The Comments of the

Biotechnology Industry Organization

on the

United States Patent & Trademark Office

Proposed Rules Changes Concerning

Continuation Practice and Claim Limitations

May 2, 2006

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BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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BY ELECTRONIC MAIL and COURIER

BY ELECTRONIC MAIL to AB93COMMENTS@USPTO.GOV

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

Attention: Robert W. Bahr

Comments to Notice of Proposed Rulemaking Entitled: *Changes To Practice for Continuing Applications, Requests for Continuing Examination Practice, and Applications containing Patentable Indistinct Claims*

Dear Mr. Bahr:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the PTO's proposed *Changes to Practice for the Examination of Claims In Patent Applications,* 71 FR 61 (Jan. 3, 2006), and *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims,* 71 FR 48 (Jan. 3, 2006). BIO is an industry organization with a membership of more than 1,100 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 United States leads the world in biotechnology research and development. The biotechnology industry, fueled by the strength of the U.S. patent system, has provided jobs for over 200,000 people in the United States, generated hundreds of drug products, medical diagnostic tests, biotech crops, and environmental products. In the healthcare sector alone, the industry has developed and commercialized over 300 biotechnology drugs and diagnostics; and there are over 370 products in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land water and nutrients and increasing farm income. Biotechnology innovation has the potential to provide treatments for some of the worlds most intractable diseases and address some of the most pressing challenges facing our society today.

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The United States patent system is designed to spur innovation and encourage research and development of new products and services for the benefit of society. Particularly in the biotechnology sector, innovation protected by strong, predictable patents catalyzes investment and growth. Jobs are created and society benefits from both the availability of new products, services or treatments and the economic opportunities surrounding these new discoveries. The ability of applicants to file continuation applications provides applicants the opportunity to obtain protection for the entirety of their inventions. Many life-saving, cutting-edge products and technologies were developed as a result of the flexibilities in the U.S. patent system to file continuation applications.

PTO's proposed rule changes will adversely impact innovation, especially in the biotechnology sector, by inhibiting the ability of innovators to obtain adequate coverage on their inventions and to attract financing for products that often take a relatively long time to reach the marketplace. The PTO's proposed rules are intended to address application pendency and backlog, patent quality, and to address the issue of delayed public notice of intellectual property rights.[1] Instead of addressing these concerns however, these rules if adopted will increase both backlog and pendency and create negative unintended consequences for the U.S. patent system.

Because the proposed rules packages are related, BIO will address concerns with both of them in this document.

Patents and Biotechnology

Perhaps no other industry is as dependent upon patents as is the biotechnology industry. It is not uncommon for a biotechnology company to expend hundreds of millions of dollars and work for more than a decade before reaping its first dollar of product revenue. In large part, 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.

The early stages of biotechnology product development are most vulnerable to perturbations in the capital markets. At these early stages a patented idea can and must generate the interest of investors, entrepreneurs, and corporate partners. Among other factors, investors in the biotechnology sector look to a robust patent portfolio before funding the development of a particular technology. Piece-meal patent protection on risky biotechnology inventions such as that likely to result from implementation of the PTO's proposed rules will discourage investors from investing in such inventions. Without capital investment, biotechnology R&D will decrease and promising technologies will not be developed. The certainty that comes from knowing an invention discovered 10-15 years prior to coming to market can be protected provides the incentive for investors to fund high risk, long-term biotechnology products. And the strength and

[1]See for example, 71 FR 48-49 (page 48 right column, page 49 center column).

scope of biotechnology patents provides investors the assurance that their investments may some day be recouped.

Thus far the flexibility of the current patent system and the ability of patent applicants to protect the full scope of their inventions through the filing of continuations has spurred the growth and expansion of the biotechnology industry. The dramatic proposals in the PTO's proposed rule packages would frustrate this growth and expansion. The U.S. biotechnology business sector has often been touted as an economic powerhouse driving the U.S. economy. It is all but certain that the proposed new rules will negatively impact this powerhouse, potentially having a disastrous trickle-down effect on the U.S. economy and ultimately the public who stand to benefit from biotechnology innovation.

Continuations and Biotechnology

Biotechnology Companies File Early and Often

Because of intense competition for capital investments, biotechnology companies are pressured to file patent applications early and often to protect both the initial concepts of their discoveries and additional practical embodiments supported by the applications. Many of these companies begin as spin-offs from initial discoveries made within an academic setting. The early years of new biotechnology companies are unstable and uncertain. Attracting investors to these high-risk ventures is difficult. However, investors are continually drawn to such companies because of the potential for high returns realized upon the discovery, development and successful marketing and/or licensing of an effective treatment or valuable product. This competitive pressure drives smaller biotechnology companies to file patent applications on inventions early in the development stage so that they may obtain that first patent to generate investor interest and to meet milestone markers established by investors. Consequently, biotechnology companies file patent applications years before a product or technology has been fully developed or commercialized. During this time, they may agree to initial narrow patents and continue to perform "proof of concept" experiments to further support their initial discovery. With the initial patent in hand, patent owners can point to other pending applications (continuations) that are broader and more comprehensive to secure further investor interest. While biotechnology patent applicants expect and often are entitled to broader claim coverage without additional information, they may not expend the resources to obtain a broader claim unless the area becomes an area of commercial focus.

As an example, while a company may have contemplated and claimed a product for human use (or a method of treatment in humans) the company may not have had human clinical data at the time of filing. In general, such companies file patent applications based on promising animal and/or *in vitro* data while fully appreciating utility in humans. It is not uncommon for biotechnology patent applicants to have to submit additional empirical evidence during prosecution. The PTO generally requires correlative evidence for patent claims to human use. Sometimes this evidence can only come in the form of clinical data which can take years to obtain. Most patent applicants do not commence these costly experiments until the need for such work becomes clear which is usually well

into the prosecution of an application. This circumstance and the time required to conduct such experiments often requires applicants to file continuation applications. Further, obtaining substantive consideration of such experiments by patent examiners often requires the filing of continuations because of the PTO's restrictive "after final" practice. Absent the opportunity to file continuation applications, a biotechnology company may be forced to accept protection on less than it had a right to protect, i.e., the invention in its entirety. In such a case, frequently, the only way a company will be able to protect the entire invention is by filing multiple stand-alone applications and paying significantly more in filing and prosecution costs. As described above, biotechnology patent applications are often filed very early in the discovery process. Frequently, during the time period between initial filing and first examination on the merits, experimentation to confirm the value of the disclosed invention continues, and investor relations are in flux.

Some resource-limited biotechnology companies may be forced to put their inventions into the public domain or turn to trade secrets as an option to protect their intellectual property. Without protection on commercially useful technologies, investors would not invest into the further development of such technologies. Consequently, promising technologies would simply languish on the laboratory shelves and gather dust.

Continuation Practice is a Legitimate Business Practice

The use of continuation applications to obtain patent protection is a legitimate business practice for biotechnology companies. In the biotechnology patenting process, the commercial aspects of a particular invention may be modified over time based on the needs of potential financial partners. A small company working on a licensing agreement may change the focus of the invention based on the needs of the licensee. For example a company may decide to seek a product claim rather than a process claim or narrow the scope of its claims, all of which are supported in the original application. This ability to obtain financial support may well depend upon the existence of a continuation application, one in which the claim form of interest to the investor or potential partner can be crafted.

Continuation Practice Helps to Rectify PTO Errors

In addition to serving as a legitimate means of obtaining adequate protection for biotechnology inventions, continuations are a means to correct PTO errors. Biotechnology inventions are complex. Because of this, it can sometimes take years and multiple rounds of patent prosecution before the PTO examiner fully understands the invention and is convinced of its merits. Thus, the sheer complexity of these cases often times necessitates multiple rounds of prosecutions provided through continuation filings. Such problems can be exacerbated by the high examiner turnover rate, where a new examiner may not have sufficient time to become familiar with inventions in pending applications.

Other Factors Necessitating Continuation Practice

Other factors beyond the control of the applicant also lead to the filing of continuation applications. Case law in the biotechnology area continues to evolve. New discoveries, followed by patent applications, often lead to unprecedented decisions in the federal court system. Such decisions have a rippling effect throughout the field, leading to immediate changes in intellectual property strategy decisions made by biotechnology companies. In some instances, the only possible response to a new court decision is to file continuations to further prosecute/amend claims to avoid potentially negative impact from such decisions. Small biotechnology companies are especially sensitive to such changes in case law, even if the changes are minor, since so much of their success depends on the value of their intellectual property. To stay competitive and to maintain interest of investors, small biotechnology companies will often file continuation applications to maintain protection of their intellectual property in response to uncertainty in the law and/or adverse court decisions.

An additional variable facing biotechnology companies is the unpredictable nature of prior art searching. It is common for an examiner or an applicant to find previously un-cited prior art after substantive prosecution has begun. The number of scientific journals published worldwide is large and increasing at a rapid pace. It is the nature of the scientific process to place a high priority on the dissemination of research results. Such dissemination precludes the possibility of redundant research and fuels the competitive advantage held by laboratories that publish first. This drive to publish empirical findings has created an equal drive to increase the number of outlets available for scientists to publish their findings around the world. With the rapid increase in the quantity of publications, and minimal resources available to search through them, especially to new biotechnology companies, it is not surprising that additional prior art may be discovered at any stage in prosecution. Again, to maintain optimum flexibility and to maintain the interest of investors, biotechnology companies need to be able to respond to such events rapidly. One common and effective means of response is the filing of a continuation containing new references material to examination and, if necessary, narrowing the claims in view of the new references.

BIO's Concerns with the PTO's Proposed Rules

The Proposed Changes to the Rules will Increase Costs and Uncertainty

The proposed rule changes disproportionately impact biotechnology companies,[2] especially smaller biotechnology companies battling fierce competition to attract critical funding while at the same time striving to adequately protect their inventions. The protection provided by initial patents to smaller, newer biotechnology companies are often their most valuable assets and the "gold" standard by which venture capitalists evaluate investment candidates. The proposed changes to the continuation rules will

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[2] *See e.g.*, U.S.P.T.O. slide presentation at Chicago Town Hall Meeting on Proposed Rule Changes to Improve Patent Examination (Feb. 1, 2006); slide available on the U.S.P.T.O. internet website *at*: http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/chicagoslides.ppt#18 (last viewed May 1, 2006)(showing that inventors with applications pending in Art Unit 1600 rely on continuation applications at significantly higher rates than applicants in other technology areas).

result in substantial and immediate increased costs to companies seeking to obtain patent protection.[3] These changes favor larger companies over smaller, newer start-up companies because of the heavy dependence small companies have on obtaining an initial patent to bring in investor funds.

In addition, the cost of obtaining patent protection will dramatically increase as a result of the proposals to limit the number of claims that will be initially examined. Applicants' representatives will be required to contact applicants and request instructions as to claim designation and to discuss prosecution strategies in light of the new changes. Resulting decisions then must be communicated to the PTO for processing before examination starts. If an applicant does not designate 10 claims, then only independent claims will be initially examined. These burdens are further compounded by the PTO's proposal to make these rules changes retroactive. BIO conservatively estimates that their retroactivity will cost applicants between $100 million to $120 million to designate 10 claims in applications currently pending before the PTO.[4]

Further, the PTO proposals will increase the degree of uncertainty for patent applicants, as these rule changes are likely to be challenged in the courts. During the period of uncertainty, while the legal system decides the fate of these rules, applicants will be required to follow the rules (or forgo obtaining patents), frequently resulting in patents of lesser value.[5] Such devaluation could cripple smaller biotechnology companies in their ability to obtain financing.

The PTO's Proposed Rules are Unfairly Retroactive

The retroactivity of the proposed rules is particularly disturbing as it unfairly penalizes applicants with pending applications.[6] If a continuing application is already pending before the PTO, a second continuing application would be prohibited without the granting of a petition. The PTO states that approximately 1/3 of the applications filed last year were continuing applications or requests for continuing applications.[7] Thus, these proposed rule changes would affect over 133,000 applications.[8] In these cases, the applicants would be prohibited from filing any continuing applications without the granting of a petition and without notice. The PTO states that applicants would be

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[3] The proposed rules changes will require applicants who file multiple applications with a common inventor, within a two month period, and having overlapping disclosures to show the PTO how the application claims are patentably distinct or submit terminal disclaimers and justify to the PTO why the applications should be maintained. Furthermore, applicants will be required to file all related applications together since serial continuation applications will be abolished.

[4] The retroactive aspect of the proposed rules changes will cost attorneys and their clients time and money to review over 600,000 applications on file today at the PTO to determine which claims are representative claims to be designated for examination and to discuss other patenting strategies. At a modest cost of $200 per application this alone will cost industry $120 million dollars.

[5] In the event that the proposed rules changes are put into effect and eventually reversed, it could result in a "bubble" of weak and/or narrow patents.

[6] See, *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 216 (1988).

[7] *See*, 71 FR 48, 50 (Jan. 3, 2006).

[8] *Ibid.*

allowed four "bites of the apple."[9] Assuming this is true; those four "bites" may have been taken unwittingly prior to the rules changes having taken effect. Additionally, the proposed claim limits would be applied to any unexamined application pending at the PTO at the time the rules changes are adopted. Thus the retroactivity of both rules packages would deprive applicants of timely notice of the rules and the option to choose a different patent strategy.

The PTO Rationale for These Proposals Should be Revisited

The PTO's rationale for the proposed rule changes includes its backlog and rare cases of abuse of the system. The proposed solutions are draconian and will not accomplish PTO's objectives. The PTO cites the number of second or subsequent continuations as being approximately 21,800. This equals 6.9% of all filings (21,800/317,000).[10] It is unclear to BIO how an about 7% decrease in applications would significantly decrease pendency, particularly since continuations are the most easily examined. Instead, rather than helping the PTO with its workload, the proposals only serve to disproportionately penalize the biotechnology sector and small entities. [11] Indeed the Small Business Administration's Office of Advocacy has concluded that the PTO's proposals would have a significant economic impact on small entities seeking patents. Moreover, they concluded that "the proposed regulations would significantly impact the most valuable and commercially viable patents, because those types of patents typically involved a high number of continuations."[12] As mentioned above, in the biotechnology sector, the continuation application practice is utilized to respond to legitimate business concerns that arise during the development of the discovery. Testing and clinical trials proceed throughout prosecution, and biotechnology applicants need to be able to respond by obtaining additional protection of intellectual property through the use of continuation applications. This process is not "abuse" of the patent system - this is a fact of the inventive cycle integral to the biotechnology industry.

According to the PTO, limiting the number of claims examined per application will "allow the Office to do a better, more thorough and reliable examination since the number of claims receiving initial examination will be at a level which can be more effectively evaluated by an examiner."[13] However, fewer claims do not necessarily provide for a "better, more thorough and reliable" examination. Such improved examination requires a well-trained, knowledgeable examining corps, along with the appropriate tools and adequate time in which to examine. Without the examination of a range of claims from broad to narrow, the appropriate amount of time and the appropriate training, it is less likely that examiners will be able to indicate allowable subject matter early in the prosecution. In fact, more claims, encompassing additional specific embodiments help to define the invention, in many cases allows examiners to better understand the subject matter sought to be protected. In addition, the imposition of these

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[9] *Ibid* at 53.
[10] *See*, 71 FR 48, 50 (Jan. 3, 2006).
[11] Over 600 BIO members fall into the small entity category as defined by the M.P.E.P.
[12] *See,* SBA Office of Advocacy, Comments *Re: Changes to Practice for the Examination of Claims in Patent Applications....Changes to practice for Continuing Applications.....*, (April 27, 2006) (page 3).
[13] *See,* 71 FR 61, 61 (Jan. 3, 2006) (column 3).

rule changes may likely yield **more** first continuing applications as applicants attempt to present amended claims of appropriate scope.

The Proposed Rules to Limit Continuations will not Achieve the Objective of Expediting Public Notice

Another rationale provided by the PTO for limiting second and subsequent continuing application filing is to provide expeditious public notice. The PTO states that "...the possible issuance of multiple patents arising from such a process tends to defeat the public notice function of claims in the initial application."[14] The PTO also asserts that "...when the continued examination process fails to reach a final resolution, and when multiple applications containing claims to patentably indistinct inventions are filed, the public is left uncertain as to what the set of patents resulting from the initial application will cover."[15] Although providing expedited public notice of patent rights is a laudable goal, the proposed rules will not promote more efficient public notice of intellectual property rights than the current rules. Moreover, the PTO's interest in expediting public notice of patent rights should not come at the expense of denying applicants the opportunity to fully prosecute the intellectual property rights to which they are statutorily entitled.

As an initial matter, the public notice function is currently adequately fulfilled by the PTO through the adoption of the PTO's 18-month publication requirements in most applications. Moreover, Congress is currently considering legislation that will expand this publication requirement to all applications.[16] In addition, the PTO fulfills its public notice function by providing the public with the ability to check the status of all published pending or issued patent applications, including continuation and divisional applications, via the Office's public internet PAIR system.[17]

Limiting continuing applications will not expedite public notice of issued claims because this limitation will inevitably lead to increased numbers of appeals filed and awaiting review. Under the current system when an applicant receives an allowance of some claims, but not all, the applicant can accept the allowance and file a continuation application in which to convince the examiner regarding his/her entitlement to the remaining claims. Under the proposed rules, an applicant who has not received an allowance of all claims to which he/she is entitled will have few alternatives except to appeal the examiner's rejection. Thus, the delay imposed by the appeals procedure will nullify the desired effect of expediting public notice via limitations on continuation applications. As such, the proposed rules to limit continuation applications will not provide improved or expedited public notice over the current system which permits applicants to publicly monitor the status of all published, pending and issued applications throughout the statutorily limited 20 year term.

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[14] 71 FR 48, 48.
[15] 71 FR 48, 49.
[16] HR 2795 (June, 2005) and HR 5096 (April, 2006).
[17] *See*, http://portal.uspto.gov/external/portal/pair.

PTO Authority to Make the Proposed Changes is Questionable

BIO questions whether the proposed rule changes are legal. The Director of the PTO has the authority to "...establish regulations not inconsistent with law..."[18] However 35 U.S.C. §§ 120, 121, and 365(c) provide for the filing of continuing applications with "the same effect" or benefit of the earlier application.[19] As acknowledged by the PTO,[20] judicial precedent indicates that the PTO does not have the authority to place limits on the number of continuing applications.[21]

The PTO Director "shall cause an examination to be made of the application," [22] and must prescribe regulations "to provide for the continued examination of applications at the request of the applicant."[23] To limit continued examination does not appear legally permissible or within the spirit of the laws promulgated by Congress.

One argument advanced by the PTO for limiting continuation practice is that it is somehow improper for an applicant to claim in a continuation a competitor's product or method. However, the courts have ruled differently. See, for example, *Kingsdown Med. Cons. Ltd. v. Hollister, Inc.* 863 F.2d 867, 9 USPQ2d 1384 (Fed. Cir. 1988) which states "that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product that the applicant's attorney has learned about during prosecution of a patent application." [24]

It is also unclear whether the PTO has the statutory authority to create a presumption of unpatentability based on double patenting without examination. The PTO has the initial burden to establish a *prima facie* case of unpatentability.[25] The proposed rules would

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[18] 35 U.S.C. §§ 120, 121, and 365(c).

[19] 35 U.S.C. § 2(b)(2) ("Powers and duties. (b) SPECIFIC POWERS.— The Office— (2) may establish regulations, not inconsistent with law, which— (A) shall govern the conduct of proceedings in the Office; (B) shall be made in accordance with section 553 of title 5; (C) shall facilitate and expedite the processing of patent applications ...")

[20] 71 FR 48, 50 (January 3, 2006), citing *In re Hogan* 559 F.2d 595 (CCPA 1977), and *In re Henriksen*, 399 F.2d 253 (CCPA 1968) and stating that the "Office does not attempt that here. No limit is placed on the number of continuing applications. Rather, applicants are required to show that later-filed applications in a multiple-continuing chain are necessary to claim the invention – and do not contain unnecessarily delayed evidence, arguments, or amendments that could have been presented earlier."

[21] *See In re Henriksen,* 399 F.2d 253 (CCPA 1968).

[22] 35 U.S.C. § 131.

[23] 35 U.S.C. § 132.

[24] Kingstown at 874.

[25] 35 U.S.C. § 131. Examination of application

"The Director ***shall cause an examination to be made*** of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." (emphasis added).

allow the PTO to make a patentability determination under proposed § 1.78.(f)(2) without examination of a single claim. Under § 1.78.(f)(2) a rebuttable presumption of patentability would be created for indistinct claims in two or more applications that: (1) are filed on the same date; (2) name at least one inventor in common; (3) are owned by the same person; and (4) contain substantially overlapping disclosures. This flies in the face of the PTO's obligation under 35 U.S.C. §§ 131 and 132 to examine patent claims and to notify applicant of its examining rationale.[26] Likewise, the PTO may lack authority to refuse to examine claims because there are too many, in its view, or contain too many alternatives.[27]

The Proposed Rules are Exacerbated by PTO's Restriction Practice

Prohibition on the filing of serial divisional applications would also have a negative impact on both applicants and the PTO. The requirement to file all possible divisional patent applications in parallel would impose a burden on the biotechnology art units at the PTO with a significant increase in filings and will discriminate against biotechnology inventions. Further, due to the cost, small companies are likely to forego protection of some of the claimed inventions. Such a requirement is not needed with 20 year term from filing and 18 months' publication.

Currently, restriction practice is burdensome and oftentimes not supported by law. It is not uncommon for the PTO to require the restriction of alternatives cited in independent claims, or require restriction and species election in place of unity determinations in applications filed under 35 U.S.C. § 371. Thus, to obtain the best protection of intellectual property, biotechnology companies are often forced to file multiple divisional applications. However, today they can file these divisional applications serially and avoid a heavy financial burden—one many companies cannot bear. The proposed changes would require them to be filed together. A fairer and more efficient system would permit biotechnology companies to keep the various aspects of their inventions together and would lighten PTO's burden due to multiple applications.

In addition, different examiners have been known to restrict a given application differently. This could subject a divisional application to further restriction requirements. The current proposals do not contemplate this scenario which would be overly burdensome to patent applications.

Thus, if these changes are adopted, biotechnology companies will be required to file all divisional applications within a specified period of time or give up valuable rights. Those smaller, newer biotechnology companies will be forced to pick and chose which aspect of

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35 U.S.C. § 132 Notice of rejection; reexamination

"(a) Whenever, ***on examination***, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined...." (emphasis added).

[26] In re Boylan, 392 F.2d 1017 (CCPA 1968).

[27] *In re Harnisch*, 631 F.2d 216 (CCPA 1980).

their invention is most desirable from a marketing perspective prior to having the information to do so prudently, due to limited financial resources which preclude pursuit of every divisional application immediately.

Proposed Requirement for Examination Support Document Would Create Uncertainty

The proposed rule requiring examination support documents (ESD) will create uncertainty for biotechnology patents. The PTO argues that more than the 10 representative claims will be examined by the PTO if applicants provide the PTO with an examination report specifying how the cited prior art impacts the additional claims. However, such a report would subject the ultimately issued patent to attack in the courts, on the basis that the applicant did not fully disclose how the prior art impacted the claims. This will be so, even if there is not much basis for doing so. Thus, in addition to increasing litigation costs, the rule would cast a cloud of uncertainty over the issued patent and would be a trap for the unwary. Until the law on inequitable conduct is changed, requesting such input from applicants would impose an unfair burden on them. Moreover, ESDs provide a disincentive for applicants to request substantive examination of more than 10 claims. The PTO indicates that non-designated claims will only be examined under 35 U.S.C. §101 and 35 U.S.C. §112 issues. By implementing this rule the PTO would arguably be denying an applicant his/her right to have each claim examined on the merits. [28] Additionally, the implementation of this proposal will add extra burden on the PTO who will be required to conduct a similar analysis in the U.S. National Phase to one conducted during the PCT stage.

PTO's Proposed Rules Will Have Unintended Consequences

Increase in PTO's Workload

Although the PTO views these proposals as the means to reduce its backlog, exactly the opposite will occur. Indeed, the PTO's own figures show that the proposed changes in continuation and claim practices will not reduce backlog, but simply maintain it at projected levels.[29] Moreover, the PTO will likely experience a spike in application filings similar to that experienced in 1995 as a result of compliance with GATT requirements. Because of the restrictive nature of the proposals, biotechnology applicants with the necessary resources will be forced to file related applications in bulk. Currently, the steady stream of divisional applications allows the PTO to adjust and respond to needs in manpower and resources. However, the proposed rules will result in biotechnology companies being required to file large numbers of related applications in order to preserve their ability to retain the filing date of their invention.

Additionally, the PTO's proposals are likely to increase the number of appeals and petitions. Applicants unable to make their case to the examiner will likely appeal to the Board of Patent Appeals and Interferences (Board). After several years of backlog, the Board has reduced its backlog and is deciding appeals in a timely manner. An increase of

[28] In re Weber, 149 F.2d 937 (CCPA 1945).
[29] Presentation by Commissioner Doll, February 1, 2006 at slides 52-54.

appeals propagated by the PTO's proposals will dramatically increase the Board's work load. In addition, Congress is currently considering legislation that would implement a new post-grant opposition procedure to be handled by the Board. The proposed rules packages do not address how the PTO intends to address the increase the Board's workload.

Increase in Cost to the PTO

The proposed rules will also add to the administrative cost and burdens of the PTO due to the need to consider petitions and claim designations as well as double patenting issues. Petitions to file a second continuation will have to be addressed, and since the standard is new and unknown there will be a significant number of petitions to resolve. And if refused, some will be appealed under the Administrative Procedures Act. The need to designate claims and process the correspondence associated with these designations will also be significant. Disagreements over the filing of related applications and whether they have patentably distinct claims would have to be addressed also. Additionally, since applicants will be limited in their ability to file continuing applications and will at most have only four bites of the apple, they will require the PTO to make those "bites" count. Applicants will not accept Office actions that are incomplete or do not address their arguments and, therefore, will demand that low quality Office actions be supplemented. This too will add to the resources expended by the PTO if the rules are changed as proposed.

Narrow Disclosures

If implemented, one unfortunate unintended consequence of the proposals is that applicants will likely file more applications on components of an invention instead of one comprehensive application to permit adequate coverage and claims of an entire invention.[30] As previously mentioned, biotechnology companies file applications on inventions early in the R&D process. The PTO's proposed rules would have the affect of limiting what can be claimed in any one application. This will inevitably result in applicants limiting the scope of disclosure in their applications as well as in publications to avoid dedicating potentially commercial embodiments to the public. This effect clearly works against the fundamental public policy of the patent system---dissemination of information to further the useful arts.

Decrease in the Quality of Examination

Under the proposals, if designated claims are found to be allowable, all other claims would be examined fully. Additional time would be required for the examiner to examine all of the non-designated claims which may necessitate their consideration *vis-à-vis* references or rejections pertaining to the designated claims. Without the appropriate allocation of time, it is likely that the quality of examinations will suffer.

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[30] This would also exacerbate the problem of multiple patents covering a single product, which already severely plagues our colleagues in the electronics, computer and semiconductor industries.

Effective Alternatives to the Proposed Rule Changes

BIO appreciates the challenges in the current patent system, both for applicants and the PTO. The PTO's proposed rule changes would not address these challenges effectively and fairly. BIO believes other specific proposals would more effectively address the PTO's concerns, without disproportionately and negatively impacting the biotech industry.

Flexible Examination: Deferred/Accelerated Examination

The PTO should consider a deferred/accelerated examination system.[31] There are certain applications that do not require immediate examination while others do. The U.S. patent system is one of the few patent systems to not offer flexibility in the form of deferred or accelerated examination as the situation requires. Under a deferred examination system, an applicant may file an application inexpensively and then decide whether to invoke examination at a later date by paying an examination fee. The market place will drive the decision to examine or not. In other systems there is a drop out rate that concentrates examining resources on the important applications while others are withdrawn by applicants for various reasons. Additionally, applicants should be able to meet certain conditions to get accelerated examination or "rocket docket" treatment of their application when necessary. This proposal would concentrate examination resources where needed and when needed, and help applicants make better use of the patent system.

Changes in the PTO Examiner Production System and After Final Practice

The need for patent applicants to file continuation applications often arises because the present PTO examiner production system discourages a dialogue between examiner and applicant. Such dialogue is necessary to efficiently resolve issues after the first office action. All too often the second action is made final without thorough consideration of the applicant's arguments. Moreover, once the application is finally rejected there is little hope the PTO will consider "after final" communications because the PTO does not allot time or credit for such communications. The patent applicant is then "forced" by the circumstances to file a continuation in order to further advance prosecution. The result is inefficient examination and unnecessary expense by both the applicant and the PTO.

A reevaluation of examiners' goals to provide more time for the initial examination and a graduated credit system, where appropriate, will ensure higher quality search and examination. A graduated credit system that takes into consideration time spent on subsequent Office actions or "rework applications" such as continuations, RCEs and Continuations-in-Part (CIPs), will provide the appropriate incentive for the patent examiner to perform a proper and thorough examination in the first Office action. It will also likely reduce "forced" continuations through the denial of amendments after final

[31] Earlier criticisms of deferred examination are addressed to a great extent by the 20 year term and 18 month publication.

action. BIO believes that a graduated credit system in conjunction with additional time per balanced disposal for consideration of amendments, evidence or prior art identified from another patent office, and after final amendments would go a long way to reducing continuation filings and lessening the backlog of applications.

Examiner Attrition Rate

One driving force behind increased continuation filings is piecemeal and incomplete examination in many PTO communications. In large part this is due to the high examiner attrition rate at the PTO. This high attrition rate (above 10% overall)[32] has resulted in the need to hire and train more examiners than can be absorbed on a yearly basis. By contrast the European Patent Office (EPO) and Japanese Patent Office (JPO) have significantly lower attrition rates, allowing them to maintain a much more experienced examining corps.[33] The PTO should consider taking full advantage of the personnel flexibilities available to immediately reduce attrition rates. Obvious sources of information on how best to achieve this goal are the EPO and JPO themselves. It may be necessary for the PTO to consider the human resource policies of these Offices as models to help improve the PTO's present ability to retain experienced staff.

BIO applauds the PTO for the recent implementation of new programs to retain examiners and improve examiner training. BIO urges the PTO to continue in these endeavors and allow sufficient time for these improvements to effect change. In particular, the PTOs implementation of a Patents' Hoteling Program wherein examiners can "telework" from home should provide a significant incentive for drawing new and retaining experienced patent examiners; just as this program has done for trademark attorneys.[34] .

Further, the PTO's recent efforts to hire and fully train a significant number of new examiners is also commendable. The PTO's hiring of 978 new examiners in fiscal year 2005 and goal of hiring 1,000 new examiners in fiscal year 2006 can be expected, *in due time*, to make substantial improvements in reducing patent pendency. Likewise, institution of the patent examiner training academy is also likely to produce significant improvements in the quality of patent examination by inexperienced examiners. These efforts by the PTO are the types of changes that will ultimately be the most effective and satisfactory means of reducing the patent examination backlog. BIO urges the PTO to allow sufficient time to obtain the benefit of these programs before implementing far-reaching and dramatic changes in the patent rules.

Improved Examiner Training

The foundation for high quality and efficient examination is a quality first Office action with a thorough search of all claims and complete consideration and comment upon all

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[32] United States Government Accountability Office Report, *Intellectual Property*, GAO 05-720, June 2005.
[33] National Academy of Public Administration, "*U.S. PATENT AND TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY*" (August 2005).
[34] *See, U.S.P.T.O. Performance and Accountability Report for Fiscal Year 2005*, pages 5-6, available on the internet at: http://www.uspto.gov/web/offices/com/annual/index.html (last viewed May 1, 2006).

claims. The biotechnology industry relies on quality patents that will withstand challenge in the courts. A thorough search along with the examiner's understanding of the invention would go a long way to ensuring quality patents without the need for multiple continuations. BIO recommends that the PTO consider using a significant portion of the fees generated as a result of the recent fee increase to provide scientific and legal training for examiners. BIO stands ready to work with the PTO to provide scientific training in the form of seminars and site visits for biotechnology examiners. BIO also urges the PTO to work closely with the patent bar to provide in-depth legal training for PTO examiners.

Modifications to Restriction Practice

One contributor to the PTO's workload is the PTO's current restriction practice. All too often the PTO restricts a single discovery into multiple groups each requiring a separate filing. At times, it may be necessary for a biotechnology applicant to file 20 or more patent applications in order to fully protect his/her invention. The current problems with the present restriction practice include the extreme complexity and demonstrated difficulty of the PTO to apply consistent standards. In this regard the PTO has not yet concluded its study on the practicality of a unity of invention practice and restriction practice. BIO urges the PTO to consider its comments submitted September 14, 2005.

Creation of an Ombudsman Position

The PTO should consider establishing an ombudsman position at the PTO to quickly and impartially evaluate, under certain circumstances, erroneous examiner decisions. There are instances when an applicant is faced with an examiner and/or a Supervisory Patent Examiner (SPE) unwilling to consider an applicant's allegation that a mistake has been made during prosecution. In these situations, the appeals process is inefficient and costly. Providing the applicant with a true ombudsman will give applicants a real opportunity to resolve honestly disputed issues without the expense and time of an appeal.

Improved Cooperation with Other Patent Offices to Reduce "Double Work"

The majority of biotechnology patent applicants file applications abroad. The PTO should consider other means of searching, such as utilizing prior art searches already performed by the EPO or JPO, in its examination or contracting out to search professionals. Additional search help would significantly reduce the examiners' balanced disposal rate per application. In addition, the PTO may want to consider batch prior art searches and examinations for related applications, regardless of filing dates.

Other Proposals

Below is a list of other proposals the PTO may consider in addressing its workload concerns.

a) As part of its modernization process, consider establishing satellite offices around the country. This may help to recruit high quality examiners as well as address the high attrition rate at the PTO.

b) Institute patentability review conferences with the applicant before a final rejection is issued. Appeal and pre-appeal conferences have brought to light the problem of numerous improper final rejections. A significant number of the final rejections are dropped or modified during these conferences. Patentability conferences will allow the examiner and applicant to better understand each other's concerns and chart a course to resolve the issues.

c) Permit interviews before the first Office action to allow applicants to provide additional education about the invention. Examiners may substantially benefit from an explanation of the technology and inventive concept and the scope of the invention, as perceived by the applicant, prior to a first Office action. Such interaction could also help to focus the search and analysis of the claims.

d) Address perceived continuation abuse through finely crafted changes to the rules based on prosecution laches. The courts have upheld the doctrine of prosecution laches in appropriate situations.[35] The PTO should establish guidelines to address the laches situation and instruct examiners to issue rejections where appropriate.

e) Offer expedited examination for PCT national stage entry applications. Encouraging the use of the PCT route could result in search reports from other search authorities that may aid in efficient examination of national stage applications.

f) Permit third parties to request accelerated examination of long-pending applications by permitting a document equivalent to the petition to make special accelerated examining procedure. The PTO may also want to consider permitting a third party to trigger accelerated examination by filing a petition in another applicant's application.

Conclusion

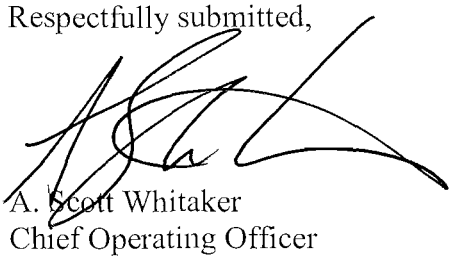
BIO appreciates the PTO's challenges and recognizes the need for improvements to the patenting process. But it is important that any change to the system does not disproportionately affect one sector over another and that the PTO share in realizing improvements to the system. Given that these proposed changes to the PTO's rules are the most dramatic in decades, BIO calls on the PTO to revise its process by issuing an advanced notice of proposed rule-making followed by public hearings. The PTO's advanced notice should clearly and specifically identify the issues to be addressed by the proposal, complete with detailed background and data. As discussed in this document, there is a clear relationship between the proposed rules and biotechnology innovation that necessitates a more robust and transparent dialogue in the user community.

BIO further recommends that before any wholesale change of this magnitude is implemented, that a pilot study be performed in which the impact of the proposed

[35] *In Re Bogese II*, 303 F.3d 1373 (Fed. Cir. 2002); and *Symbol Technologies v. Lemelson Med. Educ. & Research Foundation*, 277 F.3d 1361 (Fed. Cir. 2002)

changes are assessed before full-scale implementation. Any pilot study, however, should be done in parallel with the conventional process and not result in binding conclusions.

Respectfully submitted,



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