The Comments of the

Biotechnology Industry Organization

on the

United States Patent & Trademark Office

Proposed Rule Changes Concerning

Biological Deposits

April 21, 2008

Mail Stop Comments - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Kathleen Kahler Fonda

Comments to Proposed Rulemaking Entitled: *Revision to the Time for Filing of a Biological Deposit and the Date of Availability of a Biological Deposit*

Dear Ms. Fonda:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the U.S. Patent and Trademark Office's (PTO) proposed *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 202008). BIO is an industry organization with a membership of more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. states. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

In the Notice of Proposed Rulemaking (Fed. Reg. 73(34):9254(Feb.20, 2008)), (the ”Notice”)the United States Patent and Trademark Office (U.S. Patent Office) proposes changes in the rules of practice for biological materials deposited in support of certain patent applications. Specifically, these rules change the timing for biological deposits as well as the timing for public availability of such deposits. The current rules treat biologic deposits much like formal drawings with compliance triggered by the notification of allowable subject matter near the end of the prosecution process. Notably, the biological deposits are not made publicly available until the date of issuance of the patent. The proposed rules seek to change both the timing and public accessibility of a biological deposit to coincide with the date of publication of the pending patent application. While seemingly simple and straightforward, unfettered access to biological deposits unfairly burdens the biotechnology patent applicant and potentially greatly limits the value of the limited patent monopoly, once granted.

BIO is sympathetic to the challenges faced by the U.S. Patent Office in pursuing its stewardship mission over patent practice in the United States. For this reason, BIO consistently supports the efforts of the U.S. Patent Office to obtain full funding of its mission. However, the proposed rules fail to further that mission. In fact, these new rules, if implemented, will have a considerable negative impact on the biotechnology industry, an industry singularly burdened and disadvantaged by the proposed rules.

There is No Legal or Public Policy Rationale Supporting the Proposed Rule Changes

Nothing in patent case law – whether Supreme Court precedent or otherwise – mandates public access to biological deposits at the time of publication of a patent application. For example, Brenner v. Manson as well the other Supreme Court cases cited by the U.S. Patent

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Office in support of the proposed rule changes, state the general rule of *quid pro quo* for the grant of a limited patent monopoly is a disclosure that enables the skilled artisan to practice the claimed invention upon the expiration of the patent. Nothing requires the public have access to an invention at the time of publication. Thus, one might argue that to give effect to this proscription, the deposit should not be publicly accessible at the time of patent issuance, but rather at the time the patent expires as it is then and only then that the public is entitled to the unfettered right to practice the patented invention.

The U.S. Patent Office also looks to the American Inventor's Protection Act of 1999 (AIPA) as support for the proposed rules. The AIPA mandates publication of pending U.S. patent applications within 18 months from the earliest filing date for which benefit has been sought (with limited exceptions). As noted by the US Patent office, this publication policy conforms to the practice in many jurisdictions including Europe and Japan and is cited as a positive step in international patent harmonization.

Before addressing the issue that early publication has on deposit practice, it is helpful to understand its historical context. As pointed out by Henderson (IDEA 42(3):361(2002)) and cited by the U.S. PTO in the Notice, early publication began in Europe in the 1960s to address an issue caused by the long pendency in patent examination. A dramatic increase in the number and complexity of patent applications in the 1960s created an ever increasing pendency of filed applications. Businesses and individuals became hesitant to embark on research projects for the fear that an unforeseen patent might issue, and after their years of effort, place them in an infringing situation—the so-called submarine patent effect. By "laying open" or publishing the patent application, the public was placed on notice of the pending technology and thereby provided other inventors an opportunity to assess the situation and take steps to avoid potential infringement issues. However, such notice did not require an actual practice of the invention described in the publication and should not be transmuted into an inherent right of the public to *practice* the invention disclosed in the published patent application.

Publication as mandated by the AIPA does not necessitate simultaneous public access to a described biological deposit. The notice function of a patent disclosure addressed by the AIPA is not new. See 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 the 35 U.S.C. §112. 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. See Regents of the Univ. of Calif. V. Eli Lilly & Co., 119 F.3d 1559 (Fed.Cir. 1997). This is certainly the view of the U.S. PTO during the patent examination process. The question is, then, can the patent application publication serve its notice function without the need of providing unfettered access to the deposit? The answer is yes. Typically, the disclosure in the specification provides considerable description of the deposit and its characteristics. Providing notice to the public does not require anything further.

Harmonization of U.S. patent practice with international patent practice also fails to provide supporting rationale for the proposed rules. In its Notice on changes to the biological deposit rules, the U.S. Patent Office suggest that other jurisdictions such as European Patent Office

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have early publication and deposit requirements, and therefore the proposed rules merely further harmonize our practices. However, the EPO has no requirement for unfettered public access to a biological deposit prior to the issuance of a patent. While the EPC provides for public access to the deposit after publication, it is limited through an important safe guard to the depositor, in that for the term from publication until issue access to the deposit is limited to "experts" agreed to by the depositor and requestor. Moreover, the proposed rules contravene Rule 11.2 under the Budapest Treaty. Rule 11.2 under the Budapest Treaty requires that access to deposits prior to grant requires the permission of the depositor. Access is only allowed following grant of patent unless the patentee chooses to allow access prior to grant. In point of fact, the proposed rules are contrary to harmonization efforts with the international patent community.

The Proposed Rules Unfairly Burden Biotechnology Patent Applicants

The proposed rule disproportionately targets the biotechnology industry. Biotechnology applicants already shoulder heavier burdens as they labor under heightened written description, enablement, and utility requirements. The proposed rule submits biotechnology applicants to the additional requirement of relinquishing *tangible* property rights. No other industry is required to give up *tangible* property rights. For example, an applicant in the mechanical and electrical arts is currently not required to provide a sample or working model, let alone a self-replicating working model, of a claimed invention, and would not be required to do so with the new rules. Applicants in biotechnology, however, will be forced to submit to the added requirement on top of an already-heavy burden.

The proposed rule further singles out the biotechnology industry by requiring them to pay substantial costs for making biological deposits prior to any reasonable hope of a patent grant. Preparing deposits is not a simple or inexpensive endeavor. The proposed rules would require sample preparation early in the patent prosecution process and would create a significant financial burden, especially for small entities. Additionally, because an applicant cannot necessarily predict which embodiment of an invention will ultimately be commercially viable prior to the publication of the patent application covering that invention, applicants will be forced to incur the costs of depositing materials for all possible embodiments of an invention and not merely those that might ultimately be commercialized or patented. Furthermore, in many cases, biological deposits are made out of an abundance of caution and not necessarily required for enablement or written description purposes. In such cases, a deposit will not be made. Under the proposed rules, however, if an Examiner requires a deposit after the application has already been published; applicants will have lost provisional rights without recourse, even if a deposit is not statutorily warranted.

Beyond increasing costs of patent prosecution for biotechnology applicants, the proposed rule appears to facilitate and even promote short-term infringement using deposited materials. Under the rules proposed by the U.S. Patent Office, competitors of an applicant can readily use a deposited microorganism, cell line, or seed while an application is pending. By the time the patent issues, the competitor can have easily designed around the applicant's pending claims. Moreover, in countries that do not provide meaningful patent protections for such inventions, the infringement would not simply be short-term, but allow for long-term

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infringement of the claimed invention to begin much sooner than under the current rules. This problem is compounded by the inherent ease with which deposited technology, once accessed, can be replicated and proliferated through normal biological processes. Rarely is infringement of complex technology as easily accomplished as, for example, by merely planting genetically modified seed or cultivating hybridoma cell lines under routine conditions. Infringers in other industries, however, would not get such a wind-fall because they would not have given unfettered access to *actual embodiments* of claimed inventions before a patent issues. The proposed rules unfairly disadvantage the biotechnology applicant by requiring the applicant to choose between actually aiding those who would infringe its rights and obtaining its rightful patent monopoly. This requirement is made without ensuring that the provisional rights provided by 35 U.S.C. § 154(d) provide compensation to the patent applicant once a patent issues as the U.S. patent Office has no authority to ensure that provisional rights around a deposit are sufficient to protect the patent applicant's property right. It remains uncertain what is necessary to preserve availability of provisional rights, how such rights are determined, or how it may be enforced by an applicant. These rules appear to devalue the rights of this very discrete group of patent applicants.

In particular, BIO notes the agricultural sector of the biotechnology industry is disproportionately impacted by the proposed rules. Certain countries do not have deposit regulations and, in other countries, seeds are not patentable. Requirements to make seeds publicly available in the US, therefore, will permit others in countries with less well articulated intellectual property laws to acquire agricultural inventions much earlier than under the current rules.

In view of the increased costs and the competitive disadvantage visited solely on the biotechnology it is reasonable to assume that patent filings will decrease, as the biotechnology industry will have to rely more heavily on trade secrets to protect their invention, as opposed to filing patent applications. The result, hence, would be a decrease in patent filings in the biotechnology arena, thereby disproportionately reducing the disclosure of inventions to for public benefit, as compared with other industries.

The Proposed Rules are Beyond the Patent Office's Rule-Making Authority

Finally, the proposed rules requiring biological deposits be freely available at the time of patent application publication, even if implemented, will be found to be null and void if challenged in the courts because the U.S. Patent Office is overstepping rule-making authority. As discussed in detail in the recent case of *Tafas v. Dudas*, the U.S. Patent Office lacks authority to make substantive rules. The proposed rules amount to substantive rule making in that they substantially alter the burdens on, and affect the rights, obligations, and settled expectations of applicants. Moreover, the proposed rules run contrary to the Patent Statute as it appears to impart an additional disclosure requirement that goes well beyond that of the requirement found in 35 U.S.C. § 112, *i.e.*, an applicant now will be required to make an actual embodiment of a claimed invention freely available during prosecution of an application, even before there is assurance that (a) any patent will be granted or (b) a deposit is necessary under § 112. The rules provide no mechanism for making a conditional deposit, which could be retracted before the material is made available, in the event that remarks or

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amendments to the claims later convince the Examiner during prosecution on the merits that a deposit is not needed to meet the requirements of § 112.

Contrary to the U.S. Patent Office's protestations, the proposed change in rules is not required for a reference to be recognized as anticipatory. Substantive precedent from the courts cited by the U.S. Patent Office in its Notice acknowledges that release of the biological deposit at the time of patent issuance is sufficient. Therefore, the U.S. Patent Office lacks the authority to make this substantive rule change. The American Inventors Protection Act ("AIPA") did not provide authority for the U.S. Patent Office to make these changes in the deposit rules. As noted above, the question of whether a deposit in a given application will or will not be necessary to meet the requirements of § 112 is determined during prosecution, so it is unclear why the U.S. Patent Office would make it mandatory before such a determination has occurred.

In addition, nothing in the AIPA suggests that provisional rights should be tied to availability of a deposit or to applicability of a published U.S. patent application as prior art against another U.S. patent application. It is unclear why the U.S. Patent Office conditioned provisional rights to pre-publication of the deposit, when it is not known at the time of publication whether provisional rights will ever come into existence, given their limited application only to situations where an issued claim is "substantially identical" to a published claim. If the claims change substantially, then the premise for requiring the pre-publication deposit disappears, and the applicant has no recourse under the proposed rules. Furthermore, even in a situation where a deposit may be necessary for a U.S. published patent application to be applicable as prior art under 35 U.S.C. § 102 (a), (b), or (e), but the applicant has not made a deposit readily available to the public prior to publication, the U.S. Patent Office would still presumably be able to apply a published U.S. application under 35 U.S.C. 102(g) based on the evidence that the applicant possessed the enabling deposit.

Conclusion

In conclusion, the proposed rule altering the deposit requirements for biotechnology applicants should not be implemented because no legal, public policy or international harmonization rationale supports such a change. Instead the rules are contrary to established law and international patent practice while unfairly burdening the biotechnology patent applicant. BIO urges the U.S. Patent Office not to implement these rules.

Respectfully submitted,

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