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May 18, 2000

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The Honorable Nick Godici
Commissioner for Patents
Box Comments - Patents
Washington, DC 20231

ATTN: Karin L. Tyson

Dear Commissioner Godici:

On behalf of the Biotechnology Industry Organization (BIO), I am pleased to offer these remarks in response to the request for comments on the Changes to Implement Patent Term Adjustments Under Twenty-Year Patent Term (65 FR 17215) published on March 31, 2000.

These proposed rules attempt to implement the patent term adjustments provided by Congress in the "American Inventors Protection Act of 1999" which compensates patentees for delays occurring during the application process. BIO believes that the proposed rules are, in the respects outlined here, inconsistent with the legislative intent of the Statute, and request modification of the proposed rules. We respectfully request the implementing regulations be modified accordingly.

The whole rationale for the patent term restoration provisions is to avoid an injustice whereby diligent applicants lose term under the 20-year regime caused by delays beyond their control. The economic benefits that the patent system is designed to generate are undermined if the patent term for inventions is reduced due to government actions beyond a patent applicant's control.

BIO was, as you know, intimately involved with the drafting and enactment of the term restoration provisions of the legislation. It is safe to say that no organization had more involvement with the drafting and enactment of these provisions than BIO and the provisions would not have been included in the legislation -- going back to the Moorhead bill in 1995-1997 -- but for BIO's involvement. The whole "chess clock" approach was proposed and drafted by BIO. We were also involved with the drafting of the committee reports and other legislative history regarding these provisions.

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In addition, BIO was the group that secured the inclusion in the GATT implementing legislation submitted in September 1994 under the Fast Track procedure of the restoration of term lost due to appeals to the Board of Appeals and Interferences and courts. These provisions would not have been included in the implementing legislation but for BIO's involvement.

Throughout the legislative history, the Committee on the Judiciary (the Committee) expressed its intention that the new law compensate diligent applicants who experience delays beyond their control during prosecution of their patent application. Any reduction of the patent term adjustment period was the outcome of the Committee's intent to prevent "the few applicants who engage in intentional or unjustifiable delay tactics" from abusing the system. H.R. Rep. No. 105-39, at 66 (1997). Hence, a "reasonable efforts" clause was included in 35 U.S.C. § 154(b)(2)(C) "to avoid the submarine patent problem." *Ibid.* The intent of the Committee was that "only the most egregious and obvious delay tactics will go unrewarded by this provision." *Ibid.* Additionally, the Committee stated that "there should be no time period where a diligent patent applicant may lose term for reasons beyond his or her control without an opportunity for compensation." *Ibid.*

Inconsistent with Congress' intent, the PTO has provided such strict examples in proposed Rule 37 C.F.R. § 1.704 for satisfying "reasonable efforts," that only a "perfect applicant" rather than a "diligent applicant" will obtain patent term adjustments greater than offsetting patent term reductions.

Sections § 1.704(c)(6)-(9) are particularly harsh. By failing to fulfill certain requirements, all of these sections calculate the patent term reduction from the initial filing date, regardless of when applicant is notified of a problem. Instead, BIO recommends that these sections be modified to reflect the action of a "diligent applicant" and thus calculate patent term reduction from the date that the applicant takes extensions of time to comply with the notice.

For example, upon examination of an application, the Examiner will frequently require the applicant to amend the title or the abstract to reflect the ultimately allowable claims. Such amendments may also be required when restriction of the claims and division of the application redirects the focus of each divisional application and if the Examiner believes that the amended title or abstract would better describe the invention claimed in the divisional. An applicant who has filed an application which contains the enumerated parts cannot know in advance whether a given Examiner will object to the title or the abstract upon examination of the application or how, if at all, the claims may be restricted. This is clearly a circumstance beyond the control of a diligent patent applicant. However, as written, proposed Section 1.704(c)(9), states that such post-filing amendments would result in reducing the period of adjustment of the patent term from the filing date to the date of compliance.

Similarly, if an applicant fails to file formal drawings or a sequence listing in compliance at the time of filing the application, the proposed rules require that the patent reduction be calculated from the time of filing to compliance. Thus, if the patent office fails

to act on a case for many years, and then determines that the drawings or the sequence listing is not in compliance, the diligent applicant will not be awarded any patent term adjustment because of the offsetting reduction.

The Federal Register Notice indicates that the "Office must require these items during its preexamination processing of an application to implement the pre-grant publication provisions...." Though this may be a valid reason for requiring the various parts of the application to be present at the time of filing, it does not justify penalizing diligent applicants, such as those described above, who may be required to or chose to amend the title, the abstract, or even the figures. Furthermore, an error in the sequence listing, when recognized and then diligently corrected, should not delay the pre-grant publication process. Generally, the patent term should be reduced only during the time taken for extensions of time to bring the application in full compliance; in those few cases where the record clearly shows that amending a figure or resubmitting multiple sequence listings delays substantive examination, the patent term should be reduced from the time the applicant is notified of the problem to the time that the application is brought into compliance.

Of course there may be a "few applicants who engage in intentional or unjustifiable delay tactics," and thus abuse the system. However, Congress has made it clear that "only the most egregious and obvious delay tactics will go unrewarded" by patent term adjustments. Thus, BIO believes that reducing the period of adjustment of patent term as proposed would defeat the purpose of the newly enacted Statute. BIO believes that it would be more reasonable to calculate the reduction of period of adjustment of the patent term in Sections 1.704(c)(6)-(9) for the time that applicants rely on extensions of time to bring the application into compliance.

Additionally, Section 1.704(c)(12) states that if applicant files a supplemental paper, any patent term adjustment will be reduced by the number of days between the initial and the supplemental filing. Thus, if a diligent applicant files a supplemental IDS within three months of learning of the reference (e.g., under 1.97(c)(1)), the applicant will still be penalized by the reduction in patent term adjustments. The citation of references in corresponding foreign applications is clearly beyond the control of a diligent applicant, and thus should not be used when calculating patent term reductions. BIO recommends that proposed Section 1.704(c)(12) be modified to exclude the filing of a supplemental IDS under Rule 1.97(c)(1) and (d).

In conclusion, the Committee directed the PTO to avoid viewing the language of the Statute in a mechanistic way. H.R. Rep. No. 105-39, at 66-67 (1997). In an analogous situation, the Committee warned the PTO from arbitrarily denying any term adjustment in cases that have emerged part victorious from interferences or appeals simply because an application was not immediately ready for patent grant following an action by the Board or the Court. The Committee's advice is equally applicable to amendments to the specification, title, abstract, figures, and sequence listing or the filing of a supplemental IDS under Rule 1.97(c)(1) and (d). As the Committee has urged, the PTO should look carefully at the substance of each particular case. *Ibid.* The proposed rules arbitrarily denies a diligent applicant who has used all reasonable effort to conclude processing or examination of the

application. Hence, it fails to help implement the Statute as intended by the Congress.

We urge the PTO to modify the proposed rules to reflect more fairly the legislative intent of this statute and provide the full patent term restoration contemplated by the Congress.

We very much appreciate the PTO's support during the arduous legislative process that led to the enactment of the term restoration provisions. We now seek to work with the PTO to issue implementing regulations that ensure that the injustices that the term restoration provisions are drafted to avoid are, in fact, avoided.

Sincerely,



Charles E. Ludlam
Vice President for Government Relations

CC: Q. Todd Dickson
Edward Kazenske
Steve Kunin
Bob Stoll
John Doll



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January 31, 2000

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The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce
Commissioner of Patents and Trademarks
906 Crystal Park 2
Washington, DC 20231

Dear Todd:

1999 was a great year for the PTO and the biotechnology industry. The Congress finally passed American Inventors Protection Act of 1999 and you were confirmed as the Commissioner who will ensure its full implementation!

Thank you for including us in the meeting to discuss implementation of the Act. The invitation was yet another example of your continuing commitment to facilitating communication between industry and the PTO. In the spirit of that meeting, and after discussion among our members, we at BIO wish to express our views regarding implementation of the patent reform legislation, focusing on possible pitfalls to avoid when the PTO publishes its draft guidelines and regulations. We will also, of course, submit comments in response to the publication.

The "Patent Term Guarantee Act of 1999" (a subtitle of the American Inventors Protection Act) guarantees the patent applicant a day-for-day addition to the patent term for each day the Patent and Trademark Office fails to meet certain examination deadlines; for each day of pendency of the application beyond three years; and for delays in issuance arising because of interferences, secrecy orders and appellate review by the Board of Patent Appeals and Interferences or by a federal court. See 35 U.S.C. §154 (b) (1) (A), (B) and (C).¹ The days added to the patent term under this section are, however, to be reduced by the amount of time the applicant "failed to engage in reasonable efforts to conclude prosecution of the application." See 35 U.S.C. §154 (b) (2) (C) (i).

The new statute, which represents a significant amendment to 35 U.S.C. §154 (b), imposes on the Director two requirements to engage in rulemaking relevant to implementation of the statutory scheme for determining patent term. One is to prescribe "regulations establishing the circumstances that constitute a failure

¹ Unless otherwise indicated, reference to 35 U.S.C. 154 (b) is to the statute as amended.

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of an applicant to engage in reasonable efforts to conclude processing or examination of an application." See 35 U.S.C. §154 (b) (2) (C) (iii). The other is to prescribe regulations that establish "procedures for the application for and determination of patent term adjustments" under 35 U.S.C. §154 (b) (3). See 35 U.S.C. §154 (b) (3) (A).

The membership of BIO is keenly interested in the outcome of this rule-making activity because of its importance to the proper implementation of the statute. In that regard, statistics have shown that applications for patents on biotechnology inventions have the longest pendency in the PTO, and, therefore, are the most likely to suffer term erosion under 35 U.S.C. §154 (b) before amendment. Accordingly, we respectfully request that the following observations and suggestions be considered in the drafting of the regulatory framework required by the statute.

We believe the most difficult rule-making burden will be to clearly and fairly establish guidelines under which the efforts of an applicant will be judged to determine whether they were reasonable with respect to concluding prosecution or examination of an application. Part of that difficulty will be to set guidelines which can be applied objectively. Additional difficulty may arise because of ambiguity in the statute itself.

In almost all cases, each action required in the prosecution of a patent application must be accomplished within a time period set by statute and/or regulation. The most important of these is the period in which an applicant must respond to an office action on the merits of a claim. Currently this is set at three months under a statutory scheme that permits the Director to prescribe a time for response, which cannot be less than thirty days or more than six months. See 35 U.S.C. §133.

BIO's suggestions are, therefore, based on three premises. One is that none of the response times now imposed on applicants will be shortened; the second is that responses within the established time periods will be deemed reasonable; and the third is that responses beyond the established time period will be only *prima facie* unreasonable, i.e., will be subject to a showing that, even though a response is filed after the time set for it, that the efforts by the applicant were nevertheless reasonable.

POSSIBLE STATUTORY AMBIGUITIES

As noted earlier, we believe the statute has several ambiguities which complicate the drafting of regulations which are to be used to determine whether an applicant's efforts are reasonable or not. The least of these is probably the use of the phrase "processing or examination" in 35 U.S.C. §154 (b) (2) (C) (ii) and (iii) in light of the term "prosecution" in 35 U.S.C. §154 (b) (2) (C) (i). We believe the phrase "processing or examination" means the same thing as "prosecution."

More difficult to determine is whether there is a single standard to be applied to conduct of an applicant in all cases. The general standard seems to be "reasonable efforts" since it is used in 35 U.S.C. §154 (b) (2) (C) (i)-(iii), even though the showing under 35 U.S.C.

§154 (b) (3) (C) applicable to certain adjustments under 35 U.S.C. §154 (b) (2) (C) is that "in spite of all due care the applicant was unable to respond" (emphasis added).

Because the obligation of an applicant to engage in "reasonable efforts" to conclude prosecution is applicable to all adjustments made under 35 U.S.C. §154 (b) (1) by reason of 35 U.S.C. §154 (b) (2) (C) (i), we believe the standard of "all due care" in 35 U.S.C. §154 (b) (3) (C) must be read to mean the same as "reasonable efforts" and not to be a more rigorous standard.

THE STANDARD OF REASONABLE CARE IS MORE LIBERAL THAN THE PRIOR STANDARD

BIO believes the statute to be remedial in nature in that the intention of Congress was to prevent the erosion of patent term by more than three years unless the applicant is dilatory. To achieve this end, the statute should be applied in a manner which would not defeat the legislative intent. In that regard, the standard by which an applicant's conduct under old 35 U.S.C. §154 (b) was judged was one of "due diligence." That standard has clearly been abandoned, properly we think, in favor of a more liberal standard, i.e., "reasonable efforts." Accordingly, the mere fact that an applicant could have responded in the period set for response by a single minded attention to the application in question which might be required by a due diligence standard, should not be the standard of what constitutes reasonable efforts to conclude prosecution.

Among the situations which the regulation should excuse without penalty are:

- (1) Filing of responses after three months accompanied by a submission under the procedures of 37 CFR 1.132 where reasonable efforts to prepare the submission are shown.
- (2) Periods of time when the applicant's attorney is engaged in *inter partes* matters relating to pending lawsuits and interferences and other matters on his/her professional calendar which are appropriately given priority.
- (3) Illness, vacations of reasonable length, and other appropriate reasons for non attention to an application that occur in the everyday life of applicants and attorneys.
- (4) Time consumed in communications between the applicant, the applicant's foreign agent and the applicant's U.S. representative when the applicant does not reside in the United States.

THE PROCESS OF DETERMINING ADJUSTMENTS

The statute, we think, gives the Director broad authority to determine how to calculate negative adjustments to patent term because of an applicant's failure to use reasonable efforts. The only provision in the statute relating to an applicant's participation in the process is an entitlement to one request for reconsideration of the Director's

determination of term set in the notice of allowance. See 35 U.S.C. §154 (b) (3) (B) (ii). BIO believes this request should be by petition to the Director under 37 CFR 1.181 and handled by someone with special knowledge of the statutory burdens imposed on an applicant.

Although the statute is silent on other aspects of the applicant's role, we suggest that, prior to the Director's determination, the applicant be given the opportunity to make a showing of the facts which constitute reasonable efforts by the applicant to timely respond whenever a response is made outside the time limit set by the PTO. This could be done by the applicant on a document separate from the response or be part of the response itself. This would enable to examiner to make a preliminary determination of the reasonableness of an applicant's efforts before the determination of patent term set forth in the notice of allowance is made. If persuaded that the efforts of the applicant have been reasonable, a petition for reconsideration would be unnecessary, thereby reducing the burden on both the applicant and the Office.

NATURE OF THE FACTUAL SHOWING

If the regulatory scheme for evaluating an applicant's performance under the reasonable effort standard of the statute is not to become excessively burdensome, it should not require extensive factual showings under oath or by declaration. BIO recommends that the applicant be permitted to set forth a brief summary of the facts which are believed to apply to the determination of whether the efforts are reasonable. If done by the applicant's representative, the summary could be accompanied by a certification that the facts enumerated were determined by a review of the representative's records or upon reasonable inquiry of the applicant or others involved in the prosecution with respect to their efforts. It is not expected that such a summary would, in length, exceed a few sentences.

OTHER CONCERNS

Additional ambiguities exist in the Patent Term Guarantee Act. For example, the Act states that the patent applicant will receive a Notice of Patent Extension along with the Notice of Allowance. How then will applicant be subsequently notified of any additional patent extensions due to PTO delay in issuing the application?

Moreover, we recommend that the PTO explicitly state that the language "shall apply to any application" or "shall apply to all applications" of S. 1948, 106th Cong. §§ 4405, 4508, and 4807 (1999)(enacted) includes continuations, divisionals, CIPs and CPAs. Support for this interpretation exists by comparing the language "shall apply to any patent that issues from an original application" of S. 1948, 106th Cong. § 4608 (1999)(enacted), which would only apply to new applications.

We believe that the Act requires that only the specification and the original claims publish at 18 months. Moreover, we believe that the Act requires that the 102(e) prior art provision only apply to subject matter described in the published application.

Additionally, if the published application claims priority to an earlier application, the Act requires that the 102(e) date extend only to common subject matter that publishes. Thus, subject matter included in a priority document which is not described in the published application would not receive a 102(e) date. We also believe that the Act allows applicants to add a claim to priority, even if the 18 month date has passed, as long as applicants failed to initially claim priority in good faith. We suggest that the PTO provide explicit regulations on these issues.

Todd, we thank you for your leadership on this legislation, and look forward to commenting formally on the published guidelines and regulations to implement it. We are always ready to support the PTO and find common ground on a range of issues and projects. We consistently find that your agency and staff provide the most professional service in the Administration.

Sincerely,



Chuck Ludlam
Vice President,
Government Relations

CC: Bob Stoll
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