From:
Sent: Tuesday, June 01, 2010 7:55 PM
To: extended_missing_parts
Cc: Lila Feisee
Subject: Request for Comments: Proposed Change To Missing Parts Practice, 75 Fed. Reg. 63, 16,750-2

Dear Madam, Sir:
The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the USPTO's March 29 Request for Comments on proposed new flexibilities in missing parts practice, *see* 75 Fed. Reg. 63; 16,750-2. Please find attached our comments in MS-Word format.
Please don't hesitate to contact the undersigned with any questions regarding this matter.

Respectfully,

Hans Sauer

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Washington, D.C., June 1, 2010

The Hon. David Kappos
Under Secretary of Commerce;
Director of the USPTO

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

Via e-mail to extended_missing_parts@uspto.gov

Re: Request for Comments on Proposed Change To Missing Parts Practice, 75 Fed. Reg. 63, 16,750-2

Dear Under Secretary Kappos:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the USPTO's March 29 Request for Comments on proposed new flexibilities in missing parts practice, *see* 75 Fed. Reg. 63; 16,750-2.

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, and rely heavily on the patent system to protect the very large investments of time and resources that must be made to bring a biotechnology product from conception to market. 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 environmentally-beneficial products.

BIO welcomes the PTO's efforts to provide applicants with more flexibilities to control the timing of patent prosecution. In technologies that operate under a long development cycle - such as biotechnology - simple, inexpensive, and rationally designed processes for deferring patent examination could help applicants better coordinate patent prosecution with the slow and unpredictable pace of applied research and development. In instances where the commercial

viability of an invention is uncertain, added flexibility in prosecution timing could also facilitate a decision whether to pursue or abandon further efforts at obtaining patent protection. In its current front-loaded form, however, the U.S. patent prosecution process provides applicants with relatively few incentives to withdraw obsolete applications before a first office action on the merits is received. From an institutional perspective, this results in unnecessary search and examination work in the USPTO, and inefficient use of examination resources that could be better invested in other, more important patent applications.

BIO believes that initiatives aimed at providing applicants with more prosecution timing flexibilities should be assessed from the standpoints of (1) the applicant's interest in being better able to coordinate patent prosecution with parallel research, development, or marketing activities; (2) the public's interest in timely and accurate notice of patent rights sought; and (3) the USPTO's interest in effective workload management by facilitating more focused patent prosecution by applicants, and timely abandonment of obsolete applications. Some observations on these aspects are set forth below. Overall, however, it is not immediately apparent to BIO whether the PTO's proposed changes to the current missing parts practice would facilitate these goals in the biotechnology arts.

BIO members often express that they would benefit from more flexibilities to coordinate the timing of patent prosecution in the PTO with the slower pace of ongoing research and development of their inventions. In this regard, it is unclear whether the proposed additional 12 months to file a complete claimset would so significantly add to the existing arsenal of prosecution tools that it would be widely adopted by biotechnology companies. First, it should be noted that changes to the claims, and even whole substitute claimsets, can already be added by preliminary amendment under current practice. More importantly, it appears that the proposed changes would not add any flexibility to the actual timing of substantive examination, since the Federal Register notice points out that the nonprovisional application would be placed in the examination queue based on *its actual filing date,* (see *Id.,* at 16751, Col. 3). In other words, it seems that a late-perfected application would be taken up for search and examination in due course, no later or no sooner than other nonprovisional applications, irrespective of the date when it was perfected by paying the search, examination, and surcharge fees. BIO was therefore surprised to learn that the PTO intends to offset patent term adjustment for administrative PTO delays by debiting patent applicants who take advantage of the proposed changes to current missing parts practice. It is not understood why the PTO would want to penalize patent applicants who may wish to take advantage of the proposed program with subtractions from patent term adjustment, when "there would be no change made in the order in which applications are examined as a result of this proposal." (*Id*.) BIO believes that patent term adjustment debits would be a significant disincentive to the use of the proposed program by biotechnology applicants.

From a public notice perspective, it is equally difficult to predict the potential impact of the proposed changes. As noted by the PTO, currently in about 50% of all cases a provisional application expires without "follow-up" in the form of a nonprovisional application claiming its benefit. As an initial matter, the proposed program would thus seem to provide patent applicants with a simple and inexpensive opportunity to "defer" a decision about the scope of patent protection sought, or about pursuing patent protection at all, on an invention first disclosed in a

provisional patent application. Thus, it is possible that the proposed program could result in a substantial increase in the number of newly-filed nonprovisional patent applications that would not otherwise have been filed. Moreover, because the proposed program explicitly contemplates that the scope of claimed subject matter need not be decided until the missing parts are filed, one would expect that many such patent applications would be published with little indication of what the applicant actually claims as her or his invention. While BIO members understand from their own experience the difficulties inherent in drafting a claimset for technology that is still in the early stages of product development, there is value in incentivizing applicants to "do the best they can" in giving the public fair notice of the rights being sought. As with any process that permits deferred claiming, the interests of third party market participants in patent certainty and fair opportunities to assess freedom to operate should be accounted for.

To be sure, it may be possible that the proposed program could result in increased use of the 18 month publication system. Nonprovisional applications that would not otherwise have been filed would be published without exception, and at least some applicants who would ordinarily have filed complete applications with nonpublication requests might be enticed into filing incomplete applications that would result in additional patent application publications, thereby contributing to the body of patent literature. Whether or not the proposed changes would result in the filing of fewer nonpublication requests, however, is difficult to predict. Applicants who today choose to avoid 18 month publication of their applications presumably do so for reasons that are important enough to justify the extra cost and effort of filing a nonpublication request and foregoing the prospect of foreign patent protection. It is unclear whether such applicants would consider the benefits of the proposed changes to missing parts practice to be so significant as to outweigh their interest in nonpublication.

BIO members would additionally be interested to learn what impact the PTO expects the proposed program to have on its examination workload. As noted in the Federal Register notice, the proposed changes to current missing parts practice could result in the filing of additional nonprovisional applications that would not otherwise have been filed. In addition, at least some nonprovisional applications that would ordinarily have been filed in complete form would be expected to be filed with missing parts. Depending how many applications from both categories are perfected by the 12 month deadline, the result may well be a net growth of the PTO's examination docket. While this would not necessarily be a bad outcome *per se*, BIO would be interested in better understanding the proposed program's implications on the PTO's backlog reduction initiatives.

Finally, BIO notes that the USPTO held a public roundtable on deferred examination on February 12, 2009, at which BIO and a number of other stakeholders participated and subsequently filed comments analyzing the potential benefits and pitfalls of various deferred prosecution models, none of which discussed manipulations of the current missing parts practice. BIO's comments and detailed views on different deferral options are available at: http://www.bio.org/letters/20090529.pdf . In light of the PTO's currently-proposed changes to its notice to file missing parts practice, several BIO members have asked whether the Office has given further consideration to a system where applications would be subjected to substantive examination when requested by the applicant within a given time, optionally on an accelerated or deferred basis. BIO believes that 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. BIO also believes that a request-for-examination process would 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, thereby reducing the extent to which the Office currently carries a disproportional share of the international examination burden. 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 may permit more flexible production goals for patent examiners, providing additional time to evaluate more complex applications for which examination has been requested. Several BIO members have expressed their hope that the now-proposed changes to missing parts practice do not foreclose further discussion of a putative request-for-examination process which, if structured to properly balance the interests of applicants, the Office, and the public alike, could be an effective addition to the PTO's ongoing quality and workload reduction initiatives.

BIO looks forward to participating in further public discourse on this and other important PTO initiatives, and remains committed to assisting the Office in its ongoing efforts at pendency reduction, patent quality improvement, and outreach to the user community.

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Respectfully submitted,

/s/ Hans Sauer

Deputy General Counsel
Biotechnology Industry Organization