BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

Statement of the Biotechnology Industry Organization

Before the United States House of Representatives

Committee on the Judiciary

Subcommittee on Courts, the Internet and Intellectual Property

Oversight Hearing on the United States Patent and Trademark Office

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Summary:

The Biotechnology Industry Organization (BIO), the trade association for more than 1,100 biotechnology and biopharmaceutical companies, academic institutions and related organizations strongly supports a vibrant and effective system of intellectual property protection. Intellectual property is essential to securing the benefits of biotechnology for our society. Strong and predictable patent protection enables the flow of investment capital that is vital to achieving biotechnology's promise.

BIO supports the efforts of the Administration to strengthen and improve the patent system, to ensure adequate funding for the operations of the Patent and Trademark Office (PTO), to avoid diversion of funds to nonpatent purposes, and to improve the quality of both patent examination and issued patents. BIO can support an increase in patent fees provided that it is accompanied by realistic and effective means to prevent diversion of funds. In addition, for the reasons outlined below, BIO believes that the committee should effectively link "unity of invention" reform to enactment of a fee bill. The testimony concludes with suggestions on how to achieve these goals.

Background:

BIO represents many different entities and interests, including start-up biotechnology companies, universities, state biotechnology centers and related groups. All of BIO's members share the goal of improving the human condition through the delivery of new products, goods or services flowing from biotechnology. Before most inventions can become commercially available, years of work and millions of dollars of investment capital are required to secure the necessary approvals or to complete adequate testing. This commercialization relies on the premise that the originator of an invention should be protected against copying by imitators. BIO is an advocate of a highly effective and patent system that functions well to secure this protection. Quality examination and review that produces strong and enforceable patents of an appropriate scope and duration is an essential condition to creating the biotechnology industry's platform of success.[1/]

[1/] In 2000, approximately 21,800 biotechnology-related patent applications were filed with the U.S. Patent and Trademark Office. *See* Jeff Donn, "As Disease-Causing Genes Are Discovered, the Rush to the Patent Office Grows," AP Newswire, Aug. 21, 2001. In *all* categories, a total of 21,671 patent applications were filed in *1880.* U.S. Patent Activity, Calendar Years 1790-2001, at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm.

There is little doubt that the current American patent system has many strengths. Our patent system has shown remarkable resilience and flexibility in dealing with new technologies. Our system, however, requires replenishment with new ideas and new funds to secure improved results. For that reason, BIO supports the broad goals of the Administration's 21st-Century Strategic Plan.[2]/ This thoughtful document outlines many worthwhile reforms aimed at further improving the quality of patent examinations, the review patent applications receive in complex cases, and the strength of issued patents. While BIO believes a strong case can be made for increasing the financial resources at the Patent and Trademark Office to achieve these worthwhile goals, we look forward to seeing the details of how the PTO plans to do it.

Diversion of Funds from the PTO:

The challenge for all policy-makers in this field, however, is to provide adequate resources for the vital operations of the Patent and Trademark Office without diverting to other governmental functions fees that the PTO has collected from patent applicants. At present there is no effective mechanism for ensuring that diversions will not continue, even though the PTO insists that it wishes to avoid diversion. BIO is concerned that the pending fee bill [3]/ does not yet contain sufficient safeguards to prevent diversion of funds. The failure of the bill to address the source of the most significant problem facing the office could undermine the very goals of the strategic plan.

This committee is fully familiar with the issue of diversion and has attempted over many, many years to end this practice. BIO defers to the wisdom of the committee on how best to achieve this shared goal. It might be possible to link the achievement of improved outcomes within the PTO to authorization of fee increases. As the President noted when he signed the most recent reauthorization of the Prescription Drug User Fee Act (PDUFA), the practice of linking fees to reform (with concrete metrics like timeliness of reviews and achievement of management goals) can be a powerful incentive to secure goals in the public interest.

2/ U.S. Patent and Trademark Office, the 21st-Century Strategic Plan (Feb. 3, 2003), available at http://www.uspto.gov/web/offices/com/strat21/stratplan_03feb2003.pdf.

3/ United States Patent and Trademark Fee Modernization Act of 2003, H.R. 1561, 108th Cong. (2003), available at http://www.uspto.gov/web/offices/com/strat21/feebill.htm.

Restriction Practice/Unity of Invention:

One component of a valid strategic plan for the patent system in the United States should be the immediate, and rapid, review and implementation of reforms to the restriction practice currently used in the U.S. patent system.4 / In its strategic plan, the PTO has pledged to work with other patent offices to develop a workable international framework for these reforms, including movement toward the international examination system often called "unity of invention." While the PTO has agreed to implement unity of invention as part of its long-term agenda, it's current proposal does not seek the statutory authority to secure that goal. The PTO appears willing to submit legislation to implement changes in this area in the future but has not clearly committed to do so within a definite timeframe. While those steps are commendable, BIO believes that steps to address problems related to "unity of invention" should be taken now, in conjunction with implementation of a fee bill.

What exactly is unity of invention? In its simplest terms, it is the idea that a single invention should be filed and reviewed—and, as appropriate, issued—without being unnecessarily broken into multiple component parts. This approach to patent examination is, for the most part, already in effect in most patent offices around the world (e.g., the European Patent Office 5/, and the Japanese Patent Office 6/) either directly or as a result of the Patent Cooperation Treaty.7/ The United States currently generally follows this practice in its handling of international applications filed under the Patent Cooperation Treaty. The United

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4 / Restriction practice is a workload management tool employed by the PTO. Under the authority of 35 U.S.C. 121, the office may require an applicant to "restrict" the examination of the application to a single "independent and distinct" invention. If the finding is that the application contains more than one independent and distinct invention, the PTO requires the applicant to file an additional application to permit examination of the second or third "invention." Doing so allows the office to collect an additional set of fees, and gives the patent examiner an additional time credit.

5/ See, for example, Convention on the Grant of European Patents (European Patent Convention) of October 5, 1973, Art. 82 "Unity of Invention" ("The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept."), available at http://www.european-patent-office.org/legal/epc/e/ma1.html#CVN.

6/ See, for example, Japan Patent Office, Examination Guidelines for Patent and Utility Model in Japan, ch. 2 "Requirements for Unity of Application" (Dec. 2000) and Japan Patent Law, Section 37 (Law No. 121 of April 13, 1959 as amended by Law No. 220 of December 22, 1999), available at http://www.jpo.go.jp/quick_e/index_tokkyo.htm.

7/ Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, available at http://www.wipo.org/pct/en/.

States should take steps to implement a unity of invention examination system that is in harmony with these other offices. [8]/

Adopting a practice that allows biotechnology companies to keep related features of a single invention together in a single application will greatly facilitate the process of examining these applications. It will also significantly reduce the administrative workload of the PTO. Unlike the rest of the world, the PTO traditionally separates claims even though they are directed at one particular invention. Using the biotechnology sector as an example, the PTO currently separates claims directed at as a single DNA sequence, the protein that DNA sequence encodes and antibodies that bind to the protein into different inventions. As a result, applicants are required to prosecute what should be considered one application as multiple applications. The current restriction practice of the PTO (the practice of imposing limits on the scope of what can be examined in a single application), especially in biotech-related groups, produces unnecessary filings, work and complications for both the PTO and applicants.[9]/ Simplifying this

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[8]/ The current discretionary practice of dividing a single invention into multiple applications has a great impact on start-up biotechnology companies. Biotechnology patent applications experience the PTO's restriction practice more than any other sector of the U.S. economy. This is because biotechnology inventions are complex and the law is still developing in this area. In order for a biotechnology inventor to obtain the best possible coverage for her inventions, she must submit an application that touches on several aspects of a single invention. Although these aspects are related, the PTO divides these aspects into many different groups, forcing a biotech inventor to file multiple applications on what is in reality a single inventive concept. Each application requires additional fees and costs for the party prosecuting the application such as patent counsel as well as cost in time for the applicant's attention. Two applications multiply the cost by two; 10 applications multiply the cost by 10, etc. So when an examiner divides one application into several applications, the costs multiply accordingly.

[9]/ Restriction practice refers to the way that the PTO determines how many claims it will consider as a single application. When a patent is submitted, historically the PTO would often respond with a "restriction requirement," which separated claims into groups according to their similarity with each other. In biotech patents, this often meant that, for example, all diagnostic claims would be grouped into one "divisional application" and all therapeutic claims would be grouped in to another divisional. This resulted in the applicant filing two or more, but a small number, of separate patent applications. This policy has recently changed, however. The PTO is now restricting gene patents into large numbers of divisional applications. This results in an unmanageable number of individual patent applications, with associated unreasonable filing costs. One BIO member, a small diagnostics company, recently had an application restricted into more than 40 separate divisional applications. The governmental costs alone for this technology would be over $300,000.00, assuming the patents issue. This cost figure does not include attorney costs or any other costs associated with filing these applications.

Another biopharmaceutical member recently had an application restricted into more than 900 separate divisionals. The company would therefore be forced to decide which applications it is capable of pursuing, leading to incomplete protection of its inventions.

process would significantly improve the examination system. We recognize that the PTO, in the case of multiple inventive concepts in a single application, may appropriately demand the applicant to elect to either pay additional fees or file separate or divisional applications to obtain examination of related inventions that are presented in a single application. The fees that should be applied in these instances should be proportional to the additional work implicated by the consolidation of the related features of the invention in a single application. BIO believes, however, that the use of scores of "restrictions" on non-DNA sequence patents, or literally hundreds and hundreds of "restrictions" on DNA sequence patents, is unfair and should be ended.[10]/

BIO members are most frequently start-up firms with limited capital. The imposition of PTO "restrictions" that, in effect, divide a single application into so many parts causes prosecution of a single invention to become prohibitively expensive. This result deters investment in biotechnology and unfairly discriminates between firms solely based on their ability to bear the costs of patent prosecution. Addressing these "restriction practice" issues is a high priority for the biotechnology industry.

Linkage:

As the committee knows, BIO has previously expressed concern about the magnitude of any fee increase and its impact on the small businesses that are the bulk of BIO members. Today we are concerned that the PTO's plans for implementing its fee proposal will create uncertainty that is harmful for our members. Until the PTO's current restriction practice is replaced with unity of invention, applicants have no way of fully assessing the impact of the proposed fee increase. As the proposal is currently structured, Congress may be asked to

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[10]/ Small biotechnology companies experiencing this practice are unable to cover the whole of their invention. As an example, for one small biotechnology company, the PTO divided a single application into over 20 groups. In order to obtain coverage for a single invention, the biotechnology company would have to pursue over 20 applications. For a small company, the cost of 20 applications for a single invention is prohibitive. The company would, therefore, be forced to decide which application it is capable of pursuing, leading to incomplete protection of its inventions.

Under unity of invention practice, any inventor can pay up front to have the PTO review a number of claims in the same application instead of dividing the claims into numerous applications. This can make a significant difference in the ability of a company with limited resources, such as a small biotech start-up company, to protect all aspects of its inventions. Under the current practice in the PTO, this is not possible without exorbitant fees.

consider fee legislation twice within a one- or two-year period of time: once in a fee bill and again in an amendment to take into account changes in PTO practice around what constitutes a complete patent application (that is without undue restrictions).

Currently, the Administration is asking the Congress to pass fee legislation while promising to submit unity of invention legislation later in the 108th Congress. This two-step process should be combined. Unless the biotechnology industry knows how the PTO's fees will be implemented it cannot determine the net effect of a fee bill, especially on small and medium entities and BIO's nonprofit members. Without full consideration of a unity of invention reform measure, BIO cannot effectively gauge the impact on its members because it cannot know in advance how the PTO will divide up, or treat, its applications.

There are several ways in which the committee could achieve linkage of the two fee-related issues. First, the Congress could enact a one-year bill fee in the form of a surcharge bill and return to the fuller fee reform proposal later along with unity of invention legislation. Second, the Congress could consider, on the merits, changes to fees that would reflect an examination model that permits consolidation of related features of an invention rather than separate application with separate applications fees.

Finally, the committee could adopt an amendment that would mandate a review of the fee bill one year after enactment. In the event that no unity of invention reform was in effect then, the fee reforms proposed for future years would be held in abeyance until such a measure was implemented.

Conclusion:

BIO supports efforts to strengthen the patent system of the United States. The Administration deserves abundant praise for its efforts to secure a strategic plan to achieve that result. The Department of Commerce and the Patent and Trademark Office understand and support the efforts of Congress and others to prevent diversion of patent fees. BIO remains concerned, however, that sufficient safeguards are not yet in place to prevent the diversion of patent fees. Finally, BIO urges the Congress to take steps to make sure that unique interests of the biotechnology industry, especially those relating to unity of invention, are fully and completely dealt with in the legislative process.