



**BY ELECTRONIC MAIL to StrategicPlanning1@uspto.gov**

October 5, 2006

USPTO Strategic Plan Coordinator  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

BIOCOM appreciates the opportunity to provide comments on the USPTO's Draft Strategic Plan for FY 2007-2012 (Draft), as announced in the Federal Register on August 24, 2006 (see 71 Fed. Reg. 50048 (24 Aug 2006)).

BIOCOM is a regional advocacy organization representing more than 500 dues paying life science companies and service providers in Southern California. Strong intellectual property protection is important to attract the substantial investment required to bring new life-saving therapeutics to the market. Toward that end, BIOCOM and its member companies have a keen interest in potential changes to the patent examination process which may increase the cost of obtaining patents, increase the risk of challenge to the resulting patents, and consequently reduce the ability of small companies which do so much of the innovative research in this country to raise the capital necessary to pursue their goals.

BIOCOM supports the goals set forth in the Draft. However, since the Draft is very ambitious, touching on numerous topics, it would benefit from the addition of focus, a clear setting of priorities, and added detail as to how many of the laudable goals set forth therein are going to be achieved. Moreover, the Draft lacks metrics to measure progress towards the goals set forth therein. Measurement of such metrics should be clear and publicly transparent. In addition, the Draft should do a better job of taking into account the needs of the customers of the USPTO, today's innovators, creators and businesses.

Specifically, the customers of the USPTO require fair value from the patent examination process. Delays, poor quality, unduly limited scope of protection, protracted prosecution, excessive restriction practice—all reduce the value of the patent process. Any changes implemented going forward must take into account the potential impact thereof on the applicant. While the backlog at the USPTO can be reduced by discouraging filings (the clear impact of many current practices, including recently proposed rules changes), this cannot be accepted as a viable solution as this clearly does not foster innovation, nor enhance the dissemination of knowledge to the public.

The Draft addresses potential changes in numerous aspects of the USPTO's operations, including:

- 1) Personnel;

- 2) Quality of the search and examination process;
- 3) Fully implementing electronic filing and processing systems;
- 4) Securing long-term funding authority;
- 5) Need for an alternative examination system;
- 6) Educational programs; and
- 7) Harmonization.

However, the identification of metrics for evaluating progress towards each of these goals is substantially lacking in the Draft. Any such metrics developed to monitor such progress should be clear and publicly transparent.

In view of the substantial and growing backlog of patent applications, BIOCOM submits that the primary focus of the Draft should be on improvement of the operation of the USPTO with respect to its core competencies, i.e., processing incoming patent applications, and reviewing same for patentability. Those aspects of the Draft which most directly contribute to this primary focus should be the top priority.

Thus, issues related to point number (1) above, “Personnel” are of the highest priority. The Draft makes reference to addressing pendency and backlog issues by “hiring, training and allowing employees to work at home or offsite.” While this is a good start, the historically high turnover rate at the USPTO must be acknowledged, and consequently, programs to retain a high percentage of the newly hired examiners must also be developed. Alternatively, in recognition of the fact that the position of patent examiner has been a transitory position for many, it may be appropriate for the USPTO to create another tier of patent examination professional, thereby adapting its hiring practices to the realities of the market—certain job opportunities could then be marketed as short-term positions (not unlike a post-doctoral position in the sciences), and training programs could be adjusted as well to acknowledge this reality of the marketplace.

In addition to hiring and training, the location at which the work of a patent examiner will be carried out, has been addressed. Many variations of this should be explored—not only the concept of telecommuting, but also the regionalization of the examination process. Many examples of regional offices of the federal government already exist and can provide a model for the USPTO in this regard. Indeed, there are many centers around the country where patent examination could be conducted, especially in view of the advancing conversion of USPTO records to electronic form.

As part of any changes to be implemented in the examination process itself—it is proposed that, in recognition of the additional work required by a Patent Examiner to dispose of highly complex subject matter, the USPTO should develop flexible standards which provide variable credit to Patent Examiners for disposal of patent applications—with enhanced credit available for disposal of highly complex subject matter. The traditional “one size fits all” approach is clearly inapplicable to the broad spectrum of technologies handled by the USPTO today, especially today’s highly complex technologies.

Improving the quality of the search and examination process (point (2) above) goes hand-in-hand with the hiring, training and retention of good people. This can be further advanced by

re-visiting whether current examination guidelines are appropriate to today's technologies. The focus of many examination guidelines appears mainly addressed to making the patent examiner's job easier, and less related to the nuances of the technology involved, or the market realities in which the technology will be applied.

With respect to the implementation of electronic filing and processing systems (point (3) above), the USPTO has done a good job of developing relevant systems, and is to be both congratulated for doing so, and encouraged to continue to evolve such systems along the lines outlined in the Draft.

The issue of securing long-term funding authority (point (4) above) could perhaps be addressed by re-visiting the concept of establishing the USPTO as a government corporation.

The proposal to explore the possibility of adopting alternative examination system(s) (point (5) above) opens the door to many alternatives, for which we need only look at systems already adopted by many foreign jurisdictions, e.g., deferred examination, registration systems, and the like. Prior to adoption of any such alternative systems, however, the opportunity should be provided for public debate regarding the pros and cons of such changes to traditional USPTO practice.

Educational programs (point (6) above) and patent harmonization (point (7) above) are both laudable goals, but should not be given particularly high priority, since these are clearly long-term considerations, and will be better addressed when issues related to higher priority considerations have been addressed.

BIOCOM looks forward to continued improvement of USPTO operations, but is concerned that any changes to be implemented not impose disproportionate added burdens on life science companies. Such an impact will dramatically reduce the ability of smaller companies (who make up the majority of BIOCOM's membership) to file and prosecute patent applications.

BIOCOM appreciates the opportunity to comment on the Draft and to suggest alternative approaches to addressing problems facing the USPTO. BIOCOM welcomes the opportunity to work with the USPTO to develop a Strategic Plan that fairly addresses USPTO concerns, without losing sight of the reason for the existence of the USPTO, and the needs of those who rely on its efficient operation.

Respectfully submitted,



Jimmy Jackson  
Vice President of Public Policy  
BIOCOM