BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

Statement of
The Biotechnology Industry Organization

For the Oversight hearing on "The U.S. Patent and Trademark Office: Fee Schedule Adjustment and Agency Reform."
Before the

Subcommittee On Courts, the Internet And Intellectual Property
House Judiciary Committee
U.S. House of Representatives

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The Biotechnology Industry Organization (BIO) represents more than 1,000 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.

Intellectual property is the key to economic growth and scientific advance in biotechnology. Patents protect the fruits of research and development investment and, in doing so, provide incentives for that investment. In fact, intellectual property is the asset base for most biotech companies. Strong, predictable patent protection is essential to the success, and in many instances to the survival, of biotechnology companies in the U.S., and encourages the discovery and development of new medicines and diagnostics, agricultural products, and other breakthrough technologies.

America enjoys the most robust biotechnology industry in the world due, in large part, to the availability of reasonably priced patent protection for biotechnology inventions. A streamlined and efficient patent examination

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process is vital to the biotechnology industry. Without strong, dependable, and reasonably priced patent protection, the capital necessary to sustain and grow our industry will become unavailable. We share U.S. Patent and Trademark Office (PTO) concerns regarding the speed and quality of the patent review process.

We commend the agency's aggressive efforts to improve the services they provide to patent applicants. We look forward to working alongside the agency and this Subcommittee to address those concerns. However, the proposed fee increases included in the "21st Century Strategic Plan," put forward by PTO Director Rogan on June 3, 2002, are disproportionately burdensome for our industry and would punish the very innovation that is the lifeblood of our industry. For this reason, we oppose the fee proposal as it currently stands.

BIO appreciates the opportunity to share with the Subcommittee our concerns about the fee proposal included with the PTO's strategic plan. Included in this statement are several recommendations that correct the punitive nature of the proposed fee schedule.

End Fee Diversion

The diversion of patent filing fees to other programs should halt immediately. Patent fees have continued to be diverted to the general budget even as the PTO's workload has soared. In fact, the PTO projects that by FY 2006 the number of patent application filings will increase by 84 percent. Clearly the financial demands on the PTO are apparent and responding to these demands requires additional funding. However, before our industry is asked to incur substantial increases in fees to support services at the PTO, all patent fees collected by the PTO must stay within the PTO budget.

Reasonable and Proportionate Fees

BIO supports a fee schedule that reflects fees for services that are proportionate with the cost of providing those services. The newly proposed fee schedule would adversely affect many biotechnology companies that have filed applications based on reasonable filing strategies, and would increase their fees excessively. We believe changes are needed to the PTO's fee proposal in order to avoid

exorbitant fees, particularly for those applications that have already been filed, or for applications that will be filed in the future that must draw on earlier patent application filings for their support.

Reasonable and proportionate fees can only be predicated upon future growth projections based on accurate patent filing data. The PTO should make public patent filing trends – and the funding implications of those filing trends – so that the biotechnology industry – and other PTO constituencies – can work together with the PTO to identify appropriate triggers in the patent application process that would justify additional fees.

Furthermore, biotechnology patent applications are often accompanied by hundreds—if not thousands— of pages of nucleic acid or amino acid sequence listing as required by the PTO. These sequence listings should not be subject to fees. BIO believes that any new fee structure should be designed to minimize the unique impact on biotechnology applicants who follow prosecution practices based on legal and policy developments of the PTO.

Changes to Patent Fees should be Prospective, not Retroactive

The PTO's fee restructuring proposal would penalize biotechnology applicants that have followed reasonable filing strategies based on past PTO fee structures and examination policies. Simply limiting the application of the new fees to cases filed after the effective date of the current fee proposal will not address our concerns. The PTO should provide a safe harbor of a reasonable time frame for applications that will be filed in the future based on existing filing strategies.

BIO opposes the current fee proposal because it would penalize owners of long-pending applications for past prosecution practices that were driven by PTO requirements. Particularly within the PTO biotechnology art units, patentability policies have changed dramatically over time, resulting in applicant prosecution practices varying in direct response. For example, biotechnology applications often include lengthy disclosures and many claims to meet the written description, enablement and utility requirements as defined by PTO's

guidelines. This filing practice has resulted in claim counts and application lengths that would be severely penalized under the proposed fee schedule.

Adopt "Unity of Invention" Standards

The issue of paramount importance to the biotechnology industry is the PTO's restriction practice. Currently the PTO's restriction practice, heavily applied in the biotechnology and chemical arts, has led to the filing of a disproportionate number of applications to a single inventive concept. This practice creates an unreasonable burden on biotechnology patent applicants, an increase in PTO workload, patent applicant expense and a reduction in patent term. The PTO's strategic plan advocates an even more burdensome approach to restriction practice. BIO opposes the proposal in the current strategic plan and advocates efforts to restructure restriction practice along the lines of "Unity of Invention" standard along with European-style claim structure followed in Europe, Japan and in the Patent Cooperation Treaty.

We believe such a change would alleviate many of the problems the PTO has identified with multiple co-pending applications, and will yield practices more consistent with those in other industrialized countries. The basic concept of "one application, one examination and one patent" could then serve as the starting point for discussing improvements in patent office practice and appropriate fees to be paid by applicants.

Deferred Examination

BIO supports the PTO proposal to separate the filing and examination fees, which will decrease filing costs and save applicant expense. Moreover, this deferred examination will lead to significant workload reduction because the PTO will only examine those applications that an applicant has determined to be of continuing commercial value. The proposed 18-month deadline for requesting examination, however, does not seem compatible with the goals just noted. For example, we do not believe the PTO or biotechnology applicants will realize significant value from deferring examination unless the

deferral period exceeds 18 months from filing. This allows patent applicants the opportunity to gather pertinent information and allow for publication of potentially competing applications.

BIO recognizes that the PTO faces significant challenges in issuing high-quality patents under its current funding situation and we strongly support adequate funding for the PTO. The viability of our industry is directly related to the PTO's ability to provide timely and enforceable patents for our intellectual property. Prior to the adoption of any increases in PTO fees and any revision of the PTO's method of fee assessment, the diversion of fees to other programs must stop. In addition, PTO should provide a more substantial basis for a fee proposal to ensure that it is fair and equitable.

We believe that PTO Director Rogan has the best interest of the PTO and its user groups in mind and his efforts to strengthen the agency through this aggressive strategic plan are laudable. BIO urges a careful, measured approach, where the PTO works with its various constituencies to refine the elements of the current fee proposal in order to meet both the agency's goals and those of its user groups. We look forward to working with the PTO and the Congress to further support the American patent system.