BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

July 8, 2004

The Honorable Lamar Smith
Chairman
Subcommittee on Courts, the Internet and Intellectual Property
Committee on the Judiciary
B351A Rayburn House Office Building
United States House of Representatives
Washington, D.C. 20515

The Honorable Howard Berman
Ranking Minority Member
Subcommittee on Courts, the Internet and Intellectual Property
Committee on the Judiciary
B336 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman and Mr. Berman:

The purpose of this letter is to express the views of the Biotechnology Industry Organization ("BIO") for the written record of the Subcommittee's recent oversight hearing held on June 24, 2004, on "Patent Quality Improvement: Post-Grant Opposition." BIO is a trade association of more than 1,000 companies, universities, research institutions and affiliated organizations engaged in biotechnology research on medicines, diagnostics, agricultural products, pollution controls and industrial applications.

Our members are important stakeholders in patent system reform because the biotechnology industry was built on the ability to protect truly breakthrough inventions. To understand the importance of the patent system to BIO's constituents, it is important to understand the biotechnology industry.

About the Biotechnology Industry

The biotechnology industry is very research intensive. The U.S. biotechnology industry spent more than $20.5 billion on R&D in 2002, with the top five companies spending an average of $101,200 per employee on R&D. The biotechnology industry is also a dynamic one. There are over 1,400 biotechnology companies in the U.S. employing over

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190,000 people. This nascent industry has produced more than 370 biotech drug products and vaccines currently in late stage clinical trials that target more than 200 diseases. Some biotechnology products such as EPO, Herceptin® and Xigris® have revolutionized the way our society deals with cancer and other chronic diseases. Biotechnology is responsible for hundreds of medical diagnostic tests, which encompass everything from keeping the blood supply safe from AIDS to home pregnancy tests. Industrial biotechnology applications have led to cleaner processes that produce less waste and use less energy and water. Consumers are already enjoying biotechnology foods. However, those in the biotechnology community know that this is just the beginning. The biotechnology industry is one of the most innovative industries in the U.S. economy. The biotech sector filed over 40,000 new biotechnology patent applications with the United States Patent and Trademark Office (PTO) in fiscal year 2003 and this trend is expected to continue. BIO members have developed and will continue to develop products that have great impact on patients and consumers.

The Role of Patents in the Biotechnology Industry

Biotech companies operate in an ecosystem of federal funding of basic and applied research, intellectual property law (particularly patent law), technology transfer, collaborative activities and private investments for financing. Patents serve as a stimulus for inventiveness and creativity. Investors recognize patents as important benchmarks of progress in developing product lines and revenues. Investment provides the life-blood of a very research-intensive industry, and intellectual property protection serves as the enticement for private financing. The promise of a return on investment, rooted in patents on biotechnology inventions, helps to attract capital in these high-risk biotechnology products.

Indeed, many start-up biotechnology companies have been created based solely on the promise of their patent estates. The vast majority of biotechnology companies do not have products on the market; rather they have only patents on what may eventually become a commercially viable product or technology. This intellectual property protects the assets that entice investment for further development of a promising technology or product. The capital generated as a result of this intellectual property supports companies as they invest the hundreds of millions of dollars and the decades necessary to develop a commercial biotechnology product.

Strong domestic and international intellectual property protections have been, in large measure, responsible for the growth and development of today's biotechnology industry. Confidence in the patent system by the innovation sector, the investment community and the consuming public is especially important. Accordingly, BIO is not only attuned to the merits of the patent system but recognizes the importance of patent quality improvements as well. BIO believes that an effective patent system stimulates innovative biotechnology discoveries and inventive activities that benefit the American public, be it healthcare patients, farmers, consumers of food products or industrial workers, among others.

On behalf of BIO, I commend you and your subcommittee for its stalwart leadership on patent law issues and for already shepherding through the House of Representatives during the 108th Congress two patent reform measures supported by BIO: the Patent Fee Modernization Act and the Cooperative Research and Technology Enhancement (CREATE) Act. Both will contribute, if enacted, to a higher quality patent system.

Your oversight inquiry into a post-grant review process must inevitably consider whether the process will promote quality improvements without unduly eroding patent owner rights and thereby chilling innovation. The Subcommittee no doubt will consider proposals to establish an open-review procedure, enabling third parties to challenge the validity of issued patents on any grounds in an administrative proceeding within the PTO for a limited period. *See, e.g.,* H.R. 1333 (The Patent Improvement Act of 2001), 107th Cong., 1st Sess. (2001) (introduced by Mr. Berman); Report of the National Academy of Sciences on "A Patent System for the 21st Century" (2004) at 78; Report of the Federal Trade Commission on "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (October 2004) at Executive Summary, p. 7, and Chapter 5, pp 17-18; "The 21st Century Strategic Plan," "Post-Grant Review of Patent Claims" (PTO, April 2, 2003) at 1. PTO at 14: and Recommendations of the American Intellectual Property Law Association (Oversight Hearing on "Patents: Improving Quality and Curing Defects" Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary, 107th Cong., 1st Sess. 31-42 (2001) (statement of Michael K. Kirk, Executive Director).

As the Subcommittee is aware, both the Federal Trade Commission and the National Academy of Sciences (NAS) recently released reports that raise concerns with respect to the quality of certain patents and recommend areas where legislation may lead to improved patent quality. BIO strongly supports efforts to make the U.S. patent system more predictable and patent rights more certain and dependable through quality improvements. The more certain the law concerning the validity and enforceability of patent rights, the more likely it is that our member companies will be able to attract capital and assure investors that they will deliver a sufficient return on investments. We believe a variety of legislative reforms are necessary to accomplish this goal, and strongly encourage the Congress to actively pursue these reforms.

However, as with any effort at reform, we have some concerns about approaching major changes to the U.S. patent laws in a piecemeal manner. This is especially important given that the NAS' four-year study of the U.S. patent system suggests a collection of reforms to U.S. patent laws that are fundamental and systematic. We therefore remain optimistic that the recent hearing is only the first in a series of efforts to best understand how a coordinated and comprehensive look at changes to U.S. patent laws might be achieved in a synergistic and balanced manner to realize the goal of a more predictable, affordable, certain and prompt-acting patent system. While a post-grant review procedure is an important piece of the puzzle of patent reform, it is not the only important piece. Indeed, its enactment would make other changes to the U.S. patent laws more important and more urgent.

BIO's Position on Post-grant Review

Before addressing the specific features that are needed to make any post-grant review system viable and balanced, BIO wishes to emphasize two important predicates.

Significant Funding

First, BIO believes the Congress must address the longstanding issue of PTO financing. The PTO must have available to it – on a consistent, year-in, year-out basis –the assured financial resources needed to conduct within the Office *thousands* of contested proceedings. No proposed post-grant review can discharge its policy objectives unless it is administered in a fair, balanced and prompt manner within the PTO.

To date, the appropriations process has not succeeded in ensuring predictable and adequate funding for the PTO for its existing programs. A post-grant review procedure will entrust within the PTO new responsibilities that will force the Office to secure the services of hundreds of highly skilled administrative patent judges. We therefore urge the Congress to address financing of the new post-grant review system incidental to its work in devising the appropriate elements of the system. That financing should be guaranteed. Seed money should be set aside to undertake the hiring and training of necessary personnel before the opposition law comes fully into effect.

Additional Reforms

Second, as briefly discussed above, BIO believes that in addition to enacting a post-grant review procedure, the Subcommittee should enact additional reforms to improve the patent system: to make the patent system simpler, more predictable, less expensive to use and more prompt in its resolution of issues of patentability. BIO urges the Subcommittee to consider reform recommendations 6 (significant modifications to statutes governing willful infringement) and 7 (efforts to harmonize U.S. patent laws with that of other patent systems) set out in the NAS report as a useful starting point. These recommendations are directed specifically at improving simplicity, economy, predictability and certainty.

Among other reforms, the Subcommittee should enact legislation awarding the right to a patent to the "first inventor to file." The "proofs of invention date" system in the U.S. is complex, expensive, unpredictable and time-consuming. Moreover, Congress should reduce the number of "loss of rights" conditions in U.S. law. In this regard, it is particularly important to eliminate the so-called "forfeiture" provisions in current law based on an inventor's placement of an invention "in public use or on sale" more than one year before seeking a U.S. patent. Further, the U.S. should eliminate its "subjective" "best mode" requirements and replace them with an "objective" standard. Finally, the PTO's current discretionary practice of dividing a single discovery into multiple applications must be reformed. So-called "restriction practice" is especially deleterious

for biotechnology companies, and its elimination should be an important legislative priority.

In addition, Congress should reform the law and practice of "inequitable conduct." Allegations of inequitable conduct are made in nearly every patent litigation case as an affirmative defense to alleged patent infringement. The doctrine allows the federal courts to review the *ex parte* conduct of patent applicants before the PTO. The practice has become an absolute "plague" before the courts (*see, e.g., Burlington Indus, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)) and must be reformed. Most importantly, oppositions could potentially create new opportunities for infringers to allege a patent owner's "fraud on the Patent Office," greatly increasing the burden on the patent owner in an opposition proceeding. BIO welcomes the opportunity to provide the Subcommittee with additional detail on the benefits and structure of these reforms.

BIO believes that validity issues not typically encountered by the PTO during patent examination should not be included as potential grounds for opposition in the post-grant review process, and should only be handled by the courts (e.g., best mode). It is, therefore, important to enact the comprehensive patent law reforms described above in order to complement a post-grant review process and make the post-grant review process a more viable alternative to district court litigation. By enacting BIO's proposed patent reforms, validity issues that could be determined in a post-grant review process could be made coextensive with validity issues addressed in the courts. Consequently, a favorable outcome for the patent owner in the post-grant proceeding could largely assure that a patent could be successfully defended in a later court action, thus reducing the concern that the validity of the same patents will be challenged in a post-grant proceeding and separately in district court litigation.

Minimal Requirements for New Administrative Mechanism
With these initial points in mind, BIO supports the efforts of the Subcommittee to establish a PTO-based procedure for post-grant review of the validity of patents. However, BIO's support is contingent on the system containing sufficient safeguards to ensure that it will provide a balanced, timely and accurate review of the validity of a patent, and will not become a means for third parties to harass owners of valid patents. BIO believes several elements must be present in any post-grant review procedure to ensure that it meets this general objective.

In simple terms, any post-grant review system must be timelier, less expensive and more efficient than review by the federal courts. A post-grant administrative proceeding will be valuable only if it permits a review of validity to occur without creating expenses, burdens on companies and delays comparable to those encountered in district court litigation. BIO members are concerned that an improperly structured post-grant review system may become just another place to challenge a patent and to harass patent owners. Certain procedural safeguards will be absolutely necessary to avoid this result. In this regard, the Subcommittee's expertise in the administration of justice, including alternatives to litigation, will be particularly helpful.

Because legislative proposals have not yet been introduced, BIO will identify only several minimal standards that should be incorporated in any post-grant procedure:

- Any opposition filing should be permitted only within a very limited certain period of time (e.g. 9 to 12 months from patent issuance) and the scope of post-grant review should be limited to review of validity under 35 U.S.C. § 101 (utility), §102(a), (b), (e) and (g), 103 (non-obviousness) and 112 first and second paragraphs (except for the "best mode" requirement)). Obviously, if NAS Recommendation 7 is adopted, patent oppositions could be made coextensive with patent validity issues in a court.

- Post-grant proceedings should be available for any patent within a fixed period after its grant, regardless of the actual or effective filing date of the patent.

- Opposition proceedings should only be commenced if the requestor establishes with an adequate evidentiary showing that one or more claims of the patent are *prima facie* invalid. The PTO should be required to make this initial determination before any opposition proceeding is commenced. Therefore, a frivolous request, *i.e.*, one lacking any substantial basis, should be summarily denied.

- Simplified procedures such as the existing *inter partes* and *ex parte* re-examination procedures should be preserved, either in their existing form or within the framework of a comprehensive post-grant review authority.

- Patent holders should be permitted a reasonable and limited opportunity to amend patent claims during an opposition proceeding. BIO believes that at least one amendment must be permitted as a matter of right. The PTO should manage the overall process to ensure efficiency.

- The system should require that all evidence, except patents and printed publications, be presented through affidavits and declaration testimony.

- Except if the interest of justice requires otherwise, discovery should be limited to cross examination of affiants and declarants and an oral hearing.

- Procedures should be included to prevent "ambush" tactics.

- In any post-grant proceeding, at a minimum, the real party in interest should be identified and the burden should be on the party requesting the opposition to prove invalidity.

- Any party to an opposition proceeding should be entitled to appeal a decision of the PTO to the U.S. Court of Appeals for the Federal Circuit.

- Proceedings must be completed within a statutorily specified period of time, and measures should be provided to discourage and prevent third parties from delaying or extending proceedings.

- The system should provide that a patent owner that has commenced litigation on a patent can determine the forum in which the validity of the patent will be assessed (i.e., in a district court or in a PTO post-grant review proceeding, at the decision of the patent owner);

- Measures should be included to consolidate multiple opposition requests into a single proceeding, and such measures should also preclude one entity from commencing concurrent opposition and reexamination proceedings;

- Actions of parties in a post-grant review proceeding should not be capable of creating grounds for holding a patent unenforceable. In this regard, BIO is open to proposals that would implement NAS Recommendation 6 on elimination of "inequitable conduct" as a defense to patent enforceability altogether, provided that some acceptable alternative is devised in which to define, investigate, determine, sanction and, therefore, ultimately deter misconduct before the PTO.

- No special statutory estoppel provisions should be incorporated into a post-grant review procedure, and existing statutory estoppel provisions in the *inter partes* reexamination should be removed.

BIO encourages the Subcommittee to consider the appropriateness of additional safeguards to prevent abuse of a post-grant review process.

BIO is grateful for this opportunity to submit written comments. BIO looks forward to working with you, your Subcommittee, the PTO and other interested parties in efforts to improve patent quality through carefully crafted changes to patent law.

Sincerely,

Stephan H. Lawton
Vice President and General Counsel
Biotechnology Industry Organization