



IDEAS FOR REFORM OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Dear President-Elect Obama:

Congratulations on your historic election!

The Biotechnology Industry Organization (BIO) is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,250 biotechnology companies, academic institutions, state biotechnology centers and related enterprises across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnologies. Our members are leading the efforts domestically and around the globe to help heal, fuel, clean, and feed the world.

Patent protection is the key to economic growth and advancement in the biotechnology sector and innovation in the life sciences community more broadly. Strong patent protection is essential to the success and, in some instances, survival of biotechnology in this country. Patents allow biotechnology companies and their life science partners to transfer technology, attract capital, and make business decisions that lead to the development of medicines and diagnostics for intractable diseases, and agricultural, energy, and environmental products to meet growing global needs.

Since long before the emergence of biotechnology, the U.S. Patent and Trademark Office (USPTO) has been charged with the processing of patent applications, the dissemination of patent information, and the granting of patents to inventors. In playing its role within the U.S. patent system, the USPTO has made immense contributions to the nation's technological and economic progress – contributions that are nowhere more apparent than in the biotechnology arena.

Today, however, the USPTO is an agency in crisis. More than 1.2 million patent applications are pending before its more than 6,000 examiners. Despite a dramatic, four-fold expansion of its examiner corps and a more than ten-fold increase in its annual budget over the past decade, the USPTO has been unable to keep up with the ever-growing influx of new applications and application backlog, and average application pendency has increased by more than 50%. The USPTO's job will not get any easier over the coming years. Patent

application filing rates are projected to increase by 6% annually, continuing their significant upward trend. The rate of foreign-filed applications, at an astonishing 45%, is already one of the highest in the industrialized world, and may rise even further.

These application pressures have led to aggressive production goals for USPTO examiners, harming the agency's efforts to retain quality examiners. Staff retention is an ongoing problem: the USPTO hires two examiners for every one that stays on the job long enough to learn how to search and examine, in 20 hours or less, patent applications that took weeks or months to compile and are more and more complex. Aggressive production goals also are driving the rate of application rejections to historically-high levels. And even though the procurement of a patent is now more costly and time-consuming than ever, there is a widespread perception within the patent user community that high workload and production pressure in the USPTO today jeopardize the quality of newly-issued patents.

An erosion of confidence in the quality of U.S. patents, however, cannot be tolerated. Patent quality begins with examination quality, which is a shared endeavor between the USPTO, the applicant community, and the public. Instead of focusing on this basic premise, legislative efforts during the 109th and 110th Congresses have instead bogged down over patent litigation and other divisive back-end changes to the patent system. The passage of such legislation in the 111th Congress would impose additional challenges on the USPTO without addressing the root causes of the problems faced today. Moreover, as this multi-year legislative battle over patent reform has been proceeding, the courts have continued to take controversial issues off the table. Proposed reforms to the nonobviousness standard, the criteria for granting permanent injunctive relief, and the judicial determination of willful infringement have been the subject of landmark decisions by the U.S. Supreme Court and the Court of Appeals for the Federal Circuit. Allegedly excessive damages awards have been vacated. Much-maligned patents on abstract business methods have been given a more rigorous evaluation. With judicial landmark decisions needing time to take hold in the case law and in patent practice, it can fairly be asked whether a legislative respite is in order. Accordingly, serious consideration should first be given to administrative reforms aimed at ensuring examination timeliness, backlog reduction, and front-end patent quality.

To this end, BIO submits the following ideas for further discourse and consideration among the incoming Administration, the USPTO leadership and examiner corps, and key stakeholders across industry. It is important to recognize the interrelationship between and among many of the ideas below, which are not ends in and of themselves, but rather are various means of achieving a common goal of improving patent examination. It also is critical to

ensure that implementation of any or all of these ideas is structured in a way that does not result in unintended adverse consequences for the patent system.

- Reassessment of examiner compensation, retention, and production goals and incentives: The USPTO's production system in its current form was established in 1976 and has not been fundamentally changed since. Production goals and time per application could be adjusted to account more for the relative complexity of the technology area, and examiners could receive credit proportionate to the relative amount of work required for different applications. In addition, production metrics could be reassessed so as to reduce examiner incentives to trigger requests for continued examination or excessive divisional applications, instead providing greater reward for initial patentability determinations. The USPTO should also explore flexibilities to create more competitive compensation packages not achievable under existing government restrictions. In addition, the patent applicant community could be involved more in continuing examiner education efforts, such as technology fairs, visits to research facilities, and seminar series.
- PTO branch offices and other measures to facilitate hiring and access to talent: To facilitate hiring and retention of qualified engineers and scientists, the USPTO could consider establishing branch offices in various parts of the country. The existing telework program could be combined with a system of regional branch offices to ensure that examiner staff would have adequate supervision and "face-time" with colleagues and supervisors without burdensome travel requirements. The USPTO could explore whether the costs of regional branch offices could be mitigated by using existing space in federal facilities across the country.
- Pre-first action interviews and issuance of "short form" search reports: The USPTO could expand exploratory programs under which applicants and examiners could meet for an informal pre-examination conference to discuss the application, explain the underlying technology, and agree on ways the application could be improved for more efficient substantive examination. Such a pre-first action interview program could be combined with an abbreviated search report, under which examiners could supply a listing of relevant references with an indication of their likely impact on the patentability of the claims. Based on such preliminary feedback and discussion, applicants should be given the opportunity to make amendments to their claims before their cases enter substantive examination.
- Reassessment of current restriction practice in light of the European unity-of-invention concept: The USPTO should review whether existing U.S. restriction practice forces the filing of too many divisional applications, thereby contributing to the Office's workload without really benefiting patent quality. This practice is particularly common in the biotechnology area. Currently, there is little to prevent examiners from restricting an invention down to every patentably distinct embodiment, which would be searched and examined separately in subsequent divisional applications. The USPTO should consider

whether more examination efficiency can be gained by adopting the European unity of invention concept, under which examination could be conducted more efficiently on a single application for a group of closely-related inventions that are linked so as to form a single general inventive concept.

- Incentives for applicants to abandon obsolete applications: Patent applicants often determine on their own, and over time, that their inventions are not commercially or otherwise viable, or that patent protection is not needed or likely to be obtained. In the USPTO, more than 10% of all patent applications are abandoned by their owners without further response after a first office action. Presumably, search and examination would not have been necessary in at least a portion of these cases. In foreign patent systems where examination must be affirmatively requested after a three- to five- year deferral period, up to 30% of all patent applicants decide that they no longer want to seek a patent on their application. Under current USPTO practice, however, the examination process is front-loaded in a way that provides applicants with few incentives to withdraw obsolete applications before examiners begin working on them. The USPTO could consider notifying applicants before searching and/or substantive examination is started, offering a partial refund of search and/or examination fees for withdrawn applications, or make other adjustments to its fee structures to incentivize such behavior. The USPTO could also offer to advance the examination of other, commonly-owned applications in the examination queue for every obsolete application that is withdrawn before substantive examination.
- Flexibility and prioritization of prosecution through a request-for-examination process: The USPTO could consider a system where applications are subjected to substantive examination when requested by the applicant within a given time, optionally on an accelerated or deferred basis. A substantial portion of those applicants who do not request substantive examination at the time of filing would be expected to eventually let their applications lapse, as has been the experience in the patent offices of some of the Nation's biggest trading partners, such as the European Union, Japan, Canada, Korea, China, and Germany, all of which operate under request-for-examination systems. As an ancillary effect, a request-for-examination process would also facilitate international work-sharing with these patent offices by better synchronizing the time when counterpart applications are taken up by the examiners in the various jurisdictions, reducing the extent to which the USPTO carries the international burden of patent examination (see discussion below). The resources thus freed up could be applied, in part, towards a simplified and practical accelerated examination process for applicants who need a patent sooner than otherwise would be possible, thereby allowing for a better and more efficient prioritization of patent examination. The anticipated reduction in workload created by the abandoning of unnecessary applications also could permit more flexible production goals for patent examiners, providing additional time to evaluate more complex applications for which examination

has been requested. A request-for-examination process, however, would have to be structured in a way to avoid incentives for filing or maintaining meritless applications, to limit additional uncertainty about the patent landscape, and to permit the USPTO to effectively anticipate and manage its workload and available resources.

- International work sharing: Applying for patents is an international endeavor. Approximately 45% of all patent applications in the USPTO are today filed by residents of foreign countries who routinely apply also in their own patent examining authority. U.S. businesses likewise routinely supplement their domestic patent applications with applications in foreign patent offices. The same essential patent application is today searched and examined multiple times by examiners in the USPTO, the European Patent Office, and the patent offices of Japan, Canada, Korea, and others. The USPTO could expand existing information sharing programs so that its examiners would not needlessly have to repeat work already done by their colleagues in foreign patent offices. It could also expand electronic file sharing with foreign patent offices and provide incentives for patent applicants to apply the results of foreign patent prosecution to their domestic cases where possible. For example, applicants could be incentivized to voluntarily settle for a U.S. patent of identical scope to a foreign counterpart patent, thus allowing more focused and less redundant examination by U.S. examiners. The patent applicant community can assist the USPTO in this effort by providing additional information about related foreign filings.
- Transparency and public assistance in patent examination process: The USPTO should expand existing programs and examine other ways to create greater transparency with respect to patent applications and permit third-party submissions of prior art to improve the patent examination process.
- USPTO fees: The USPTO needs greater ability to set and modify its fees and fee structures. Examination fees could be structured to be more directly proportional to the amount of examination work required. Authority to retain and reinvest its revenues, and to set fees to more appropriately match the resources expended on patent examination, would help the agency in planning its operations to meet the challenges of the coming decades. But to gain the patent applicant community's support for such changes, there must be a permanent end to USPTO fee diversion to other government programs.

BIO believes that the above ideas are worthy of further review and consultation with appropriate stakeholders, and that many of them, if ultimately pursued, could be accomplished in whole or in part through administrative action by the USPTO, without the need for legislation. The new Administration thus has an opportunity to address concerns with the patent system as an additional means to spur economic growth and innovation.

BIO is eager to engage constructively in the continuing debate on improving the timeliness, quality, transparency, and efficiency of the patent system, upon which

BIO's members and biotechnology innovation so greatly rely. BIO and its members look forward to working with you and your Administration in this critical endeavor.

Sincerely,

James C. Greenwood
President & CEO