From: Dana Colarulli
Sent: Monday, April 21, 2008 9:48 PM
To: ab99.comments
Subject: IPO Comments on Proposed Rules related to Biological Deposits
Importance: High

Attached, find IPO's comments on 73 Fed. Reg. 9254. Please confirm receipt of this submission and contact me if you have any questions .

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April 21, 2008

Hon. Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office (USPTO)
Mail Stop Comments—Patents, Commissioner for Patents
P.O. Box 1450
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ATTN: Kathleen Kahler Fonda
Submitted by email to: AB99.Comments@uspto.gov

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 Director Dudas:

I am writing on behalf of the Intellectual Property Owners Association (IPO) to comment on the proposed changes to the rules of practice relating to biological deposits, which were published in the Federal Register notice of February 20, 2008 (73 Fed. Reg. 9254). IPO appreciates the opportunity to comment.

IPO is a U.S. trade association representing intellectual property owners in all industries and fields of technology. Our current membership represents more than 250 companies and more than 10,000 individuals involved in IPO through their companies or in other member classes. IPO corporate members file about 30 percent of the patent applications filed in the U.S. Patent and Trademark Office ("USPTO") by U.S. nationals. We strive to ensure that IP laws and practices provide appropriate incentives for advances in science and technology.

We believe that the proposed rule changes are not required by, or consistent with, current law and, if adopted in their present form, would have an unnecessary, adverse impact on applicants who make deposits. Therefore, we urge that the proposed changes not be adopted. However, if the USPTO does implement rules, we urge the adoption of the protective provisions similar to those in the corresponding rules of the European Patent Office.

Summary of the Proposed Rule Changes

The Notice proposes changes to the rules of practice governing the deposit of biological materials to require that such a deposit be made before the publication of the patent application in which it is referenced and that all restrictions on access to the deposited material imposed by the depositor be removed upon publication. Currently, deposits must be made, and restrictions on access removed, by the issue date of the patent. The changes are said to be necessary to provide the public access to the biological materials referenced in the published specification to the same extent that it has access to the rest of the disclosure.

USPTO's Rationale

The USPTO makes several arguments in support of the rule changes. First, the 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, with certain exceptions, pending applications be published 18 months after the claimed priority date. It also provided, in new Section 154(d), for certain provisional royalty rights for the period between publication and issuance. Such rights are available only if the specification of the published application contains an enabling disclosure for the claimed invention. Therefore, according to the USPTO, 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.

Second, the rule changes are necessary for parity of treatment between biological and other types of inventions. The USPTO states that, with a few exceptions, the patent statute does not distinguish among different areas of technology and further that the Federal Circuit accords the same treatment to all forms of invention.

Third, the rule changes will ensure that published applications referencing biological deposits will be anticipatory prior art under Sections 102 (a), (b) and (e). Without a requirement for a deposit prior to publication and a release of the deposit upon publication, the published application will not be enabled and, therefore, cannot be anticipatory prior art.

Fourth, the proposed changes will 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 to any person from the date of publication. Thus, for both U.S. and EPC applications, members of the public will be informed of the existence of the deposited material and be able to request samples after publication at 18 months.

USPTO's Legal Analysis Is Faulty

IPO disagrees with this analysis. The AIPA does not require the proposed rule changes. There is no specific requirement in the Act for unrestricted deposit prior to publication. In fact, Congress considered such a change, was well aware of the risks involved, and mandated that the Comptroller General (in consultation with the USPTO) 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.

The Notice took issue with this conclusion as being based on an incorrect interpretation of *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). However, the key case is *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985), in which the Federal Circuit held, for a deposit that would meet the public availability requirements of the rules after the patent issued: (i) the applicant's deposit of the biological material in his own laboratory met the enablement requirements of Section 112 and the requirements for a constructive reduction to practice, and (ii) the addition of

depository information (e.g., the deposit date and accession number) after the application's filing date did not constitute the addition of new matter.

The USPTO discussed *Lundak* in the Notice, but distinguished it on the grounds that it was superceded by the later-adopted AIPA. In fact, in view of Section 4805 of the statute and the conclusion of the GAO report, we believe that *Lundak* is still controlling law. *Lundak* had been decided well before the AIPA was passed, and Congress chose not the overrule it. Instead, it required the Comptroller General to study the issue. Therefore, the proposed rule changes are counter to case law and represent an attempt to change substantive law.

We also do not believe that the rule changes are necessary for parity of treatment of inventions. As explained below, 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 applicants in the biological arts at a significant disadvantage compared to other applicants. Parity of treatment requires that the proposed rules not be adopted.

The Notice also argued that the rule changes are necessary for published applications to be prior art under Sections 102(a), (b) and (e). In the notice, the possibility is raised that a published patent application may somehow be defective as a prior art reference because it may not be an "enabling" disclosure without a publicly accessible deposit. However, the enabling requirement of a prior art reference is similar to but not identical to the scope required by section 112 of the Patent Act to support the issuance of a patent. If that were not the case, a great majority of the non-patent references cited by the USPTO itself would fail. Scientific articles with much less disclosure than found in a patent application, indeed even "abstracts" of such articles, with or without a recitation as to the availability of the biological material are routinely cited by the USPTO. Even if the material is "available upon request," the request may not be honored or if so, likely comes under the provisions of an Material Transfer Agreement with restrictive terms. We do agree that published applications will not be prior art for claims of another applicant directed to the same biological material, if a deposit was necessary to enable the relevant claims in the published application. However, even if access to the deposit were restricted during prosecution, such a published application, coupled with the existence of the deposit, would appear to be prior art under Section 102(g) because it would show the existence of a prior invention by another person. Therefore, the rule change is unnecessary for prior art purposes.

Lastly, the Notice argued that the rule changes would be a significant step toward harmonizing U.S. practice with EPO practice because the public availability of deposits referenced in U.S. applications at publication would be consistent with Rule 28. However, the Notice failed to mention that Rule 28 (now Rules 31-33) also provided for protections to EPC applicants that are not available to U.S. applicants.

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.

Therefore, the applicant is protected from competitors using the deposit for commercial purposes if the European patent issues. 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. (As discussed in the next section of this letter, the scope of the issued claims is critical to the issue of whether or not a U.S. patentee will have provisional rights.) However, if the patent does not issue, the material becomes freely available.

In addition, Rule 32 permits the applicant to restrict access to an expert nominated by the requester who is also 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 patent application is not granted. Since the U.S. rules do not provide this type of protection, the proposed changes would enhance harmonization only at the expense of applicants who make deposits.

The Proposed Rule Changes Will Adversely Impact Applicants that Make Deposits

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, still requires a competitor to actually make the claimed invention, learn about it under real world conditions, optimize it for commercialization and scale it up for production. In contrast, a biological deposit essentially provides the competitor with the finished product and the factory making it because the deposit is self-replicating. The proposed rules would require biotechnology applicants to give up substantial tangible property rights; there is no requirement to provide samples or models in other arts.

For example, if the invention is a new antibiotic produced by a new bacterium found by exhaustive screening of soil samples, the applicant will, in all likelihood, deposit a culture of the bacteria. However, when a competitor gains access to the deposit, he or she has both the finished product and the means for producing it. The situation is even more dramatic for seeds, which simply require some land, water and fertilizer to reproduce in bulk.

Under the current rules, a competitor can gain access to the deposit only after the patent is issued, and the patentee can rely on the patent to protect his or her rights. Under the revised rules, provisional rights, in theory, might provide the patentee with a reasonable royalty for a competitor's use of the deposit during the time between publication and issuance. However, such rights are likely to be limited or non-existent in practice.

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). However, under the realities of biotech patent prosecution, the invention claimed in the patent is unlikely to be substantially identical to that claimed in the published application because the claims are usually narrowed during prosecution. In addition, because of restriction practice, it is highly likely that an

applicant's genus claim will be restricted to numerous species. This will result in a narrower genus claim or in an extended delay in obtaining claims to the material itself. For example, the desired claims may not be obtained until one or more divisional applications have been issued. A related problem results from the fact that a plurality of deposits may be made to support a genus claim, but the issued claims may only cover some of the deposits, or no claims may issue at all, resulting in the application being abandoned. (This may also be the case for published applications that do not refer to a deposit, but again, a critical distinction lies in the fact that a deposit provides competitors with so much more than a written description alone.) In all of these cases, the applicant will lose provisional rights, or such rights will be severely limited. In addition, because prosecution history on PAIR is now open to the public after publication, a competitor could choose to monitor patent applications where claims had been amended post-publication, and to subsequently request deposits free of concerns over reasonable royalties, based on the prosecution history.

Further, such a deposit may be made out of an excess of caution. By the end of prosecution, the deposit may not have been needed for enablement. However, by this time, the applicant will have placed "the factory" into the public domain.

An alternative case would be where the applicant did not believe a deposit to be necessary and, therefore, did not make one. However, the examiner may take and hold a different position, and the applicant may accede in order to get the patent issued. This is likely to be well after the application has published. The current rules provide a safety net by allowing the applicant to make the appropriate deposit prior to issuance. The new rules would remove this safety net.

IPO, therefore, believes that the proposed changes, if adopted, would likely have a substantial adverse impact on depositor applicants, including small entities, contrary to the statements made in the Notice.

Conclusions and Recommendations

For the reasons stated above, IPO opposes the proposed changes to the rules for biological deposits. They would likely adversely impact applicants who make such deposits and would disadvantage them with respect to other applicants. Moreover, the changes are not required by the AIPA and, in fact, are inconsistent with case law. Finally, the other reasons advanced by the USPTO to support the changes are not persuasive. Therefore, IPO recommends and urges that the proposed changes not be made.

If rules are adopted, IPO recommends that the USPTO also adopt provisions substantially the same as those in EPC Rules 32 and 33 to provide at least some protection to applicants and patentees.

Sincerely,

Steven W. Miller
President