From: Hans Sauer
Sent: Friday, May 29, 2009 9:32 AM
To: AC6/Comments
Cc: Bahr, Robert
Subject: BIO comments on Deferred Exanination Roundtable; 74 Fed. Reg. 10036

Dear Acting Under Secretary Doll:
Please find attached the comments of the Biotechnology Industry Organization on the USPTO Feb. 12 Roundtable on Deferred Examination, which are hereby submitted for the public record pursuant to the Office's Federal Register notice at 74 Fed. Reg. 10036.

Respectfully submitted,

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The Hon. John J. Doll
Acting Under Secretary of Commerce;
Acting Director of the USPTO

Mail Stop Comments-Patents
Commissioner for Patents
P.O.Box 1450,
Alexandria, VA 22313-1450

Via e-mail to AC6comments@uspto.gov

Re: Request for Comments and Notice of Roundtable on Deferred Examination for Patent Applications, 74 FR 17, 4946

Dear Acting Under Secretary Doll:

The Biotechnology Industry Organization (BIO) thanks you for the opportunity to participate in the USPTO's February 12 Roundtable on Deferred Examination for Patent Applications. See 74 FR 17, 4946 (Jan. 28, 2009). This submission is intended to complement BIO's statements made during the Roundtable, and to further explain the basis of BIO's support for the inclusion of an examination-on-request concept in a broader public discussion of future examination practices in the USPTO.

BIO is an industry organization with a membership of more than 1,200 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. The U.S. biotechnology industry, fueled by the strength of the U.S. patent system, has provided jobs for more than 200,000 people in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products. In the health care sector alone, the industry has developed and commercialized more than 300 biotechnology drugs and diagnostics and there are over 370 products in the pipeline. In the agricultural field biotechnology innovations are simultaneously increasing food supplies, reducing pesticide

damage to the environment, conserving natural resources of land, water and nutrients, and increasing farm income and economies worldwide. Biotechnology innovation, if allowed to progress, has the potential to provide treatments for some of the world's most intractable diseases and address some of the most pressing agricultural, energy and environmental challenges facing our society today.

Biotechnology operates under a long innovation cycle

The biotechnology business model is based on a long innovation cycle. It is not uncommon for a biotechnology company to work for more than a decade, and expend hundreds of millions of dollars, before it reaps its first dollar of product revenue. This is due to the huge investments in time and money required to bring a product through the discovery and lead optimization phase and, in the case of healthcare products, preclinical testing, and then clinical trials required to gain market approval. Both pharmaceutical and agricultural products are subject to extensive regulatory approval before commercialization. Once on the market, biotechnology products also tend to be long-lived. Biologic medicines that were approved more than 20 years ago are today as valuable as ever in providing patients and physicians with vital treatment options. Biotechnology crops have been in increasing commercial use for more than 12 years, and today continue to provide benefits in the form of increased yields and reduced herbicide and pesticide use with no sign of becoming obsolete as newer and improved crops with multiple traits are introduced.

Biotechnology businesses must seek patent protection early

Despite long product development times, biotechnology companies almost universally find that they must seek patent protection early, and that delay is not an option. Venture capital or corporate partners view patent protection as a prerequisite for funding even the initial stages of the costly and lengthy development, approval, and marketing process for biotechnology inventions. Patent applications may need to be filed to meet milestones in the company's business plan. Research-driven biotechnology businesses often participate in scientific discourse through early publication and participation in scientific meetings. Securities laws sometimes compel public disclosure of significant research findings. And last but not least, biotechnology businesses often find themselves in a race with multiple competitors pursuing solutions to the same problem. For these and other reasons, biotechnology companies must apply for patents early in the innovation cycle.

Biotechnology patent strategy parallels product development strategy

Biotechnology companies often find that their need for early-filed patent applications stands in tension with the realities of applied biotechnology research and product development. Even after a patent application has been filed and proof of concept has been established, many years may pass before a biotechnology company can decide which of several disclosed embodiments, if any, should be developed into a commercial product.

Biotechnology is cost- and capital-intensive. Cash-poor companies, especially in the current investment climate, sometimes find themselves forced to postpone promising development programs due to interruptions in funding.

Biotechnology is also unpredictable. Promising lead products may be found to display properties that make them unsuitable for commercial development, forcing a switch to an alternative candidate product sometimes years into a development program.

For biotechnology companies facing these realities, patent prosecution strategy and product development strategy are but two sides of the same coin. Decisions made during the arduous process of translating inventions into viable commercial products directly affect how applicants prosecute patent applications. Conversely, the options available to applicants during the patent prosecution process directly impact product development and investment decisions. And yet, biotechnology companies faced with the complexities and business realities that today intertwine research, development, and patent prosecution often find it difficult to coordinate their patent application efforts with the slower, and more unpredictable, pace of their applied research and development activities. In short, biotechnology businesses often need more time than the U.S. patent prosecution process currently allows.

BIO's experience with examination-on-request systems

BIO members commonly account for the length and complexity of biotechnology product research and development - and for the pace of investment therein - by seeking substantive patent examination at a later point in time in foreign jurisdictions than is currently possible in the United States. The majority of foreign patent systems in which BIO members seek patent protection operate as examination-on-request systems. In other words, the foreign patent office conducts a search and/or substantive examination only if requested to do so within a designated time period after filing a patent application. Of the top 10 U.S. foreign trading partners, only Mexico does not have a formal request-for-examination system. Examination-on-request is, in fact, the standard in countries such as Canada, China, Japan, Germany, the United Kingdom (UK), Korea, France, Brazil, Australia, India, Russia, Taiwan, and other important U.S. foreign trading partners in which BIO members often seek patent protection.

Opt-in examination: The examination-on-request systems in these jurisdictions almost universally operate through an "opt-in" process where the default is "no examination," resulting in a formal deferral of substantive examination. Examination-on-request systems generally have one or more check points at which applicants must take affirmative steps to advance their application into substantive examination, such as filing a formal demand for examination. In contrast, the USPTO offers an "opt-out" deferral process where search and examination is the default, unless the applicant submits a fee and a request for deferral under the suspension of action provisions of 37 C.F.R. § 1.103. Thus, while BIO members commonly defer the filing of requests for examination in foreign patent jurisdictions, the USPTO's suspension of action regulations are rarely if ever used.[1] Many BIO members believe that opt-in examination is simpler and more efficient than opt-out examination, and should be given preference in further discussions of a putative deferred examination program in the USPTO.

[1] Currently, suspension of prosecution under 37 C.F.R. § 1.103 offsets patent term adjustment for USPTO delays under Section 154(b). This has been cited as a major disincentive by BIO members.

Examination and search: In examination-on-request systems, some form of preliminary examination often occurs at the time of filing or prior to publication, which may include subjects such as formal compliance, industrial applicability, and unity of invention. In many foreign systems, the subsequent novelty search and examination will then be conducted together upon request. In a minority of jurisdictions, the search and substantive examination are conducted separately, and a request for examination must be filed within a set time after issuance or publication of a search report (this is the case, for example, in the European Patent Office, Germany, the UK, Spain, and some Andean Community countries). Many BIO members believe that a published search report would be a useful element of an examination-on-request system, because it provides a preliminary indication of the merits of a patent application that helps applicants to decide whether to file a request for examination or withdraw, and third parties to gage the likelihood that a patent will eventually issue.

A number of jurisdictions provide for third-party "activation rights," under which examination of a published application can be requested not only by the applicant, but also by interested members of the public. This is the case, for example, in Canada, Germany, India, Japan, Korea, and Russia. In the experience of BIO members, such third-party requests for examination, despite being freely available, occur only very infrequently. BIO members would, however, support the consideration of an appropriately crafted activation right in further discussions of an examination-on-request program in the USPTO.

Length of deferral: In foreign examination-on-request jurisdictions where BIO members commonly seek patent protection, the time from filing/priority date within which a search or substantive examination must be requested ranges from about 18 months to 7 years, and most commonly from 3 – 5 years. For example, the applicable period is 5 years in the Canadian and Korean patent offices, 3 years in the Japanese and Chinese patent offices, 7 years in the German patent office, and 24 months in the UK patent office. While examination can typically be requested earlier if desired, BIO members often defer the filing of a request until the due date under the applicable law. For purposes of a putative examination-on-request program in the USPTO, modeling studies should be undertaken to inform further discussion of the optimal length of the deferral period. In the first instance, however, BIO notes that deferral periods at the short end of the international spectrum (i.e. 18-24 months) would likely be "swallowed up" in the existing examination backlog, and expects that longer periods would be necessary to make a meaningful difference to current examination and prosecution practice.

Drop-out rates of applications that do not advance to substantive examination: While BIO members eventually file a request for search/examination in the majority of their applications, not every application proceeds to search and examination. When measured across all technologies, foreign patent offices report significant numbers of withdrawals or abandonments by the time examination must be requested. For example, for 2007 the European Patent Office (EPO), which requires the filing of a request for examination within 6 months of publication of the European Search Report (usually around 18 months), reports that requests for examination were received in 94.5% of all applications.[2] For the same year, the Japan Patent

[2] 2007 Trilateral Statistical Report. The actual rate of applications that do not proceed to examination in the EPO is likely to be higher than 5.5% because the trilateral report only counts applications for which the time for filing a request for examination has expired and no request for examination has been received. The report does not count

Office (JPO), which operates under a longer, 3-year deferral period, reported that only 66.2% of all applications advanced to substantive examination.[3] Before the JPO transitioned to its current 3-year limit for requests for examination in 2001, the applicable deferral period was 7 years from the filing date, which resulted in an even higher dropout rate of over 45% - in other words, almost half of all applications were deemed withdrawn when the deadline for requesting examination was reached, and it appears that the number of examination requests in the JPO increased after its deferral period was shortened. Significant application drop-out in the range of 30% or higher has also been reported for the Canadian Intellectual Property Office,[4] the Korean Intellectual Property Office, the German Patent and Trademark Office, and IP Australia.[5]

While the precise reasons for these application drop-out rates may be complex and multifactorial, BIO believes that an examination-on-request system would reduce substantive examination demands on the USPTO. For one, in internationally filed cases, patent offices that operate on an examination-on-request basis may frequently benefit from previous work done in other earlier-examining patent offices. Adverse results of earlier novelty searches, or patentability defects established during earlier substantive examination, may impact how applicants subsequently behave in patent offices where examination is deferred, including decisions to forego requests for examination in problematic or "hopeless" cases.[6] The same dynamic may drive applicant decisions in patent offices where search and substantive examination is conducted separately, and where requests for examination must be filed subsequent to receipt of a search report.[7]

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applications in which a request for examination has been made at the time of filing or prior to publication of the European Search report, but was later withdrawn or not confirmed.

[3] See the Trilateral Statistical Reports, 1996-2007, available at http://www.trilateral.net/tsr/.

[4] James Rogan, keynote remarks at ABA/IPL Summer Conference, Philadelphia, June 27, 2002 ("In Canada, they have a 5 year deferred examination. They have a dropout rate of about 35 percent. That means 35 percent of those files that the Canadian Patent Office receive, they never have to have their examiners yanked off the line to examine them when the thing isn't going anywhere. We estimate with an 18-month deferred examination, conservatively we estimate there will be a 10 percent dropout rate.").

[5] Application drop-out rates informally communicated to BIO were: about 28% for KIPO (2004); about 40% for GPTO; and about 30% for IP Australia. These numbers are subject to further verification.

[6] From a cross-jurisdictional perspective, deferred examination would generally seem to lead to an unequal distribution of examination burden between those patent offices that operate under deferred examination and those that do not, with deferred examination offices getting the benefit of earlier substantive examination of related cases in non-deferral jurisdictions. Notably, the U.S. has the highest rate of foreign-filed applications in the world, with close to 50% of applications filed by foreign nationals (compare Japan, where >80% of applications have domestic origin). It has been noted that the USPTO shoulders a disproportionate share of the international examination burden, especially since so many foreign patent offices defer their own search and examination while the USPTO proceeds with processing.

[7] Some foreign patent offices deliberately create an applicant decision point at the time a search report is issued. The UK IPO, for example, in its Patent Factsheet: Search Report, instructs applicants as follows: "Study the documents supplied with the Search Report carefully. You must then decide, in light of these documents, whether you wish to proceed with your application. If what you have invented is sufficiently different from what has been shown in these documents, you may decide to request substantive examination of your application (if you have not done so

More significantly, many applicants may over time determine that their application need not undergo substantive examination, [8] or that patent protection has become altogether unnecessary or unfeasible in light of commercial or technical developments. Additionally, applicants may not deem related cases pending in different jurisdictions to all be of equal commercial value. The enforceability and exclusionary force of issued patents, especially in the biomedical sector, varies widely across jurisdictions. The size of domestic markets, the market potential of inventions, and the presence of competitors likewise varies. Thus, applicants may be more inclined to request substantive examination and "fight for" even difficult applications in jurisdictions where patents are strong and the market potential for their inventions is huge, and less inclined to do so in jurisdictions where markets are small or patent enforceability is weak.

Accordingly, it is by no means clear which rate of examination drop-out the USPTO would experience if it were to implement an examination-on-request program. According to a 7 year-old USPTO estimate, an application drop-out rate of at least 10% would conservatively be expected under a relatively short 18-month deferral.[9] While BIO does not expect that an 18-month deferral period would be sufficient under today's conditions, updated modeling studies should be undertaken to account for current application load and examination capacity.

A putative deferred examination system in the USPTO is not free of concerns and should be explored cautiously

BIO believes that an examination-on-request program in the USPTO could significantly advance the USPTO's goals of quality, timeliness, cost-effectiveness and transparency if rationally designed and implemented. However, such a program could also be highly problematic if done wrong, and concerns that have been voiced must be given careful consideration. These concerns include possible further delays in eliminating poor-quality patent applications from the system[10]; a facilitation of "claim creep" and "waiting in the wings" by royalty-seeking applicants who, instead of actively pursuing issuance of a patent, wait and watch competitors' activities, and then shift or broaden claimed subject matter during prosecution to obtain patent coverage of a competitor's product; as well as potential additional uncertainty about freedom-to-operate for manufacturing or development businesses. While such concerns exist also under the current system, deferred examination might exacerbate the problem by making it easier and cheaper to simply keep an inactive application pending while watching competitor activities. Conversely, businesses faced with a potential freedom-to-operate problem

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already). If it is not, then you may decide to go no further with the application." http://www.ipo.gov.uk/factsearch.pdf

[8] For example, applicants may opt, instead of substantive examination, to "down-convert" to a utility model or other registered intellectual property instrument.

[9] James Rogan, ABA/IPL keynote remarks 2002, see above, note 4.

[10] Indeed, Jensen et al. found some empirical evidence in a 1990-1995 data set from the European and Japenese patent offices suggesting that patent applications that do not result in a patent grant after substantive examination are more likely to have been deferred for longer periods than successful applications. See Jensen et al., IPRIA Working Paper 01/08, available at: www.ipria.org/publications/wp/2008/IPRIAWP01.2008.pdf

would have to wait longer under a deferred examination regime before they can know whether the patent applicant will actually obtain a patent, and what the precise scope of that patent is.

Deferred examination could also, at least conceivably, create a disconnect between examining capacity and the examination queue, where USPTO resources would be underutilized during times of low backlog. Financial management issues for the USPTO could arise if fees were no longer front-loaded. In addition, some BIO members are concerned that a deferred examination system with a low threshold for initial application filings would lead to an increase of poor-quality filings, thereby triggering more public criticism of the patent system. Some BIO members would also be hesitant to abandon the long-standing goal of 18-month application pendency, and fear that deferred examination could undermine other efforts aimed at achieving this goal.

To account for such concerns, BIO believes that a number of questions would first need to be answered before implementation of a USPTO request-for examination program could be considered. First, it must be asked whether deferred examination would be likely or unlikely to contribute any patent uncertainty over and above that which is already built into the current U.S. patent system through various aspects of patent prosecution, including the *de facto* deferral of examination through long application pendencies. Second, many foreign patent systems have been operating under deferred examination systems for a long time, and it should be explored whether there is evidence that patent uncertainty and gaming of the system is any more pervasive there than it is in the United States.[11] Third, it should be explored whether certain safeguards that are built into foreign request-for-examination systems are effective at preventing abuses and suitable for incorporation into a putative examination-on-request program in the USPTO. For example, it is likely that mandatory publication of all applications would be necessary to ensure transparency and adequate public notice. Members of the public may also need to be given "activation rights," i.e., the right to seek patent certainty by requesting examination of pending applications.[12]

Concerns with deferred examination must be balanced against its potential benefits

While legitimate concerns would need to be addressed, BIO believes that a rationally designed examination-on-request system holds promise as a workload management tool for U.S. patent examination and could further facilitate US business' innovation and competitiveness by encouraging cost-effective patent prosecution. As described above, available information from examination-on-request systems in non-U.S. jurisdictions indicates that deferred examination

[11] As noted above, BIO members routinely seek patent protection under the request-for-examination systems of Japan, Canada, Korea, China, India, Australia, Germany, and other industrialized countries, and have not yet reported that deferred examination creates unmanageable uncertainties in the patent systems of these countries. Further input on this question is needed, however, because BIO's experience may not reflect the experience of patent applicants from other technology areas.

[12] Whether the costs for such third-party requests should be borne by the requestor, the applicant, or both would need to be resolved in ways that avoid, on the one hand, (i) unfair shifting of applicant costs to third-party requestors, and on the other hand (ii) frivolous third-party examination requests. Additional safeguards may be necessary to ensure potential abuses of a third-party activation right while ensuring its availability to legitimate requestors.

leads to a substantial reduction in patent applications undergoing substantive examination. Foreign patent offices experience significant numbers of withdrawals or abandonments by the time examination must be requested, with drop-out rates often reaching 20-30% or more. In its own study, the USPTO estimated that an 18-month deferred examination period in the U.S. would conservatively result in a 10% drop-out rate. While it is not clear which drop-out rate would result in the USPTO if it were to implement an examination-on-request process, a drop-out rate sufficient to positively impact the current USPTO backlog can reasonably be expected. It is undisputed that too many patent applications in the USPTO are today needlessly examined. For example, to BIO's knowledge more than 10% of all patent applications in the USPTO are today abandoned without any further response after receipt of a first office action. Presumably, for at least a part of these applications, there would have been no need for substantive examination. Under the current front-loaded U.S. examination system, however, drop-outs by patent applicants who have decided they no longer need a patent are rare, leading to inefficiencies in the Office and increasingly wasted examination time that could be avoided under an examination-on-request system.

BIO also submits that examination-on-request likely will lead to a more equal spread of examination burden internationally. Currently, the USPTO appears to shoulder a disproportionate share of the international examination burden, as most foreign patent offices defer their own search and examination while the USPTO does not. The USPTO today routinely examines applications at a time when foreign priority applications are still under deferral in the foreign office of first filing. This leads to an unequal examination burden between patent offices, exacerbated by the fact that the U.S. has one for the highest foreign-filing rates among the bigger, industrialized countries (for example, currently close to 50% of U.S. applications are of foreign origin, compared to approximately 20% in Japan). Accordingly, an examination-on-request process in the USPTO will operate to drive more examination work to the patent offices of first filing, thereby providing for more reciprocity between patent offices and allowing U.S. examiners to receive a more equitable benefit from the international search and examination work done among the key patent offices.

Another benefit of an examination-on-request process in the USPTO lies in the facilitation of ongoing international work sharing initiatives. At this time, the USPTO is actively engaged in a multilateral process with the European, Japanese, Chinese, Korean and other patent offices to standardize patent application formats, prior art databases, electronic file formats, the procedures for searching and examining patent applications, patent examiner training, and the patent classification system, amongst others. Yet the USPTO remains the only one of the Big Five patent examining authorities not operating under some form of examination-on-demand process. Even if ongoing standardization efforts create significant commonalities between the patent offices, significant international time lags in the examination of related applications will continue to exist if the USPTO continues to operate in a default examination system. An examination-on-request process in the USPTO would facilitate synchronization of patent searching and examination in key patent offices, thus creating additional efficiency gains from ongoing standardization and work sharing efforts.

As described above, examination-on-request also provides businesses with more prosecution flexibilities needed in light of long development and innovation cycles and the

realities of current patent application and prosecution in the USPTO. Many BIO members believe that an examination-on-request program in the USPTO would provide more time to evaluate the commercial feasibility of their early-stage inventions, to better synchronize patent prosecution with development, commercialization, and funding of their technologies, and to, over time, eliminate those claims or applications that have little or no commercial value.

Deferred examination should be seen as only a partial solution

BIO believes that examination-on-request, if rationally designed and implemented, is a partial solution in ensuring efficient, timely, and quality examination under a transparent system that provides applicants with needed prosecution flexibilities and that encourages open and constructive applicant-examiner interaction. Other steps may include more flexible hiring and compensation structures for examiners, more international work sharing, more flexible fee structures to better match applications with the resources needed to review them, changes in current examination policies in the USPTO, and more incentives for applicants to abandon applications that time has demonstrated do not need or would not benefit from substantive examination. BIO's views and proposals in pursuit of these goals were previously laid out in BIO's Open Letter to President-Elect Obama of December 17, 2008, available at http://www.bio.org/ip/domestic/BIO.PTOReform.pdf.

Conclusion

BIO believes that the potential benefits of a deferred, or request-for examination, process merit its inclusion in a broader public debate about future examination practices in the USPTO. Deferred examination cannot be discussed outside the context of other USPTO reform measures such as the ideas expressed in BIO's Open Letter – it cannot and should not be a "standalone" idea. BIO is optimistic that it may be possible to address continuing and valid concerns about deferred examination – some of which are expressed by its own members – through appropriate procedural safeguards that have already been subject of much discussion within BIO's membership. At any rate, the detailed elements of deferred examination would need to be worked out among all public stakeholders, including industry sectors whose business models and patenting needs are very different from biotechnology. BIO believes that the USPTO's February 12 Roundtable was a valuable and productive first step in that direction, and looks forward to participating in further public discourse on this important topic.

Respectfully submitted,

/s/

Tom DiLenge

General Counsel & Vice President

Legal & Intellectual Property