September 14, 2005

Robert A. Clarke
Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Mr. Clarke:

The Biotechnology Industry Organization (BIO) appreciates the efforts of the Patent and Trademark Office (PTO) to review its restriction practices and seek alternatives. The PTO correctly perceives that its current restriction practices pose a number of difficulties for its customers, and these difficulties are particularly severe for those customers in the biotechnology industry. BIO thanks the PTO for the opportunity to comment on its proposed revisions.

BIO represents more than 1,100 biotechnology companies, academic health centers, and research institutions worldwide. Our members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

Intellectual property is critical to economic growth and scientific advances in biotechnology. Patents protect the fruits of research and development investment and, in doing so, provide incentives for that investment. Intellectual property is the primary asset base for many of BIO's members. Strong,

predictable patent protection is essential to the success, and in many instances to the survival, of biotechnology companies. Effective patent protection encourages the discovery and development of new medicines, diagnostics, and agricultural products.

America enjoys the most robust biotechnology industry in the world due, in large part, to the availability of reasonably priced patent protection. A streamlined and efficient patent examination process is vital to the biotechnology industry. Without strong, dependable, and commercially affordable patent protection, the capital necessary to sustain and grow our industry will become unavailable.

The PTO's current application of its restriction standards results in requirements to divide a single discovery into multiple applications. The trend in PTO practice toward ever-narrower restriction requirements has made obtaining complete coverage difficult for many biotechnology companies.

Biotechnology patent applications experience restrictions more than other technology sectors at the PTO largely because of the developing and complex nature of the technology. Under current PTO restriction practice, if an applicant seeks patent coverage for various related aspects of a discovery, it must file multiple patent applications to obtain patent coverage for every commercially useful aspect. In the case of a disease gene, for example, the applicant would likely be required to file separate applications for the gene itself, antisense molecules to inhibit the gene, diagnostic applications, therapeutic use of the gene or antisense molecules, antibodies against the gene product, and their diagnostic and therapeutic uses, and so forth.

Even though several related inventions can flow from a single basic discovery, the effect of current restriction practice is to require a biotechnology company to file multiple applications, often costing hundreds of thousands of dollars, to obtain comprehensive patent protection. In this environment, a small biotechnology company, academic medical center, or research institution cannot

afford to fully protect a discovery. Such an applicant is therefore forced to leave some of its inventions open to competitors.

Piecemeal patent protection can delay or even halt the development of a promising therapeutic or diagnostic product because investors and industrial collaborators will not invest in a concept that is not fully protected. In addition, multiple patent applications create uncertainty in the market because aspects of a single discovery are patented over a period of years, rather than in a single patent.

Although the PTO has replied to some of these concerns by stating that applicants are free to file as many divisional applications as they choose, BIO does not believe that the current approach addresses the serious problems faced by the PTO's customers. It is not economically feasible for many small biotech companies to file 5, 10, 20, or more divisional applications for each new set of claims they present for examination. BIO does not agree that the filing of an unlimited number of divisional applications is a solution to the present problems with restriction practice.

Any solution to this problem must keep commercially effective patent protection within the reach of the enterprises that depend on it. At the same time, BIO members understand that the PTO needs to charge application fees that cover the work required to examine applications effectively. BIO members believe that the most appropriate solutions will allow several closely related inventions to be examined in a single application. Such reforms would make the process of patent examination more efficient, and they would thus allow the PTO to charge fees that reflect the elimination of duplicative work in families of applications. Reforms to restriction practice that result in the filing of fewer divisional applications would also likely reduce backlog and pendency in the PTO.[1]

[1] An oft-cited justification for restriction is that, in its absence, search and examination occupy too much time to allow Examiners to meet their production quotas. In this regard, we note that a recent GAO Report ("INTELLECTUAL PROPERTY: USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain, GA)-05-720) states, at page 5: "Patent examiners' awards are based largely on the number of applications they process, but the assumptions underlying their application processing quotas

General Comments on Current Practice

As an initial matter, many BIO members believe that problems with current restriction practice result from an unreasonable application of the standards for restriction. For example, restriction requirements are often based on nothing more than alternative limitations in dependent claims. The PTO often justifies such restrictions by stating that searching all of the alternatives would constitute an undue burden. This rationale appears to have risen to the status of a *per se* rule in the PTO. However, when a reasonable number of alternative embodiments are closely related, a search broad enough to cover all of them is not an unduly burdensome extension of the search for any one.

Broadly speaking, it does not appear that restrictions are based on a uniform set of standards. It is still the experience of many BIO members that restriction criteria vary among different Art Units and from examiner to examiner within the same Art Unit. Therefore, in addition to any other changes that may be made, BIO encourages the PTO to improve the training and evaluation of examiners so that the correct standards for restriction are applied consistently and uniformly.

In this regard, it is also important to mention that restriction practice, as currently carried out and exemplified in the MPEP, is at odds with the Statute and Rules governing PTO practice. 35 U.S.C. § 121, 37 C.F.R. § 1.141 and 37 C.F.R. § 1.142 all require that, for an application to be restricted, the alleged different inventions must be both independent and distinct. Nonetheless, the PTO has consistently applied an "independent or distinct" standard, basing restriction on only one (usually distinctness) of these two statutory requirements. In the view of BIO's members, adherence to the law by the PTO would, in and of itself, constitute a significant improvement in restriction practice.

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have not been updated since 1976." Perhaps it is time for the PTO to revisit these assumptions, especially in light of the complicated technology covered by biotechnology applications.

Comments on Proposed Options

Option 1

This option involves essentially no change to current restriction standards. The potential for reducing the total number of applications needed to comprehensively claim the inventions resulting from a discovery would provide some benefit as compared to current practice; although the procedure for doing so, as set forth in Option 1, would favor resource-rich applicants.

However, BIO members are concerned that Option 1 would not make the examination of different inventions claimed in a single application any more efficient. Thus, adopting this option as proposed would not help the PTO reduce pendency. Moreover, because it would be no more efficient than current examination practice (and the need for greater efficiency has clearly been established), it would not provide a basis for reducing prosecution costs for biotechnology patent applicants.

Option 2

Option 2 envisages applying a "unity of invention" standard to all US national applications. This option appears to provide for more efficient examination of related subject matter than Option 1. Thus, BIO members believe that this option has the potential to address many of their concerns.

As proposed, determining unity in the PTO would require not only a prior art search, but also a quasi-examination for compliance with the first paragraph of Section 112. It thus appears that the PTO envisions conducting a nearly complete search and examination of the claimed subject matter simply to determine whether or not unity exists. BIO considers that such extensive review would not be needed for purposes of assessing unity, and that "front-loading" the examination in this way could impair the efficiency of the overall examination process. BIO

encourages the PTO to clarify and simplify the standards that would be used for restriction under a unity of invention standard.

BIO notes that adopting Option 2, as presently proposed, would result in different "unity" standards for US national applications filed under 35 U.S.C. §§ 111 and 371.[2] BIO members believe that the PTO should work toward defining a single unity of invention standard that would apply to all national and international applications. Doing so would simplify international filing strategies for all applicants, and it would particularly benefit small companies with finite, and often limited, resources.

Option 3

BIO proposed what is now Option 3 as a way to address issues that have become critical for biotechnology patent applicants. BIO members continue to believe that this proposal provides a reasonable solution that would benefit applicants in many technologies. It would be an effective solution because it accounts for the search and examination burdens that accompany additional sets of claims, and it allows the PTO to charge fees that proportionately reflect those burdens.

BIO notes, however, that the PTO proposes that the present "independent or distinct" standard would be applied to initial grouping of claims under Option 3. The fact that current "independent or distinct" restrictions are almost always justified, in part, by search burden raises the concern that, under Option 3 as currently envisioned, most, if not all, additional inventions would be placed into Tier 3, resulting in essentially no change from current restriction practice.

BIO members believe that substantial advantages for both the PTO and users of the patent system would result from implementing Option 3 as originally proposed by BIO, and that the benefits would more than justify the effort. The

[2] Moreover, the PTO appears to assume that applications filed under 35 U.S.C. § 371 are already treated under a unity of invention standard. In the experience of many BIO , this is not the case.

PTO has concluded that the standards reflected in this option would not be easy to understand or easy to implement. Without doubt, a transition to new restriction standards would involve certain significant changes in Office practice, and new tools for assessing "relatedness" would have to be developed. However, BIO members feel strongly that practical and workable standards can be developed.

We encourage the PTO to continue exploring this option and we stand ready to work with and support the PTO in this effort.

Option 4

The PTO considered "re-interpreting" the standard of 35 U.S.C. §121 for independence and distinctness. The Green Paper states that the proposal for implementing such a standard was too difficult and unpredictable to be practical. BIO finds the PTO's proposal for implementing this option unnecessarily complicated. Standards for both independence and distinctness already exist[3] and standards for distinctness are already being applied by Examiners. All that is necessary is additionally to apply standards for independence and to ensure that both requirements are met before an application is restricted. Thus, many BIO members see merit in this proposal simply because it would result in fewer restriction requirements and consequently would help minimize the costs associated with fragmentary patent protection.

Conclusion

BIO appreciates the PTO's efforts to study different mechanisms for reforming restriction practice. They believe that further efforts should more fully address the problems that characterize current restriction practice. Such problems include, for example, arbitrary standards for restriction, the commercial harm that results from multiple applications and fragmentary coverage of inventions, and long application pendency in the PTO.

[3] *See, e.g.*, MPEP 802.01, 806 and 806.04

BIO urges the PTO to continue exploring all of the options that would result in more efficient and cost-effective examination. We would be pleased to work with the PTO to develop standards that are fair to applicants and practical for the Office.

Sincerely,

Lila Feisee
Director for Intellectual Property