From: Michael K Kirk
Sent: Monday, April 21, 2008 1:09 PM
To: ab99.comments
Subject: Comments on Proposed Rules Concerning the Time for Filing and the Date of Availability of a Biological Deposit

Kathleen Kahler Fonda
Legal Advisor
Office of the Deputy Commissioner for Patent Examination Policy

Dear Ms. Fonda,

Attached are the comments of the American Intellectual Property Law Association on the proposed rules concerning the time for filing and the date of availability of a biological deposit.

I would greatly appreciate confirmation of receipt of these comments.

Thank you very much.

Sincerely,

Michael Kirk
Executive Director
AIPLA

AIPLA

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April 21, 2008

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Comments on Proposed Rule: "Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit"
73 Federal Register 9254 (February 20, 2008)

Dear Under Secretary Dudas:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments regarding the Notice of Proposed Rulemaking (the "Notice") proposed by the U.S. Patent and Trademark Office (PTO) regarding "Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit."

AIPLA is a national bar association whose more than 17,000 members are primarily lawyers in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

I. Introduction

In the Notice the PTO proposes changes in the rules of practice with respect to biological materials deposited in support of certain patent applications. Specifically, deposits, if required, must be made prior to the publication of the patent application. Currently, deposits are treated similar to formal drawings with compliance triggered by the notification of allowable subject matter near the end of the prosecution process with all restrictions to public access removed as of the date of issuance of the patent, except that the need for formal drawings (unlike a deposit) is rarely an issue during examination. The proposed rules change the timing of the deposit and would further require the applicant to remove all restrictions on public access to the deposit as of the date of the publication of the patent application. We are of the opinion the latter provision is unnecessary and has the potential to do great harm.

A. There is no legal, public policy, or international patent harmonization reasoning that compels the rule changes proposed by the PTO

The Supreme Court cases cited by the PTO in the Notice, e.g., *Brenner v. Manson*, state the general rule that the *quid pro quo* for the patent grant is the enabling of the skilled artisan to practice the claimed invention upon the expiry of the patent (emphasis added). One might argue that to give effect to this proscription, the deposit should not be publicly accessible until the patent expires,

because it is then and only then that the public is entitled to the unfettered right to practice the patented invention.

The passage of the American Inventor's Protection Act of 1999 (AIPA) mandated the early publication of most pending U.S. patent applications. The publication, with certain exceptions, takes place 18 months from the earliest filing date for which benefit has been sought. This conforms to the practice in many jurisdictions, including Europe and Japan, and is cited as a positive step in international patent harmonization. Publication is not mandatory in all cases, and can be avoided by limiting filing to the United States.

Before addressing the issue that early publication has on deposit practice, it is important to understand why early publication was adopted in the first place and the problem that early publication was intended to address. As pointed out by Henderson (IDEA 42(3): 361(2002)) and cited by the PTO in the Notice, early publication began in Europe in the 1960s to address an issue caused by the long pendency in patent examination. The 1960s had seen a dramatic increase in the number and complexity of patent applications and hence the pendency of applications rose. Inventors were hesitant to embark on research projects for the fear that a patent might issue and, after their years of effort, place the inventors in an infringing situation—the so-called submarine patent effect. By "laying open" the patent application, the world is placed on notice of the pending technology and thereby provides other inventors an opportunity to assess the situation and take steps to avoid potential infringement issues. However, there is no need to actually practice the invention described in the publication.

The fundamental problem with the rationale behind the rule changes proposed by the PTO is that somewhere in time the notice function of an early publication became transmuted into an inherent right of the public to practice the invention disclosed in a published patent application. The notice function of a patent disclosure was appreciated in the United States long before the enactment of the AIPA (*Vas Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). Indeed this function is achieved by complying with the written description requirement of 35 U.S.C. §112. While there may be some views to the contrary, the weight of judicial guidance is that the written description requirement is separate and distinct from the enablement requirement of Section 112 and must be independently satisfied (*Regents of the Univ. of Calif. V. Eli Lilly & Co.*, 119 F.3d 1559 (Fed.Cir. 1997). This is certainly the view of the PTO during the patent examination process. (*See*: 35 U.S.C. §112 First Paragraph Enablement U.S. PTO Training Manual, page 35, August, 1996). The question is, then, can the patent application publication serve its notice function without the need of a deposit? The answer is yes. The published specification often contains pages of taxonomic and physiological data describing the properties and functions of the biological material that is the subject of the deposit. As pointed out by the Notice and the articles cited therein, the deposit practice arose to address an enablement issue, namely, "how to make" the claimed invention.

Why did the focus shift to the enablement of a published patent application? One reason can be gleaned from the Notice itself. There, 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. This argument rings hollow. The enabling requirement of a prior art reference is similar, but not identical, to the scope required by section 112 of the Patent Act to support the issuance of a patent. If it were otherwise, a great majority of the non-patent references cited by the PTO 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 PTO. Even if the material is "available upon request," the request may not be honored or, if it is, would likely be subject to the provisions of a Material Transfer Agreement with terms much more onerous than anything proposed by the PTO.

Further, whether a patent application publication is enabling or not is a concern best addressed by the applicant. As noted below, courts have held that a patent needs to have an enabling disclosure for the invention claimed in the patent only at the time of patent grant. At the time of patent application publication, the claims that are ultimately allowed may not be present in the application, and whether provisional rights under 35 U.S.C. § 154(d) can be enforced is uniquely the concern of the patent applicant/owner. While it may be convenient for the Office to ensure enablement at the time of publication for prior art purposes, that concern should not compromise the rights of the applicant to provide enablement for only that subject matter that is covered in the claims of the issued patent when enablement depends on a deposit of biological material.

Another rationale for the rule changes is that they represent an attempt to harmonize U.S. patent practice with that of other major industrialized nations, specifically those who are members of the European Patent Convention and/or Japan. It is suggested in the Notice that since these countries all have early publication and deposit requirements, we should look to their practice for a solution in the interest of harmonization. In fact, the EPC and Japan have two very different solutions, neither of which compromises the interests of the patent applicant in the manner proposed by the PTO. Japan, even though it has early publication, still does not require public access to the deposit until the patent issues. Europe, on the other hand, provides for public access to the deposit after publication, but provides an important safeguard to the depositor, in that for the term from publication until issue, access can be limited to "experts" agreed to by the depositor and requestor. EP Rule 28(3) provides:

> (2) Said issue shall be made only if the requester has undertaken vis-à-vis the applicant for or proprietor of the patent not to make the biological material or any biological material derived therefrom available to any third party and to use that material for experimental purposes only, until such time as the patent application is refused or withdrawn or deemed to be withdrawn, or before the European patent has expired in all the designated States, unless the applicant for or proprietor of the patent expressly waives such an undertaking.

There are several other key differences between European prosecution and US prosecution that would make the proposed rules exceedingly cost prohibitive. First, requiring each biological deposit prior to publication requires the applicant to pay deposit fees of approximately $2000.00 per deposit without a guarantee of protecting that deposit. Second, European prosecution allows election of more than one invention, thus allowing protection of all deposits in the same application; whereas US restriction practice requires separate prosecution of each "invention." Thus, the effect of the rules would be to exponentially increase prosecution costs and make it very unlikely that all deposits will be protected in the same patent or at the same time. Third, the proposed amendments to Section 1.808(a)(2) are more demanding than EP requirements, which allow deposits to be fully released only on patent grant (Rule 31; *Art. 78*, *83*, *128*, *129*, *R. 26*, *34*). Rather than electing one of the existing modes of deposit practice, the PTO proposes yet a third mode that, for reasons given below, is the most damaging to the patent applicants' rights and fails to harmonize with any of the major jurisdictions.

B. The Provisional Rights Granted Under 35 U.S.C. §154(d) are inadequate to protect the Depositor's Rights

The implementation of the proposed deposit rules may result in counterintuitive situations, such as the following hypothetical: A plant breeder spends seven to ten years developing a new inbred corn variety useful as a parental line in the generation of hybrid corn varieties. She decides to file a patent application to protect the variety and to be able to prevent others from making, using or selling the new variety for the term of the patent. She is not interested in licensing the use of the variety to

competitors and goes to extraordinary efforts to protect the variety from unauthorized access by others. As a result of the patent examination process, it is determined that a deposit of the seed of the new variety is required. Under the proposed rules, if implemented, she must remove all restrictions on the deposit and rely on the provisional rights granted in 35 U.S.C. §154(d) as her sole remedy for unauthorized use of her invention prior to the issuance of the patent. The remedy, such as it is, is nothing more than a compulsory license, and what's more, it is an automatic grant in that the requestor does not have to establish any compelling reasons for the grant of such a license.

Moreover, a competitor would merely need to access the deposit and export the seeds to any country where no counterpart patent exists. Further, such ex-US use would not be actionable under 35 U.S.C. §154(d). Even if the seeds are not exported, a competitor would not want to use the patented inbred directly in hybrid production, because it would be liable for infringement when the patent issues. A competitor would be motivated to incorporate the inbred into its own breeding program, such that the resulting inbred will be sufficiently different from the deposit to avoid infringement, but still retain useful features of the invention.

Essentially, all the competitor needs to do is cross plants from the deposited seed with plants of the competitor's collection and then back cross the resulting plants using the competitor's plant as the recurring parent and never need to use the deposited seed again. Thus, after the initial cross there is no use of the invention. The patent, when it issues, is of no use with respect to that competitor. At least if that activity had occurred during the term of the patent, it would not be considered to be *de minimus* use and, hence, would be actionable as an infringement.

What public benefit is achieved by placing the true innovator at such risk? The fact that the GAO in its report was unable to uncover a documented example of deposit misuse is no reason to think the risk does not exist. There were, at the time of the study and continue to be, law suits directed to the misuse of germplasm. Because of secrecy orders, the details of the suits could not be discussed with the GAO and often "when the handwriting is on the wall" in these suits the parties settle. Again the terms of the settlement preclude disclosure of the details. It is not surprising that GAO did not find the example it was looking for. That does not mean it did not exist.

C. It is contrary to sound public policy to require unnecessary deposits and access, and to incent U.S. industry to seek patent protection only in the U.S. or to maintain the invention in confidence

Under current practice, as embodied in 37 C.F.R. § 1.802(c), the mere reference to a biological deposit in an application disclosure or even the actual deposit of such material does not create any presumption that such material is necessary to comply with any requirement for patentability or that it must be accessible to the public at any point in time. Indeed, these determinations can only be made when the scope of the claims is finally determined along with a determination of whether public access to any particular biological deposit is necessary to support any requirement of the statute. One purpose of this provision was to permit an applicant to make reference to any biological material and even a deposit at the time the application was filed to satisfy a requirement in other countries for such a deposit if it was necessary, but to leave to a determination by the relevant patent offices whether public access to any particular deposit was necessary. This provides an appropriate balance between the rights of patent applicants and the public - no greater or lesser access is required than mandated by the claimed invention at the time of patent grant.

The proposed rules, on the other hand, ignore this fundamental balance, and would require public access to any and all biological materials mentioned in the specification at the date of publication, "regardless of whether the deposit was necessary for compliance with any statutory

provision." Proposed Section 1.808(a)(2). This seems both unnecessary and unreasonable to meet any legitimate interest of the public or the Office. If the proposed rules are interpreted to apply *only* to a deposit of a biological material "necessary to preserve the availability of provisional rights under 35 U.S.C. § 154(d)" (Proposed Section 1.804(a)), a practice will emerge among those applicants seeking to avoid the policy implicit in these proposed rules of filing claims for inventions for publication that do not require access to a biological material, and then file a preliminary amendment to add, or substitute claims for examination before first action. With an average pendency to first action that is currently 22.7 months in TC 1600, this practice could become routine among applicants adversely affected by these rules. In many of these applications, there is at least one aspect of the invention that does not require access to a biological deposit.

Finally, as observed in the GAO Report (p. 12), a patent applicant could avoid 18-month publication by choosing not to file applications in other countries. By avoiding 18-month publication, the issue of a deposit to preserve the availability of provisional rights under 35 U.S.C. § 154(d) never arises. For many small biotech companies, this may already be an economic reality. For those who would also seek more global protection, or voluntarily choose to describe an invention in a published patent application, what domestic interest is served by adding to the burdens and vulnerabilities of American industry that want to publish or seek protection outside the United States? The proposed rules create an unfortunate disincentive to publish and to file in other countries applications that are directed to inventions that may require a deposit of biological material.

II. Comments on Specific Rules

A. Proposed Rule 1.804 - Time of making an original deposit in order to preserve availability of provisional rights under 35 U.S.C. §154(d)

Section 1.804 is proposed to be amended to provide that if a deposit of biological material is necessary to preserve the availability of provisional rights under 35 U.S.C. §154(d), an original deposit of the biological material must be made prior to filing an application or during the pendency of an application, provided that the deposit is made before technical preparations for publication of the application as a patent application publication have begun (*see* § 1.215(a)).

We request that current Rule 1.804 should be retained unchanged. While 35 U.S.C. §122(b)(5) seems to support the proposed rule if an applicant desires §154(d) provisional rights**,** it is the patentee's choice whether to enforce provisional rights. Satisfying the conditions of obtaining these provisional rights can be more difficult than satisfying the conditions for obtaining a patent, even for an invention that is new, useful, nonobvious, and completely disclosed and enabled. An applicant may reasonably believe that the probability of harm due to losing an invention (in the form of a biological deposit) to the public, if a patent is not granted for an application, outweighs the probability of benefit due to §154(d) provisional rights. Many biotechnology patent applications do not receive a first substantive Office action until well after the start of technical preparation for publication of the application. Retaining the current, unchanged Rule 1.804 gives an applicant the option of providing a required deposit of biological material accessible to the public if provisional rights are deemed important.

The PTO points to the availability of a provisional right under 35 U.S.C. §154(d) to obtain a reasonable royalty if the invention as claimed in the published patent application is substantially identical to the invention claimed in any patent that may issue therefrom, as an exchange for this early disclosure. However, to assert this provisional right, the patent owner must know who is using the deposit. As currently proposed, a party needs to identify itself to obtain the deposited sample, but there is no restriction on giving it to a third party. If for example, a competitor hires another entity to obtain the samples, that entity can then forward the material to the third party competitor without

revealing the identity of the third party competitor. The third party competitor could be residing in the U.S. or in a different country where patent protection is not available, as in the case of plant related inventions. To obtain a royalty for the use of the deposited material under provisional rights, and for the resulting material created by the use of that deposited material, the inventor must incur the cost, most likely in litigation, of showing that the infringer obtained and used the deposited material (if it was not the entity that originally requested the sample) and that the resulting product (new inbred line for example) was made using the deposited material.

B. Proposed Rule 1.808(a)(2) - Furnishing of samples

Section 1.808(a)(2) is proposed to be amended to provide that all restrictions imposed by the depositor will be irrevocably removed upon the earlier of publication of the application under § 1.211 and 35 U.S.C. §122(b) or grant of the patent, and to indicate that the rule applies regardless of whether the deposit was made to satisfy a statutory provision.

We request that current Rule 1.808(a)(2) be retained unchanged. *In re Lundak* and other court cases decided before November 29, 2000 required that biological deposits necessary to enable disclosure be made before the patent issue date, accomplishing on the patent issue date concurrent exchange of an enabling disclosure of the claimed invention to the public, for grant of a patent and its associated rights to the applicant (*Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985)). Section 122(b) of title 35, based on the American Inventors Protection Act of 1999 (AIPA), temporally uncouples that exchange for many applicants, forcing them to incur the financial risk of providing a written description to the public before (promptly after expiration of 18 months from the earliest filing date for which a priority benefit is sought), and without certainty of, receiving grant of a patent and its associated rights for a disclosed claimed invention.

The modification making the deposit available at publication is being suggested in view of the American Inventors Protection Act (AIPA). The PTO points to the GAO study noting it found no documented cases where a sample of a biological deposit was obtained and then used to infringe the patent. However, the GAO study is replete with references to the fact that the study was conducted when the deposits were in fact <u>not</u> available until patent issuance. The GAO study at page 4 states that "[t]his result to date does not mean that no potential risk exists. To the contrary, because samples of a biological deposit can be obtained once a patent is granted, the potential exists today and will exist into the future that an individual or an organization could use the deposit to infringe the patent." At pages 4-5 of the study it further states: "[t]he new 18-month publication requirement for the patent applications need not have any effect on risks for patent infringement because this requirement does not change when biological deposits can be released to persons other than the applicant…. The time required for releasing deposits continues to be the time a patent is granted." The PTO wants to change this time of deposit availability and therefore the risk will be even greater than anticipated by the GAO study.

The GAO study did appear to suggest that the risk of infringement via use of the deposits, in particular deposited seeds, was minimal by pointing to an analysis of the 52,841 patents granted in the last three months of 1999. It pointed to only 308 of these having deposits, and only 53 of those were for seeds. However, this conclusion appears flawed in that it takes into account all granted patents, including mechanical, electrical, etc. What would the numbers have looked like if they had accounted for the percentage of biotechnology patents that have deposits or the number of seed applications that have deposits? The percentages likely would have been much higher than the 0.6 percent of <u>all</u> patents on which the report relied. Also, if 308 patents were granted in only 3 months, that would suggest that over 1,200 applications a year would be affected by these proposed rule changes. While perhaps not a large number in comparison to all patents, it is a large number of potential patents that could require

litigation to protect the rights resulting from misuse of the deposited biological material. This could result in significant economic impact on the patent owners, including universities and other small entities.

The GAO study did point to the higher burden of risk that would be assumed by the seed industry. They noted the self-replicating plant variety, such as soybean varieties and inbred lines of maize, is its own "factory." A potential infringer merely needs to obtain the sample to have the invention ready to use at a very low cost. Balancing the low cost of access to the seed deposits and the release of these deposits prior to the issuance of a patent against the potential high cost of proving that any resulting developed lines were created using the deposited lines under the provisional rights once the patent issues, the seed company patent owner is put at a decidedly unfair disadvantage.

The GAO indicated that the USPTO may wish to seek legislation to effect access of biological deposits at the time of publication. *See Deposits of Biological Materials in Support of Certain Patent Applications*, GAO-01-49, pgs. 11-12 (October 2000).

C. Proposed Rule 1.809 - Examination Procedures

1. Proposed Rule 1.809(b)(1)

Proposed rule §1.809(b)(1) provides that applicants shall reply to a rejection to a deposit by making an acceptable original, replacement, or supplemental deposit or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of §1.805.

We request that current Rule 1.809(b)(1) be retained unchanged for the reasons given above in the comment for proposed rule change 1.804. In addition, an applicant should be able to request that actually making a deposit in accordance with these rules be held in abeyance only if it is agreed that the current claims would require a deposit to satisfy a statutory requirement.

2. Proposed Rule 1.809(b)(2)

Proposed rule §1.809(b)(2) requires that a request to hold the making of the deposit in abeyance will not be considered a bona fide attempt to advance the application to final action. Applicants may still argue why the application meets the requirements of 35 U.S.C. 112, first and second paragraph without requiring a deposit.

We request that current Rule 1.809(b)(2) be retained unchanged for the reasons given above in the comment for proposed rule change 1.804. Even as proposed, we do not understand how the proposed procedure would work where the examiner should be making a rejection if a claim requires a deposit that has not been made in compliance with the regulations. Simply making a requirement under penalty of abandonment prevents an applicant from having the issue addressed on appeal. The need for a deposit should be an appealable issue, not one that is addressed on petition.

3. Proposed Rule 1.809(c)

Proposed rule §1.809(c) provides that if an application is otherwise in condition for allowance except for a needed deposit, applicants will be notified and given a period of time within which the deposit must be made in order to avoid abandonment.

We request that current Rule 1.809(c) be retained unchanged for the reasons given above in the comment for proposed rule change 1.804.

4. Proposed Rule 1.809(e)

Proposed rule §1.809(e) requires that an amendment required by paragraphs (d)(1), (d)(2), or (d)(4) of this section for a biological deposit that is necessary to preserve provisional rights under 35 U.S.C. §154(d) must be filed:

1. within a period of sixteen months after the date of filing of the application or, if the benefit of an earlier filing date is sought under 35 U.S.C. §§119(e), 120, 121, or 365(c), within the later of four months of the actual filing date of the later-filed application and sixteen months from the filing date of the prior-filed application; and

2. before or with any request for early publication.

We request that current Rule 1.809(e) be retained unchanged for the reasons given above in the comment for proposed rule change 1.804.

D. Miscellaneous Issues and Inquires Raised Regarding Proposed Rules

A number of issues are raised by the proposed rules that are not addressed in the notice. If the PTO decides to adopt these rules in some form, it should make clear whether an applicant potentially would only lose provisional rights for failure to submit the deposit prior to publication. It was not clear how the proposed rules would be implemented in terms of an effective date, whether continuing applications would be treated in the same manner as a first nonprovisional application, whether the proposed rules would apply to published PCT applications that designate the U.S. and whether deposits can be withdrawn after the required conditions have been satisfied and the consequences of such action. Clarification is requested.

III. Alternatives to the Proposed Rules are available and should be considered

While AIPLA has a preference for the status quo in the area of biological deposits, a system that has served all interested parties well over the last 18 years, there are alternatives to the changes proposed by the PTO that more closely parallel an international norm for the handling of biological deposits.

One alternative is to follow the conclusion of the GAO report that public access to the deposit is not required at the time of publication of the application. Release of the deposit would occur, as it does presently, at the time the patent issues. An applicant concerned with enforcing provisional rights under 35 U.S.C. § 154(d) could take steps to ensure that a deposit was made in accordance with any provisions that may be necessary to achieve that goal.

Another alternative is to adopt the European approach, which would include the "expert solution" such that the deposit does not actually reach the hands of the requestor. EPC Rule 33 requires that the requestor of the deposit not make the biological material, nor any biological material derived there from, available to any third party and to use the material for experimental purposes only. Moreover, EPC Rule 32 allows the applicant to limit availability to an expert approved by the applicant or recognized by the President of the European Patent Office and this limited availability to an expert lasts for the period of the patent life or for 20 years from filing in the event the application is refused or withdrawn. The PTO proposed rule changes do not include these protections and safeguards to the applicant, thus failing to bring us into full harmonization and, more importantly, putting applicants in the U.S. at a disadvantage. If it is determined that the proposed rule changes are

approved, then at a minimum the same restrictions should be imposed in the U.S. as those currently imposed in the EPO.

Finally, it is interesting to note that in the Notice itself, the GAO report, and the law review cited there was no discussion of a deposit system in respect of another intellectual property right. Under the Plant Variety Protection Act (PVPA) deposits may also be required. In this system the deposits are not publicly available and are maintained by Federal Seed depositories for the use by the PVPA examiners to aid them in their evaluation of the PVPA application.

We appreciate the opportunity to provide comments on the proposed rule and are available to assist the PTO in further developing patent practice and procedures.

Sincerely,

Michael K. Kirk
Executive Director
AIPLA