The Comments of the

Biotechnology Industry Organization

on the

United States Patent & Trademark Office

Proposed Rule Changes Concerning

Information Disclosure Statements

September 8, 2006

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

Attention: Hiram H. Bernstein

Comments to Proposed Rulemaking Entitled: *Changes to Information Disclosure Requirements and Other Related Matters*

Dear Mr. Bernstein:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the U.S. Patent and Trademark Office's (PTO) proposed *Changes to Information Disclosure Requirements and Other Related Matters,* 71 FR 131, 38808-38823 (July 10, 2006). BIO is an industry organization with a membership of more than 1,100 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.

The United States leads the world in biotechnology research and development. Fueled by the strength of the U.S. patent system, the biotechnology industry has provided jobs for more than 200,000 people in the United States, and generated hundreds of drug products, medical diagnostic tests, biotech crops, and environmental products. In the healthcare sector alone, the industry has developed and commercialized over 300 biotechnology drugs and diagnostics; and there are over 370 products in the pipeline. In the agricultural field, biotechnology innovations are simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land, water and nutrients, and increasing farm income and growing the economy worldwide. Biotechnology innovation, if allowed to progress, has the potential to provide treatments for some of the world's most intractable diseases and address some of the most pressing challenges facing our society today.

The biotechnology industry relies heavily on the strength, scope and predictability of its patents to innovate and develop cutting-edge products and technologies that improve and enrich human life. For a more detailed overview of the importance of patents in

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biotechnology, we refer you to our comments pertaining to limits on the filing of continuation applications and claims examined in an application, dated May 2, 2006.

Uncertainty in term, scope and enforceability of patent rights may have far-ranging unintended consequences and damaging impacts on biotechnology innovation and therefore on the U.S. economy and the public at large. Technologies such as those that can transform switch grass to energy, prominently noted by President Bush in his most recent State of the Union Address, may be delayed or not developed at all. Medicines for diseases that affect developing countries, such as malaria and TB, may never reach the hands of those in dire need of treatment. Companies with innovative solutions to age-old problems may not be able to generate financing to take their ideas to the next level. Others may simply go out of business. As such, the actions of the PTO, the agency charged with issuing perhaps the single most important asset of small biotechnology companies, are closely followed by BIO and its members.

BIO is, and has always been, sympathetic to the challenges of the PTO in regards to its tremendous workload and constrained funding. For this reason, BIO has consistently supported Congressional and administrative efforts to fully fund the PTO. BIO also has offered to provide its services in training and the continuing education of PTO examiners in science. While the proposed IDS rules may appear to be innocuous to some, BIO believes that, if implemented, the rules will have a considerable negative impact on patent quality and PTO work load. In addition, if promulgated, BIO believes that the rules would unnecessarily increase the burden and cost of obtaining patents, which serve as the basic currency for biotech innovation.

THE PTO's PROPOSED RULES

According to the PTO, the proposed IDS rules will improve the quality and efficiency of the examination process by enabling the Examiner to focus on the relevant portions of submitted documents at the very beginning of the examination process, thereby providing higher quality first actions and minimizing wasted steps. The PTO purports to do this by establishing disincentives to filing large numbers of references, and by requiring new applicant disclosures that specifically explain the relationship between a reference and the invention, describe why submitted documents are not cumulative to other documents of record, and requiring the applicant to "justify" the patentability of the invention over the references. While BIO applauds the PTO's objective of simplifying PTO processes and enhancing patent quality, we are concerned that the rules will not achieve these objectives, but – to the contrary – will increase the PTO's workload, create fodder for increased litigation and create costly and burdensome work for the patent applicant. In addition, BIO believes that the rules would disproportionately impact the members of the biotechnology sector over other sectors.

BIO'S PRINCIPAL CONCERNS WITH THE PTO's PROPOSED RULES

The Proposed Rules Will Not Accomplish the PTO's Goals

As a threshold matter, it is not apparent how the proposed rule changes will accomplish the PTO's stated goal of improving the quality and efficiency of the examination process. According to the PTO, about 85% of all applications will not even be impacted by the proposed First Period's 20-reference threshold number of listed documents. Thus, this new requirement will not lead to enhanced examination quality and efficiency in the vast majority of applications, and time savings are likely to be minimal in the aggregate. BIO believes it is unlikely that significant gains will result even for the residual 15%, or for documents that exceed the new 25-page size limitation. Nothing in the proposed rules will absolve the Examiners of their responsibility to independently construe the claim language and review the content and evaluate the relevance of each submitted document – whether or not such documents are submitted with an Explanation or other additional disclosure. Under the proposed rules, Examiners would now face the *additional* tasks of evaluating each new applicant disclosure against the affected claim and the submitted document and, presumably, will have to arrive at some conclusion about the accuracy and responsiveness of the submission – a series of steps no less complex and time-consuming than the current "mandatory cursory review of each document cited," which will continue to be required at any rate.

The proposed rules will also not support quality and thoroughness of the examination process because they disincentivize prior art searching by applicants, and encourage risk-taking to not submit references when the applicant is in doubt about their materiality. As a result, Examiners will have less information to make considered decisions, thus diminishing examination quality. Any residual efficiency and quality gains would largely be offset by additional PTO work required in evaluating, setting standards for, and adjudicating content and responsiveness of the new applicant disclosures.

The Proposed Rules Disparately Impact Biotechnology Applicants

Biotechnology continues to be a rapidly-developing field characterized by an exponentially-increasing literature. Particularly in areas of great scientific or commercial importance, research publications and patent applications are often closely-timed and address closely-related aspects of the same subject matter, resulting in significant amounts of "close" prior art against subsequently-filed patent applications. Accordingly, biotechnology applicants must often cite numbers of documents that would seem unusual in other technology areas, yet are necessary and entirely within the norm in their field of endeavor. In explaining what it considers to be an "unusually large amount of information before a first office action," the PTO cites an internal survey of over 10,000 patent applications, conducted across all technologies, to determine that a number of 20 documents would be an "appropriate" threshold number for submission during the First Period without the requirement for an Explanation.

BIO believes that the PTO's basis for setting a 20-document threshold requires further explanation. This threshold number appears to represent an average across very different technology areas, where available literature differs qualitatively and quantitatively. Averaging across a broad range of technologies does not do justice to the realities of fields characterized by high publication rates, including biotechnology, and unfairly prejudices inventors who operate in complex and rapidly-developing technology areas.

Further, with respect to the proposed 25-page limit, the PTO has not even attempted to explain why it considers documents exceeding this page number to be "unusually large." BIO believes that this limit is arbitrary and fails to account for the actual information content of different kinds of documents. Original scientific articles, for example, are normally published in densely typeset form and often contain large amounts of information, but will rarely exceed 25 pages. Another common category of document – international patent applications published under the PCT – routinely exceeds 25 pages in the biotechnology arts. BIO seriously doubts that the PTO would earnestly assert that there is anything "unusual" about the length of a 26-page PCT biotechnology application.

Yet, in many of these instances, the applicant will now have to explain the relevance of the reference with specificity in relation to the invention and, where necessary, that it is not duplicative of another submitted reference. In addition, the applicant will have to revisit and update these statements with every subsequent claim amendment. These new requirements would add significantly to the financial burden of applicants, especially in the biotechnology field. To impose new and insufficiently-justified burdens in such a way that will prejudice certain classes of patent applicants (e.g., life science companies), with little, if any, impact on other classes of patent applicants, is inherently unfair.

The Proposed IDS Rules Would Contribute to Uncertainty in Patent Law and Practice

As explained previously in BIO's comments to the PTO's proposed changes to claims and continuation rules (submitted May 2, 2006 [1]), life sciences companies depend heavily on the strength of their patent portfolios for their valuation, and for attracting funding and partners. Examination under the proposed IDS rules will create biotechnology patents of uncertain validity and enforceability – thereby lowering their economic value – and, thus, negatively affect the businesses and innovation conducted by their owners. The proposed rules will create confounding legal uncertainty, resulting in negative impact especially on applicants from the biotechnology sector, for at least two reasons.

The first cause of uncertainty relates to the fact that the PTO would require new affirmative statements relating directly to the patentability of the applicant's invention just at a time when the substantive standards for patentability themselves are being revisited with uncertain outcome both in the United States Congress and in the United States Supreme Court. Pending House and Senate patent reform bills currently incorporate the most sweeping revisions to

[1] Available at <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/bio.pdf>

Section 102 in over 50 years, [2] and the Supreme Court is about to address the judicial test for nonobviousness for the first time in 30 years. [3] These new developments will require time to be digested and understood by Examiners and applicants alike. Without clarity on how documents may be combined to render an invention obvious, for example, the impact of the now proposed rule changes is, at best, uncertain. Neither the PTO nor applicants would be well-served by new rules that will clutter the record with applications of unsettled law, or with explanations on how to apply references that should continue to speak for themselves.

The second cause of uncertainty relates to the PTO's proposed requirements for additional applicant disclosures in the absence of meaningful inequitable conduct reform. Once again adding to the unpredictability in this important area are the pending House and Senate patent reform bills, which both contain new inequitable conduct provisions that differ from each other and from existing law. BIO is hopeful that these and other proposals will eventually lead to meaningful reform. In the meantime, however, patentees must expect having to defend against allegations of inequitable conduct whenever they try to enforce their patents. It is in this context that the proposed rules provide rich litigation fodder: incenting applicants to select fewer or shorter references, or to select "relevant" portions of longer documents for submission, risks later allegations of omission of material information. Explanations of how to apply which feature of which reference to which claim element provide fuel for prosecution history estoppel and judicial claim construction battles. An applicant's reasons why the claims are patentable over the information of record provide later litigants with a roadmap for alleging that prior art was affirmatively misrepresented, and for probing whether the patentees truly had a reasonable good faith belief in the validity of their claims at the time of prosecution.

The PTO recognizes the fact that the new applicant disclosure requirements create traps and pitfalls even for reasonable and well-meaning applicants, and purports to create a safe harbor for inventors, attorneys and agents by proposing new rule 1.56(f). This rule provides that "[t]he additional disclosure requirements for documents in [proposed rule] § 1.98(a)(3) would be deemed satisfied" by a reasonable inquiry into the relationship of the cited IDS documents to the claimed invention, and acting in good faith to comply with the new requirements by having a reasonable basis for the disclosure statements made. BIO notes that conducting a "reasonable inquiry" into documents prior to submission, acting in "good faith," and having a "reasonable basis" for statements to the PTO have long been part of proper practice under Rule 56 and the Canons and Disciplinary Rules. It is entirely unclear what this new rule adds to existing practice, and which additional protections are being conferred by this safe harbor. Even more importantly, the scope and applicability of this provision cannot be readily understood. The PTO's language: "*The additional disclosure requirements* [...] *would be deemed satisfied...*" is confusing because it refers only to the technical requirements of proposed rule 1.98(a)(3), not to any applicant duty with respect thereto. Does the PTO mean to say the applicant's duty of candor and good faith, or the duty of disclosure, would be deemed satisfied by adhering to new rule 56(f)?

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[2] *See* S. #3818 and H.R. #2795; 109th Congr.

[3] *KSR Internat'l Co. v. Teleflex Inc.*, No. 04-1350, *cert. granted* Jun. 26, 2006.

How, then, is an applicant to decide whether a document is material under Rule 56 so as to compel submission to the PTO under the proposed rules? BIO's member companies commonly experience that an Examiner's idea of what is material to patentability, or cumulative to previously cited references is different from the applicant's. Under current practice, the PTO expects that applicants will submit information for consideration by the Office rather than making and relying on their own determinations of materiality, thus resulting in a strengthened patent and avoiding later questions of materiality and intent to deceive (MPEP 2001.04). This policy is entirely appropriate because it recognizes that the arbiter of patentability – the Examiner – must also be the one to decide the materiality or cumulative nature of prior art. Accordingly, the Office has encouraged a practice of "when in doubt, submit," with the understanding that doing so is *not an admission* that the submitted reference is material to patentability (see Rule 1.97(h) (filing of IDS is not construed to be an admission of materiality)).

By inducing applicants to submit as few references as possible, and by requiring explanations of the documents' relevance and other disclosures under the proposed rules, the Office would now require applicants to effectively admit their belief that there is, at the very least, something especially relevant about the documents they submit. Only later litigation will show how perilously close a submission of such an IDS under the proposed rules comes to an admission of materiality.

Fundamentally then, if not paired to inequitable conduct reform in the courts or in Congress, it is entirely unclear whether the proposed amendment of Rule 56 will provide an adequate safe harbor in patent litigation. This result is far from reassuring for applicants, especially those from the biotech sector, who know full well that their investors will not invest where patent rights can be so easily challenged. Like the PTO, such applicants can at best only be "hopeful that a court in deciding a duty of disclosure issue will take the proposed safe harbor into account."[4]

The Proposed Rules Would Increase Expense, Effort, and Risk for Applicants

Most biotechnology companies, and indeed the majority of BIO's members, are early-stage businesses with limited financial resources. These companies often have to make the hard decision between filing and prosecuting patent applications that can yield funding down the road, and carrying out important research on a novel product or technology. Furthermore, in many instances, applicants put resources toward additional testing necessary to convince the PTO of the merits of their invention. The PTO's proposed rules would add significantly to

[4] Courts have repeatedly declined to be bound by "safe harbors" created by the PTO. *See Digital Control Inc. v. Charles Machine Works*, 77 USPQ2d 1823, 1829 (Fed. Cir. 2006) (noting that the PTO's adoption of a narrower standard of materiality does not supplant or replace the court's case law); *see also Dayco Products, Inc. v. Total Containment, Inc.*, 66 USPQ2d 1801, 1806 (Fed. Cir. 2003) (stating that the court had not decided whether the standard for materiality in inequitable conduct cases is governed by equitable principles or by the Patent Office's rules); *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 56 USPQ2d 1001, 1006 (Fed. Cir. 2000) (refusing to honor the "safe harbor" for cancelled claims articulated in 37 C.F.R. § 1.56 and noting that the materiality of intentional false statements may be independent of the claims of a patent).

the financial burden on these biotechnology companies. For example, the proposed requirement for an Explanation of documents when the 20-document limit or the 25-page limit during the First Period is exceeded will add substantially to patent prosecution costs.[5]

The requirement of an Explanation for foreign-language documents is equally burdensome. Non-English language documents accompanied by English language abstracts are routinely found in the results of in-house prior art searches. While there may of course be factual instances where applicants would need to submit a complete translation, the new requirements for an "identification" of relevant passages and their "correlation" to claim elements would now virtually always require obtaining an expensive English language translation, followed by painstaking review. Moreover, the Office's expectations with respect to such Explanations should be clarified. Many times, it is a figure or a graphic in a foreign language reference that appears relevant to the claimed invention. This would be as readily apparent to the Patent Examiner as it is to an applicant who also has no or little command of the foreign language. Without further clarification as to what is acceptable, the proposed requirement is burdensome and unduly vague.

Additional costs are triggered by every subsequent claim amendment, which requires that all Explanations of record be, once again, carefully reviewed, and updated as necessary. In the not unlikely event that a dispute arises over the accuracy or responsiveness of a new disclosure requirement, the applicant's burden would be exacerbated by the Office's co-pending proposed continuation rules: the Office's refusal to consider a submitted document for failure to comply could easily necessitate the filing of a Request for Continued Examination (RCE) as the last resort to get the document considered, thus "eating up" the applicant's only continuation as a matter of right.

Further, while BIO supports early submission of documents, applicants have no control over the timing at which foreign patent offices issue search reports for foreign counterpart applications. If such a search report happens to issue with additional references late in prosecution (Third Period or later), applicants would be required to supply an extensive Patentability Justification, including reasons why the affected claims are patentable over the submitted documents, or in some cases including an admission that one or more claims are "unpatentable" in view of the art of record. BIO does not understand the purpose of this disclosure requirement. This late in prosecution, the Examiner will have a good grasp of the application's subject matter to quickly and appropriately evaluate the submitted document. With regard to patentability, the Examiner will have to make her or his own determination anyway – time savings would only be realized if the Examiner were to simply adopt the applicant's reasons for patentability, which, BIO believes, would be neither in the Office's nor the applicant's interest. What such disclosures do accomplish, however, is to provide

[5] The Explanation required under proposed rule 1.98(a)(3)(iv) requires not only an "identification," but also a "correlation" of the identified specific feature, showing, or teaching to the specific claim language. It would seem that the "identification" step would be sufficient if the goal is to save Examiner time, because the pertinent sections of the documents will have been pointed out by the applicant. The Examiner, applying his or her own claim construction, is then better positioned to independently decide how and to which claim element the reference is to be applied. Eliminating the "correlation" requirement would support an objective, unbiased evaluation and application of submitted references, which, BIO believes, is more conducive to examination quality and efficiency.

later litigants with a treasure trove of prosecution history estoppel and inequitable conduct arguments. Accordingly, the preparation of such disclosures for submission to the Office will require extensive, and expensive, legal analysis.

BIO's RECOMMENDATIONS REGARDING THE PROPOSED IDS RULES

BIO understands the examination challenges faced by the Office and the applicant community in today's patent system, and appreciates the PTO's efforts to improve the current process. The proposed new processes for withdrawing reexamination proceedings from publication, opportunities to make technical amendments after the close of prosecution without having to withdraw an application from issue, and added flexibility in protest proceedings, for example, are all beneficial steps likely to gain the support of the user community.

However, given the current legislative and judicial uncertainty in patent law and the ongoing lamentable state of inequitable conduct litigation, the Office's proposed changes to rules 56, 97, and 98 in particular do not provide an adequate and fair solution. In this regard, BIO recommends the following:

1. The PTO is strongly urged to delay promulgation of any new IDS rules until (i) Congress has passed comprehensive patent reform legislation that clarifies *both* the future scope of Section 102 prior art and inequitable conduct reform, and (ii) the Supreme Court has decided the questions before it in *KSR v. Teleflex*. Any rule changes promulgated after these time points should be applied only prospectively, so as to avoid the uncertainty of how to proceed with IDSs already on file in applications under active prosecution, and the burden that a retroactive application would place on Examiners and applicants.
2. The PTO should continue to study the examination and search practices in the European Patent Office (EPO), Japanese Patent Office (JPO) and other foreign patent offices. In particular, the Office and the applicant community should enter into a serious discourse over whether to eliminate the duty of disclosure requirement from 37 C.F.R. § 1.56 altogether, or to require disclosure only of references that are not available by on-line searching, such as instances of public use, sale, or offers for sale.
3. BIO understands that the current IDS process permits the submission of a potentially unlimited number of documents of varying size in early and (with payment of a fee) mid-stage prosecution, and acknowledges that the Office may wish to set reasonable limits on document numbers, length, and timing of submissions. BIO also supports the concept that literature should be brought before the Examiner early in prosecution. But BIO proposes more reasonable limits for documents that should be exempt from the "explanation" requirement of proposed rule 1.98(a)(iv) during the First Period. To establish fair and empirical reasonable limits, the PTO should conduct a technology-specific impact analysis (e.g., establish, by Technology Center, the numbers of submitted references and the length and category of references), and then set technology-specific number and length limits at the 90th percentile. The length limits should be specific to different common categories of submitted documents (e.g., published articles, scholarly treatises, and patent application publications). The treatment of foreign-language documents should be maintained as under current practice.

4. Once the PTO has established fair and empirical limits for the number and size of submitted documents, the Office could – in lieu of requiring statements relating to the cited references by applicants – set an excess document fee analogous to excess claims fees. This step should be accompanied by implementing standards that provide additional credit for Examiners who work in complex technologies requiring relatively more document review. Documents cited in a foreign counterpart application should be exempt. The Office should implement a practice under which restrictions are issued earlier, or under which applicants are at least given an early indication of a forthcoming restriction requirement. This would help applicants in compiling more focused submissions of documents.

5. To provide incentives for filing references early, a reasonable burden placed on references filed after a first action on the merits may fairly balance the interests of the Office and the applicant community. To this end, the Office could require applicants to provide an "Explanation" as set forth in proposed rule 1.98(a)(3)(iv)(A) for documents submitted after the mailing date of a first action on the merits. Such an Explanation should not include the correlation step of proposed rule 1.98(a)(3)(iv)(B). Documents identified in a foreign search or examination report should be exempt. Clear guidance on the content and form of such Explanations would be needed, and the Office should provide a special time window during which defects could be cured, as well as a mechanism for quick adjudication of any disputes over the responsiveness of the submission. The Office should eliminate the requirement for a Non-Cumulative Description, as well as the requirement to update each Explanation with every subsequent claim amendment. The fee structures of rules 1.97(c) and (d) could be maintained in their current form, or revised to reflect a per-document charge, to further support the examination of references filed during mid- and late-stage prosecution.[6]

6. For the Third and Fourth Periods, the Office should eliminate the requirement for a Patentability Justification under proposed rule 1.98(a)(3)(vi) (A) and (B) for documents identified in a foreign search or examination report. For all other documents, the Patentability Justification should neither require the applicant to provide reasons why the independent claims are patentable over or in view of the documents of record, nor to admit unpatentability. If, for any reason, the filing of a RCE is necessary to get a reference considered, the Office should exempt such RCEs from the "one continuation as of right" limitation in the co-pending continuation rules so long as the applicant acted in good faith in submitting the reference late or in trying to provide a responsive disclosure.

7. The Office should make clear that disclosure requirements in any new IDS rule shall *not* be construed as an applicant admission of materiality (or lack thereof) of references submitted in new IDSs, or of references submitted in earlier related applications.

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[6] Alternative and more flexible fee-based procedures for examination of references could be developed, for example, under the PTO's draft Strategic Plan – 2007-2012, in which the Office continues to develop its vision of a modern, alternative examination system that could offer a wide range of examination processes and patent products that applicants could elect and tailor to meet their business needs and resources. Under such a system, for example, more in-depth review of larger numbers of references could be requested by applicants who need a very high level of assurance that the property rights they obtain will likely withstand future challenge. The draft Plan is available at http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012v6.doc.

CONCLUSION

While perhaps not ideal, the examination process has worked well in supporting the patent system as an important driver of innovation in this country. BIO hopes that the Office and the applicant community alike will continue to strive for a modern, nonadversarial process to meet the examination challenges posed by exponentially growing prior art in an ever-evolving industrial and research landscape. It is therefore important that practice changes in the PTO do not disproportionately impact one technology sector over another, and that the burden of improving the system be evenly distributed among all stakeholders. The proposed IDS rules are part of a rules package that would introduce the most dramatic changes to patent practice in decades, and would shift significant examination burdens from the Office to the applicant community at a time of mounting legislative and judicial uncertainty in patent law. Far from acknowledging that the Office and the user community are "in the same boat" with respect to shaping a modern, efficient examination system, the proposed rules in effect leverage the deplorable state of inequitable conduct litigation against the applicant community and create patent uncertainty that will directly impact the businesses and research activities of life sciences innovators. BIO refers to its previously-submitted comments on the PTO's proposed rule changes concerning continuation practice and claim limitations, and recommends that promulgation of the now-proposed IDS rule changes be postponed until legislative patent reform is concluded. Doing so will allow the Office and the applicant community, including BIO, to engage in further meaningful and transparent dialogue in pursuit of their common goals.

Respectfully submitted,

Thomas DiLenge
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Biotechnology Industry Association