applicants who make such deposits. Therefore, the changes will not provide parity. Instead, they will place such applicants at a significant disadvantage compared to other applicants.

Proposed Rules Do Not Provide Harmonization with EPO

The proposed changes are argued to increase harmonization with European Patent Office (EPO) practice. The Notice cites European Patent Convention (EPC) Rule 28, which requires a deposit to be made by the filing date of the patent application and for samples to be available from the date of publication.

The proposed charges, however, do not provide harmonization because EPC Rule 28 (now Rules 31-33) do not provide for unlimited access to the biological deposits as in the proposed rule changes. By contrast, EPC Rule 28 provides for significant protections to EPC applicants that are not provided to U.S. applicants under this proposal.

Rule 33 states that a sample shall be made available from the publication date of the European application to any person (a "requester") who undertakes: (i) not to make the material, or any material derived from it, available to a third party, and (ii) to use the material for experimental purposes only. These restrictions apply until such time as the application is refused or withdrawn, or until the patent has expired in all the designated States. The Rule also requires that the requests be made to the EPO and that the requester certify that he or she is entitled to a sample.

If the European patent issues, the applicant is protected from competitors using the deposit for commercial purposes. This period of protection is 20 years from filing, regardless of the scope of the claims in the patent, if the issued claims still cover the material. Only if the patent does not issue, does the material become freely available.

Rule 32 permits the applicant to restrict access to the deposit. More specifically, access may be restricted to an expert nominated by the requester who is approved by the applicant or recognized as an expert by the EPO. Under Rule 32(2)(b), the expert must regard the requester as a third party and must use the deposit for experimental purposes only during the Rule 33 time periods. The Rule 32 restrictions apply until the patent is granted or for 20 years from filing, if the application is not granted.

The proposed rules do not provide these same restrictions and thus do not provide the same protections to U.S. applicants as provided by the EPO. Harmonization thus will not be achieved by the proposed rules.[1]

The Proposed Rules Will Adversely Impact Small Entities

It is believed that the proposed rule changes will have a substantial adverse impact on applicants, in particular small entities. Requiring deposits to be made prior to publication will result in deposits being required prior to any prosecution, including issuance of a restriction requirement. Unlike patent prosecution, small entities are not given discounts on the fees required for making and maintaining deposits. These fees can be substantial (e.g., often around $2000.00). Requiring such fees prior to any indication of what is likely to even be examined in the application would disproportionately impact small entities by significantly increasing the costs required to file an application. At the very least, such deposits should not be required unless the deposited subject matter will in fact be examined in a given application.

Conclusions and Recommendations

The BPLA Patent Office Practice Committee thus opposes the proposed changes to the rules for biological deposits. The proposed rules are not necessary for the reasons set forth in the Notice. The proposed rules would likely adversely impact applicants who make such deposits and would disadvantage them with respect other applicants. These proposed rule changes would also significantly adversely impact small entities because of the increased costs required for making deposits made early prior to any indication of what subject matter will be patented. The reasoning provided in the Notice is flawed and thus the proposed rule changes are not necessary.

While the current rules are should be maintained, should any rule changes be made to require that deposits be made available upon publication, at the very least restrictions on access to the biological deposits should be include at least to the same degree provided by EPC Rules 32 and 33. Such restriction would provide at least some protection to applicants prior to issuance of a patent.

Thank you for consideration of our comments.

Sincerely,

Leslie Meyer-Leon

Leslie Meyer-Leon
President

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[1] Japan likewise does not require public access to the deposit until the patent issues.