



**The Statement of the
Biotechnology Industry Organization
On the Patent and Trademark Office'
Strategic Plan—2007-2012**

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Attention: USPTO Strategic Plan Coordinator

*Comments of the Biotechnology Industry Organization (BIO) to Request for
Comments on USPTO's Draft Strategic Plan for FY 2007-2012*

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the PTO's Draft Strategic Plan for FY 2007-2012. 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 health care, agricultural, industrial, and environmental biotechnology products.

Perhaps no other industry is as dependent upon patents as is the biotech industry. In 2004 alone, more than 10% of the PTO's application filings were in the biotechnology sector. This is because patents are often the most valuable assets of biotechnology companies the majority of whom have no products on the market. These innovative companies rely on their patents to generate the financing to further develop and commercialize a product or technology. This development process often requires decades and hundreds of millions of investment dollars. Gaps in patent protection or weakened protections drive investors away from the biotechnology sector and toward less risky endeavors. As such BIO has a keen interest in the strength and integrity of the patent system.

The United States leads the world in biotechnology research and development which is fueled by the strength of the U.S. patent system. The United States patent system is designed to spur innovation and encourage research and development of new products and services for the benefit of society. This system, administered by

the United States Patent and Trademark Office (PTO), is by far the best and the most widely utilized system in the world. However, because of this global nature of the patent system, the PTO is experiencing challenges unlike that which it has experienced before. The PTO's workload has increased dramatically over the past decade as new technologies are eligible for patent protection and as more research results in fruitful discoveries. BIO understands that large numbers of applications present administrative challenges, but also notes that large numbers of patent applications are a sign of a healthy, dynamic and growing national economy on the cutting edge of science and technology – a positive sign that should be welcomed as a contribution to the overall public good. Moreover, the PTO's harmonization efforts, the courts' increasing interest in patent matters, and Congressional efforts to reform the system are likely to lead to significant changes in patenting practice.

Taken together with the PTO's workload, these challenges may seem daunting. Indeed each of these challenges may suggest its own solution. However, BIO urges that none of these challenges be addressed in a vacuum. The PTO will need to develop creative strategies to address these challenges without weakening or limiting existing protections. Our members would like to work with the PTO to develop viable solutions that can address some of these administrative challenges while at the same time maintaining the integrity of the world's best patent system. We note with appreciation the PTO's flexibility and willingness to be creative in addressing its challenges and for calling on its customers to provide input into this very important process.

The Strategic Plan

While BIO in general agrees with the contours of the strategic plan, it cautions that many of the underlying assumptions of the plan are either unclear or uncertain. For example, there is no number for the percent increase in patent application filings through 2012 (see page 9 of the Draft Plan). Further, there is no guarantee that fee diversion will be permanently addressed, or that other countries' patent offices will lend their support to U.S. efforts. The PTO's goals to address patent pendency, quality and enforcement are to be commended. However, details of how these issues are to be addressed have the potential to impact all segments of the U.S. economy, some more than others. Accordingly, it is important that the PTO consider very carefully any potential changes to the existing system against the backdrop of a sound and vibrant U.S. economy. Seeking input from the users of the patent system through a transparent process will help to ensure that existing protections are not weakened or undermined and will also ensure that certain industry sectors are not disproportionately impacted. BIO urges the creation of a taskforce of stakeholders and PTO professionals to begin the planning process.

Alternative Flexible Examination Systems: Areas of Concern

“Petty” Patents

BIO lauds the PTO's efforts to develop an alternative examination system to address pendency and quality challenges. Our members believe that alternative approaches to examination would better serve the public interest in this age of rapid technological breakthrough. However, BIO believes that these approaches should provide for options in initiating the timing of examination rather than in the level of protections. The PTO must ensure that the strength and integrity of the patent system are in no way compromised as a result of the options presented. For example, BIO urges the PTO to guard against the development of a “petty patent” system of the nature that exist in some European countries and Japan. Such patents, which are generally granted without examination, reduce legal certainty and represent a potential problem for innovative industry sectors. In the main, because the requirement for inventive step of these patents is lower than utility patents, though to what extent is less than clear. The existence of such petty patents, by its very nature, induces obstacles to competition and innovation in the biotechnology and pharmaceutical sectors. Indeed the majority of the European community has not adopted such a system primarily because of its potential to hinder competition. BIO urges the PTO to guard against institution of such weak patents.

Peer Review Concept

BIO also has strong concerns about the Peer Review concept indicated in the Strategic Plan. While BIO is aware of the increase not only in the number of applications, but the complexity of today's applications, BIO disagrees that “work sharing” such as what is proposed by the PTO will serve the public good. BIO is specifically concerned that such a program is uncontrollable and may become a tool for harassment of patent applicants. Such a program on its face appears to be an informal pre-grant opposition procedure that can lead to delays in the patenting process. BIO request clarification about the details of such a program, specifically in light of the recent PTO proposed rules pertaining to Information Disclosure Requirements. The sheer uncertainty that can result from the possibility of inequitable conduct violations will make the patenting process an oppressive environment. Furthermore, it is not clear what standards and criteria would be employed or how the PTO proposed to implement such a program. It is also unclear how open examination of the kind implied by the program would implicate current standards of patentability. BIO is also concerned that PTO's directive as the administrative agency responsible for the independent reviewer of inventions will not be met. All of this adds uncertainty to the patent system that is already in the midst of substantial review from various quarters. Instead of

creating a new ill defined peer review system of patenting, BIO urges the PTO to hone and leverage its information technology systems; expand its data bases; develop new search tools and better train its examiners. BIO also urges the PTO to consider expanding its system of third party prior art submission and/or work with other patent offices and search authorities to obtain the best prior art. BIO firmly believes that the burden and the role of examination lie with the trained patent examiner, not the public.

Alternative Flexible Examination Systems: Areas to Consider

Applicant Choice for Timing of Examination

Despite the concerns expressed above, BIO does believe that a more flexible system of examination is necessary to meet the needs of the inventor, the public and the PTO. Such systems could include mechanisms for initiating a thorough examination of what applicant considers as his invention. This type of mechanism may require changes in the existing fee structure. Another alternative could include new and effective means of accelerating examination on particular applications. This would allow applicants who are able to meet certain conditions to get accelerated examination or "rocket docket" treatment of their application when necessary. Still another system can include expedited examination for PCT national stage entry applications. Encouraging the use of the PCT route could result in search reports from other search authorities that may aid in efficient examination of national stage applications. In addition to the above, the PTO could consider implementing a limited form of deferred examination in situations where applicant does not require immediate or expedited examination of his application. Such a limited system would allow the PTO to attend to certain applications that require immediate examination, and place in a separate queue others that do not. This, of course, requires a fundamental change in the way the PTO views patent pendency.

Restriction Practice Reform

One contributor to the PTO's workload and inconsistent patent quality is the PTO's current restriction practice. All too often the PTO restricts a single discovery into multiple groups each requiring a separate filing. At times, it may be necessary for a biotechnology applicant to file 20 or more patent applications in order to fully protect his/her invention. The current problems with the present restriction practice include the extreme complexity and demonstrated difficulty of the PTO to apply consistent standards. In this regard the PTO has not yet concluded its study on the practicality of a unity of invention practice and restriction practice. BIO urges the PTO to consider its comments submitted September 14, 2005.

After Final Reform

Biotechnology patent applicants often times require multiple rounds of back and forth before they can convince the PTO of the merits of their invention. Such dialogue is necessary to efficiently resolve issues after the first office action. All too often the second action is made final without thorough consideration of the applicant's arguments. Moreover, once the application is finally rejected there is little hope the PTO will consider "after final" communications because the PTO does not allot time or credit for such communications. The patent applicant is then "forced" by the circumstances to file a continuation in order to further advance prosecution. The result is inefficient examination and unnecessary expense by both the applicant and the PTO.

Patentability Review Conferences and Pre-FAOM Interviews

Appeal and pre-appeal conferences have brought to light the problem of numerous improper final rejections. A significant number of the final rejections are dropped or modified during these conferences. Patentability conferences will allow the examiner and applicant to better understand each other's concerns and chart a course to resolve the issues.

The option to conduct pre-first Office action interviews may help the examiner to better understand the invention. Such interaction could also help to focus the search and analysis of the claims.

Other PTO Enhancements

Regional Offices and Personnel Flexibilities

BIO strongly urges the PTO to consider investing in regional offices around the country. While it is certain that the PTO cannot hire its way out of a backlog, it is equally clear that a well trained and incentivized workforce will significantly help to address this challenge. One of the stated challenges of the PTO is the difficulty in hiring and retaining qualified examiners. Regional offices will expand the PTO's workforce and provide for stronger incentives to retain employees. This initiative is sure to help in the recruitment of high quality examiners as well as address the high attrition rate at the PTO.

The PTO should look to other offices to address its attrition issues. The high attrition rate (above 10% overall) has resulted in the need to hire and train more examiners than can be absorbed on a yearly basis. By contrast the European Patent Office (EPO) and Japanese Patent Office (JPO) have significantly lower attrition rates, allowing them to maintain a much more experienced examining

corps. The PTO should consider taking full advantage of the personnel flexibilities available to immediately reduce attrition rates. Obvious sources of information on how best to achieve this goal are the EPO and JPO themselves. It may be necessary for the PTO to consider the human resource policies of these Offices as models to help improve the PTO's present ability to retain experienced staff. BIO also applauds the PTO for the recent implementation of new programs to retain examiners and improve examiner training. BIO urges the PTO to continue in these endeavors and allow sufficient time for these improvements to effect change. In particular, the PTO's implementation of a Patents' Hoteling Program wherein examiners can "telework" from home should provide a significant incentive for drawing new and retaining experienced patent examiners; just as this program has done for trademark attorneys.

Re-evaluating Examiners' Goals

A 21st century PTO requires innovative 21st century initiatives. These initiatives should not be limited to practice changes, rather changes in how the Office views workload. A reevaluation of the examiners goals to provide more time for the initial examination and a graduated credit system, where appropriate, will ensure higher quality search and examination. A graduated credit system that takes into consideration time spent on subsequent Office actions or "rework applications" such as continuations, RCEs and Continuations-in-Part (CIPs), will provide the appropriate incentive for the patent examiner to perform a proper and thorough examination in the first Office action. BIO believes that a graduated credit system in conjunction with additional time per balanced disposal for consideration of amendments, evidence or prior art identified from another patent office, and after final amendments would go a long way to reducing continuation filings and lessening the backlog of applications.

An "Ombudsman"

The PTO should consider establishing an ombudsman position at the PTO to quickly and impartially evaluate, under certain circumstances, erroneous examiner decisions. There are instances when an applicant is faced with an examiner and/or a Supervisory Patent Examiner (SPE) unwilling to consider an applicant's allegation that a mistake has been made during prosecution. In these situations, the appeals process is inefficient and costly. Providing the applicant with a true ombudsman will give applicants a real opportunity to resolve honestly disputed issues without the expense and time of an appeal.

Examiner Training

The foundation for high quality and efficient examination is a quality first Office action with a thorough search of all claims and complete consideration and comment upon all claims. The biotechnology industry relies on quality patents that will withstand challenge in the courts. A thorough search along with the examiner's understanding of the invention would go a long way to ensuring quality patents without the need for multiple continuations. BIO recommends that the PTO consider using a significant portion of the fees generated as a result of the recent fee increase to provide scientific and legal training for examiners. BIO stands ready to work with the PTO to provide scientific training in the form of seminars and site visits for biotechnology examiners. BIO also urges the PTO to work closely with the patent bar to provide in-depth legal training for PTO examiners.

Conclusion

In conclusion, BIO supports and applauds the efforts of the PTO to develop creative ways to address its ever growing challenges. In doing so however, BIO urges that the PTO continue to be a good steward of the U.S. patent system. The Strategic Plan should carefully include flexibilities in examination and personnel management while at the same time maintaining the strength and integrity of the world's best patent system. In developing its strategies for the next five years, the PTO should take into consideration the landscape of patent reform in the Courts and in Congress so as to ensure a streamlined patent process. BIO offers its assistance in helping the PTO to develop such a system.

Respectfully submitted,



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