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From: Powers, Peggy [mailto:Peggy.Powers@maxygen.com]
Sent: Wednesday, May 03, 2006 5:23 PM
To: AB94Comments; AB93Comments
Subject: Comments on USPTO's proposed rule changes regarding continuation practice and claim examination practice

Dear Sir or Madam:

Attached please find comments submitted on behalf of Maxygen, Inc. in response to the USPTO's proposed changes to the rules governing continued examination practice and claim examination practice (71 FR 48 and 71 FR 61). Please note that the attached is a PDF document containing Maxygen's comments. Previously today we submitted an identical WORD document containing our comments. We would appreciate if you would post the attached PDF document in place of the previously submitted WORD document. The WORD document may be discarded.

Thank you for your consideration of these comments.

<<Maxygen_comments.pdf>>

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Comments on the United States Patent and Trademark Office's Proposed Changes to the Rules Governing Continued Examination Practice and Claim Examination Practice

by
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May 3, 2006

The following comments are submitted on behalf of Maxygen, Inc., headquartered in Redwood City, California. Maxygen is a biotechnology company focused on the discovery, development, and commercialization of improved next-generation protein pharmaceuticals for the treatment of disease and serious medical conditions. Patents and other proprietary rights are important to our business. At present, Maxygen has over 120 U.S. and foreign patents and numerous pending patent applications relating to its recombination-based directed evolution technologies, protein modification methods, and protein pharmaceuticals.

Introduction

Biopharmaceutical-related inventions are often complex and multi-faceted, and the processes of developing and testing of biopharmaceutical-related inventions, including new biopharmaceuticals and therapeutic treatment methods, are extremely lengthy, difficult, and costly. Furthermore, many new drugs embodying biopharmaceutical inventions require approval by the U.S. Food and Drug Administration (FDA) and comparable foreign entities before they can be marketed. Notably, the average time from discovery through regulatory approval for a new therapeutic drug is 10-15 years and very few of the many compounds that enter preclinical testing are ultimately approved for sale for use in humans.

Biopharmaceutical innovators need a flexible patent system that allows them the ability to protect their inventions fully. Where an invention is complex and multi-faceted, multiple patent applications may be needed for sufficient protection of various embodiments. In addition, biopharmaceutical applicants need a patent system that permits them to respond to issues that may arise during the prolonged pre-clinical development, clinical development, and regulatory approval phases. For example, during these phases issues may arise that oblige biopharmaceutical innovators to modify their biopharmaceutical drug candidate or its formulation, or to proceed with a different candidate or alternative embodiment – often due to clinical results or regulatory requirements that could not have been anticipated at the time of initial filing of a patent application, e.g., data developed in clinical studies or FDA concerns with safety. Furthermore, throughout development and approval phases, significant improvements to an invention and additional advances may be realized.

Applicants need to the ability to revise or modify claims defining an invention, and update applications to protect improvements or advances that may be made in the course of the long period to market. These combined factors almost always necessitate the filing of more than one continuing application. Typically, several continuing applications are needed.

The very high product development costs, long time to market, and additional hurdles that must be met for commercialization of biopharmaceutical products clearly distinguish this industry from many others. Adequate patent protection is essential for continued investment in biopharmaceuticals. Without a flexible system that allows for adequate patent protection, incentives to invest capital in biopharmaceutical research and development will be greatly stifled.

Several commentators have suggested that the continued examination practice appears to be particularly important to the biotechnology and pharmaceutical industries. *See, e.g.*, M. Lemley et al., 84 *B.U.L. Rev.* 63 (2004). We agree, and we believe many, if not most, applicants in these industries rely on continued examination practice. Current continued examination practice allows biopharmaceutical applicants to protect complex biopharmaceutical-related inventions, including varied embodiments, improvements, and alternatives developed and/or necessitated during the unusually long and often unpredictable research, development, and regulatory phases.

The proposed rule changes restricting the number of continuing applications that can be filed as a matter of right would have a significant negative impact an applicant's ability to obtain patent protection on novel therapeutic products. As noted above, the development cycle for a pharmaceutical product spans many years from initial discovery of lead candidates to testing of one product candidate on human subjects during clinical trials and is time consuming and expensive. During this period, a large number of novel molecules may be identified as potentially having therapeutic benefit, but require further development and testing. The initial candidate molecules may fail at any stage during this subsequent testing and the development cycle may be repeated with one or more alternative product candidates, necessitating development and testing of other molecules.

Due to the highly competitive nature of the biopharmaceutical business, applicants often file early in the development cycle on many product candidates that meet the requirements for patentability. For example, advances in biotechnology enable an inventor to create many polypeptide and polynucleotide sequences that meet the criteria for patentability and that have the potential to become commercial products. Current continuation practice enables an applicant to prosecute claims directed to a product candidate at any stage of the development cycle. Implementation of the proposed rules without modification will force applicants of biopharmaceutical inventions to choose between: (1) filing later in order to obtain claims focused on their products, but assuming the risk of relevant patent filings or publications by others; and (2) filing early, but assuming the risk of not being able to obtain patent coverage on their products.

Without the ability to obtain sufficient patent protection, continued substantial investments in the biopharmaceutical sector would likely not be made and biopharmaceutical innovation and R&D would be severely impacted. Health-care advancements would be significantly curbed. The rules would also serve as a disincentive to the public disclosure of improvements and advances. Moreover, given that the biopharmaceutical sector plays a strong role in the U.S. economy, the proposed rules would likely have a significant impact on U.S. economic growth and strength.

The proposed rules restricting the number of continuing applications that can be filed would especially severely impact the ability of an applicant to obtain patent protection on pioneering inventions. Under existing case law, inventors of pioneering inventions are entitled to the broadest scope for their inventions. Developers of such inventions require time to explore all of the possible applications and aspects of a pioneering invention. The proposed rule changes

could effectively prohibit inventors from obtaining patent protection on the diverse embodiments of such pioneering inventions, thereby depriving those inventions that are most deserving of patent rights adequate patent protection.

Although we appreciate the interests of the United States Patent and Trademark Office (PTO) in reducing the current application backlog, expediting prosecution, and improving efficiency and allocation of resources, we believe the proposed changes to the rules of continued examination practice and claim examination practice would cripple the ability of biopharmaceutical innovators to fully protect their inventions. Simply put, in our view, the proposed "cure" is worse than the existing problem, and would significantly damage the ability of the U.S. patent system to adequately provide patent protection for biopharmaceutical inventions.

We offer the following comments and suggestions on the proposed rules.

Rules Affecting Continued Examination Practice

I. The number of continuing applications that can be filed as a matter of right should not be restricted as proposed by the PTO. Alternative solutions to address the PTO's concerns regarding continuation examination practice should be considered.

Applicants seeking patents relating to biopharmaceutical and other complex technologies should have the ability to protect their inventions comprehensively. Under the proposed rules, the ability to do so would be severely limited because the proposed rules provide that only one continuing application (e.g., one continuation application, one continuation-in-part (CIP) application, or one request for examination (RCE)) that claims the benefit of a prior-filed nonprovisional application will be permitted as a matter of right. A second or further continuing application would be permitted only to obtain consideration of an amendment, argument or evidence and only if a petition to the Director were filed and granted. For such petition to be granted, an applicant would need to submit a fee and show to the satisfaction of the Director that the amendment, argument, or evidence could not have been previously submitted during prosecution of the prior-file application. *See* proposed 37 C.F.R. § 1.78(d)(1)(iv).

These proposed rules would significantly restrict an applicant's ability to file multiple continuing applications to protect multiple aspects, embodiments, and alternatives of his/her invention. Under the rules, the filing of a continuation or CIP[1] directed to another inventive aspect – as is commonly done and typically necessary for adequate protection of multi-faceted and complex biopharmaceutical inventions – would not be permitted unless the applicant could satisfactorily demonstrate that some argument, evidence, or amendment relating to such aspect could not have been presented in the previous application. However, the purpose of a continuation or CIP application may not be to obtain consideration of an amendment, argument,

[1] As explained in Section V below, in our view, no limitation on RCEs should be included in any limitation on the number of continuation or CIP applications. However, even if RCEs were not included in these limits on continuing applications, the proposed restrictions on continuation and CIP applications would still make it extremely difficult for an applicant to protect his/her invention fully.

or evidence relating to an aspect claimed in the prior-filed application, but to protect a different aspect of the invention. Consequently, these proposed rules essentially curtail an applicant's ability to file multiple applications to cover and protect various aspects and embodiments of the invention.

The PTO has indicated it is concerned that the current rules give applicants an unfettered right to file continuing applications. We can appreciate the PTO's concerns. However, limiting the number of continuing applications that can be filed as a matter of right to one such application is an extremely severe "solution." The PTO does not appear to have fully understood the impact of such "solution" on the biopharmaceutical industry. Under the proposed rules, for complex and multi-faceted inventions, it would be difficult, or impossible, to obtain comprehensive patent protection for all aspects of the invention. One continuing application as a matter of right is simply not enough.

It is unclear how the proposed rules would be implemented. For example, under the proposed rules, it appears an applicant could not properly file a second RCE, continuation application, or CIP in the same priority chain of applications prior to actual approval by the Director of a petition which demonstrates to the Director's satisfaction that the amendment, argument, or evidence submitted for consideration could not have been submitted during the prosecution of the prior-filed application. If an applicant files a second RCE, continuation application, or CIP along with a petition, and if the petition is subsequently denied, what is applicant's recourse? Would the second RCE, continuation application, or CIP be denied a filing date? What if the applicant filed a petition requesting to file a second continuation application, CIP, or RCE (e.g., in response to a final rejection of the prior-filed application to which the second continuation application, CIP, or RCE claims benefit) before the prior-filed application's abandonment date, but a decision on the petition was not reached until after that abandonment date. Would any application be pending at that point? The proposed rules do not provide any indication as to, e.g., how long the petition process may take, whether the PTO would timely notify an applicant of a decision on the petition before the abandonment date of the prior-filed application, what would happen procedurally if a petition were denied, or what recourse would be available to the applicant in the event of the petition is denied.

If the PTO wants to discourage the filing of multiple continuing applications, it can do so simply by requiring that an applicant pay an increased filing fee or surcharge (compared to the filing fee paid for the first continuation) to offset any potential examination burden. Increased fees could also be used as an alternative to permit an applicant to file a second, third, or subsequent continuing application without any showing (i.e., as a matter of right). Additionally, the PTO could further discourage continuation practice by increasing (proportionally or otherwise) the filing fees for subsequent continuing application filings.

However, if the PTO persists in limiting the number of continuing applications that can be filed as a matter of right, we recommend that it set a higher limit on the number of applications that can be filed as a matter of right. For example, we recommend that an applicant be permitted to file at least four continuing applications as a matter of right. In this way, an applicant's right and ability to protect his/her invention fully would be preserved.

II. If the number of continuing application filings permitted as a matter of right is restricted in any way, the PTO should provide for an optional, meaningful deferred examination.

If the Patent Office is going to curtail the ability of an applicant to file continuing applications in the manner proposed, or in any other manner, applicants should have the option of deferring examination of their applications for a meaningful time period. In our view, this period would be longer than the one that is currently allowed under the rules. The current proposed rules penalize those industries having product development timelines that extend over a time period of several years. By deferring examination, applicants in these industries can ultimately focus their claims on their commercial products. Applicants can also abandon applications subject to deferred examination without causing the Patent Office to undertake unnecessary work. By allowing applicants to defer examination for a meaningful period, the Patent Office will achieve its objective of efficient prosecution and applicants in industries like the biotechnology and pharmaceutical industries will be able to file early and still be able to prosecute claims directed to their products.

The rules currently provide for the deferral of examination under 37 C.F.R. § 1.103(d). While that rule is sufficient with the current rules governing the practice for continuing applications, we encourage the Patent Office to consider modifying it to provide applicants with alternatives that would otherwise be foreclosed by the proposed rule changes relating to continuing application practice. We believe that a modified 37 C.F.R. § 1.103(d) would provide these companies with a realistic route to obtaining patent protection on their commercial products.

Deferred examination is currently allowed at the request of the applicant for a period that does not extend beyond three years from the earliest filing date for which benefit is claimed under Title 35 of the United States Code. 37 C.F.R. § 1.103(d) requires, *inter alia*, that:

(1) The application is an original utility or plant application filed under § 1.53(b) or resulting from entry of an international application into the national stage after compliance with § 1.495;
(2) The applicant has not filed a nonpublication request under § 1.213(a), or has filed a request under § 1.213(b) to rescind a previously filed nonpublication request;
(3) The application is in condition for publication as provided in § 1.211(c); and
(4) The Office has not issued either an Office action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

If the proposed rules restricting the number of continuing applications that can be filed as a matter of right are adopted, we believe the Patent Office should consider the following modifications to 37 C.F.R. § 1.103(d):

1. Lengthen the period of deferral from 3 years from date of earliest benefit claimed under Title 35 to 5 years from the actual filing date of the application for which deferred examination is requested.

2. Modify part (1) of § 1.103 to allow an applicant to also defer examination of one or more continuation-in-part applications if all prior application(s) are also subject to deferred examination.

In addition, we proposed that the rule changes to continuation practice apply to applications for which examination has been deferred, with the exceptions set forth in (a) and (b) below.

(a) Original and continuation-in part applications for which examination has been deferred would be subject to the new rules only when examination commences;

(b) An applicant may abandon an original or continuation-in-part application(s) for which examination has been deferred prior to the commencement of examination (i.e., during the period of suspension). Applications so abandoned would not be counted in determining the number of continuation applications permitted. A subsequently filed continuation-in-part application that is subject to deferred examination and which claims priority to applications, all of which were subject to deferred examination but abandoned prior to commencement of examination, would be treated as if it were an original application for the purpose of determining number of continuation applications under the proposed rule changes.

Proposal 1 would lengthen the duration of deferred examination to provide sufficient time for applicants in industries like the pharmaceutical industry to determine which claims to pursue in order to secure coverage for their products. Extending the time period of deferral to 5 years would allow an applicant to file early, yet still present claims for examination that are directed to commercial products.

Proposal 2 would allow applicants to file continuation-in-part applications early, without imposing any burden on the Patent Office with respect to examination. Where examination for all members of a patent family is deferred, double patenting between family members is not an issue during the period of suspension.

Once examination commences, proposal (a) would subject any deferred applications to the rules governing the practice of filing continuation applications. Proposal (b) would allow an applicant to abandon an original or an original and one or more continuation-in-part applications, in favor of a later filed continuation-in-part application, without being penalized by the proposed rules governing continuation application filing practice.

We believe that the proposal relating to deferred examination will accommodate the needs of companies with long product development timelines, while at the same time reducing the current examination burden on the Patent Office. We also believe that implementation of an effective deferred examination procedure will help mitigate the severe impact the proposed rules relating to continuing application practice will have on the pharmaceutical industry. A meaningful deferred examination process may also help minimize the number of submissions containing a showing to support a second or subsequent continuing application of any type.

III. If Applicants must petition to file additional continuation applications, the grounds for petition should be reasonable and well defined.

The proposed rule changes suggest that a second or subsequent continuation or continuation-in-part application and subsequent requests for continued examination of an application would be permitted if the applicant provides a showing to the satisfaction of the Director as to why the amendment, argument, or evidence presented could not have been previously submitted. The proposed rule changes, however, provide no guidance as to what grounds, if any, will satisfy the Director. An ad hoc system of petition review by the Patent Office will essentially deprive applicants of any ability to file more than one continuing application of any type.

We propose that the Patent Office accept any of the following specific grounds as being sufficient with respect to the "showing to the satisfaction of the Director" requirement of the proposed rule changes:

1. New prior art raised in a Final Office Action or discovered by Applicant after Final Office Action in a parent application;

2. Evidence of an interfering patent or application with respect to the claimed subject matter of the second or subsequent continuing application;

3. New experimental results or new inventions relating to the claimed subject matter of the second or subsequent continuing application.

4. A statement by a patentee, licensee, or assignee that a regulatory filing has been made on the claimed subject matter of the second or subsequent continuing application.
5. The second or subsequent continuing application is subject to deferred examination along with all prior non-provisional applications, and all applications or all but one prior application have been abandoned prior to commencement of examination.

6. The Examiner has raised a new rejection in a Final Office Action in the prior application that could have been raised in a prior Office Action.

7. Evidence of an exclusive licensee with business interest in claimed subject matter of the second or subsequent continuing application.

8. The second or subsequent continuing application is sought by a subsequent assignee or licensee of the prior applications, in recognition of the fact that in the biopharmaceutical industry, products are often taken to commercialization by an entity other than the one owning the original patent, e.g., a university.

9. The first continuing application contains both allowed and rejected claims and the claimed subject matter of the second or subsequent continuing application is directed to the subject matter of the rejected claims.

IV. Applicants should be allowed to file both an Appeal in the prior application and a second or subsequent request for continued examination.

Under the current rules relating to the filing of a Request for Continued Examination, an applicant cannot have pending both an appeal and a Request for Continued Examination. Pursuant 37 C.F.R. § 1.114(d), a Request for Continued Examination (RCE) made after the filing of a Notice of Appeal, but prior to a decision on appeal, is treated as a request to withdraw the appeal and to reopen prosecution of the application. Therefore, if issues remain after Final rejection, one can either appeal or file an RCE. Under the current rules, this limitation is not problematical because applicants have more certainty that the Request for Continued Examination will be accepted, so that an appeal will not be necessary.

However, with the proposed rule changes, applicants will be left in the untenable position of having to choose between: (1) appealing rejections in a prior application, even if the applicant believes amendments could be made to overcome the rejections; or (2) filing an RCE that is "counted" as a second or subsequent continuing application with a petition explaining why the amendment, argument, or evidence could not have been presented earlier, and risking abandonment should the petition be denied. If the applicant chooses the latter option and the petition supporting the filing of this RCE that is counted a second or subsequent continuing application is denied, the applicant is left with no remedy aside from appealing the denial of the petition.

V. RCEs should not be included in any proposal to limit the number of continuing applications that can be filed as a matter of right.

35 U.S.C. § 132(b) permits an applicant to submit a Request for Continued Examination of an application (i.e., RCE) upon payment of a fee, without requiring the applicant to file a new continuation application under 37 C.F.R. § 1.53(b). *See also* MPEP 706.07(h). The statute itself does not impose any restrictions – other than a fee – on such a request. The PTO's proposed rules group RCEs together with CIP applications and new continuation applications and specify that the PTO would permit the filing of only a single RCE, CIP, or new continuation application as a matter of right. Under the proposed rules, any second or subsequent filing of an application (which would include an RCE, CIP or continuation application) must be supported by a petition showing why the argument, evidence, or amendment could not have been submitted during prosecution of the first application. Thus, under the proposed rules, if an applicant submits a request for continued examination of an existing application, he/she would be prevented from

filing a new continuation or CIP application claiming priority to the first application as a matter of right.

For this reason, we strongly recommend that RCEs not be included under the PTO's proposal to limit continuing applications that can be filed as a matter of right. In our view, the proposed restrictions on RCE practice, in combination with the other proposed restrictions on continued examination practice, would seriously hinder an applicant's ability to advance prosecution effectively, to obtain well-defined and well-examined claims, and to fully protect its innovations. The negative impact of these proposed restrictions on RCE practice on applicants clearly outweighs any benefits the PTO believes it may derive.

Moreover, the existing rules governing RCE practice sufficiently restrict its use. An RCE is not a new application, but a request to continue examination of the same application following the close of prosecution. 37 C.F.R. § 1.114; MPEP § 706.07(h). The existing rules limit the conditions under which an RCE may be filed. *Id.* Notably, an RCE cannot be used to obtain continued examination on the basis of claims that are independent and distinct from the claims previously set forth and examined as a matter of right. 37 C.F.R. § 1.145. Thus, an RCE cannot be used to "switch inventions." MPEP § 706.07(h). On the contrary, an RCE is typically used to address limited issues relating to a claimed invention following the close of prosecution and effectively advance prosecution of the same application to finality. The time needed for RCE examination is typically much less than that required for a new application and RCE examination is often much simpler than the examination of a new application, as the same Examiner acts on the RCE and he/she is already familiar with the application. In fact, RCE practice was implemented to expedite prosecution and increase PTO examination efficiency by allowing an applicant to avoid having to file an appeal or a new application.

Contrary to the PTO's suggestions, an RCE is not typically used for delaying purposes, as RCE examination usually proceeds very quickly, because the Examiner is familiar with the application's contents and the issues are focused. An applicant would more likely file a new application if his or her purpose were to delay prosecution.

Furthermore, RCE practice improves patent quality and serves the public by allowing better-defined and better-examined claims to issue – typically in a relatively quick manner. Moreover, the applicant pays amply for this additional review. For each RCE, the applicant pays a filing fee equivalent to that paid for examination of an entirely new application, despite the fact that the Examiner is already familiar with the application and the examination is limited.

RCE practice plays an extremely important role in ensuring that an application is examined fully, fairly, and competently. An RCE can be a vital course of action, e.g., where an Examiner has not fully addressed or has misunderstood an applicant's claimed invention, arguments, or evidence, has not met his or her burden of establishing a *prima facie* case for a final rejection, or has made erroneous assumptions or errors. It can provide an efficient, yet often critical, means by which to respond to a second and final rejection that contains a new ground of rejection(s) or new art not previously cited in the application, to rectify errors or deficiencies in the examination process, including errors in examination caused by inadequate

review or misunderstanding of the invention or prior art by the Examiner, and to make corrections (even minor corrections) that an Examiner will not permit after a final rejection. Maintaining a flexible RCE practice is of particular importance to innovators whose inventions involve highly complex technologies, as Examiners typically need more assistance in understanding such inventions compared to some other arts and initial examination is often incomplete or inaccurate.

The proposed restrictions on RCE practice would also adversely affect the PTO, because an applicant's only choice to advance prosecution may be to file a very costly and time-consuming appeal. The appeal process would add considerably to pendency of an application, since an appeal typically takes several years. By contrast, RCE examination usually adds only about one year (and sometimes significantly less time) to the pendency of an application. Considerably more PTO resources would be consumed by an appeal filing than an RCE filing. The PTO states that 52,000 requests for continued examination of an existing application were filed during fiscal year 2005 out of total of 369,000 "application filings" (317,000 nonprovisional applications and 52,000 RCEs). Thus, requests for continued examination of an existing application comprised only 13% of the total "filings" in fiscal year 2005. Even if in only a portion of those cases an appeal were filed instead of an RCE, the decrease in PTO productivity caused by such appeals would be greater than any improvement in productivity the PTO hopes to achieve by the proposed rules. Further, the PTO's objective of providing prompt public notice as to what an applicant regards as his/her invention would actually be thwarted, since more appeals would likely be filed under the PTOs proposal, resulting in increased pendency of an application and dramatically delaying the public notice of allowed claims.

We believe the existing rules of RCE practice properly limit its use and satisfy the PTO's stated objectives of efficient prosecution and providing the public with prompt notice as to what an applicant regards as his/her invention. We recommend against any limits on RCE practice. An applicant should be permitted to file an RCE in any application without justification, as under the existing rules, and RCE filings should not be included in any proposal to limit the number of continuation or CIP applications that can be filed as a matter of right. Furthermore, an applicant should be permitted to file one or more RCEs, as needed, in any divisional application. At the very least, an applicant should be permitted to file two RCEs without justification in any application.

If desired, the PTO could curb the number of RCE filings by instituting a filing fee surcharge for an RCE. The surcharge could be substantial. In this way, the PTO's objectives could be met without significantly affecting the rights and interests of innovators in obtaining appropriate examination of and coverage for their inventions. The public's interest in obtaining better-examined and well-defined claims would also be served.

In addition, there are steps the PTO could take that would facilitate advancement of an application and prevent the need for an applicant to file an RCE. For example, the PTO could permit interview prior to the first office action. Alternatively, the PTO could permit after-final interviews as a matter of right. The PTO could permit an Examiner to issue a second non-final

office action (instead of a final office action) if, in his or her judgment, the applicant is making a good faith effort to progress the application to finality.

VI. Applicants should be permitted to file divisional applications in succession, while still retaining the priority date of the first-filed nonprovisional application.

Under the PTO's proposed rules, to retain the earliest priority date, all divisional applications must be filed during the pendency of the originally-filed application. A divisional application filed subsequently would be entitled only to the filing date of the then-pending application. Further, divisional applications only would be permitted for separately patentable inventions subject to a restriction requirement. Voluntary divisional applications would not be permitted.

Given the long research and development time for biopharmaceutical-related inventions, the additional barriers many biopharmaceutical drug candidates face prior to commercialization (e.g., preclinical testing, clinical trials, FDA approval requirements, etc.), and the uncertainty as to whether a particular drug candidate may make it to human testing and be approved for use in treating a particular disease or condition, the PTO's proposed rules relating to divisional application practice would disproportionately adversely affect applicants for biopharmaceutical patents. The proposed rules do not allow such applicants the flexibility to make decisions regarding their inventions over time to take into account information resulting from preclinical and clinical studies – information often obtained long after an initial patent application filing.

The problem is compounded by the PTO's current harsh restriction practice, which already severely impacts biopharmaceutical innovators and their ability to protect their inventions in a cost-effective manner. For example, suppose a biopharmaceutical company discovers and develops three new therapeutic protein candidates that are believed effective in treating a particular human disease or condition. The company would likely file one patent application covering at least the protein sequences of each of these three proteins, the nucleic acid sequences encoding each of these three proteins, and the method(s) of using each such protein or nucleic acid. Under the PTO's current restriction practice, each protein, nucleic acid, and method would be deemed to constitute an independent and/or distinct invention and restriction to one invention would be required. As a result, the applicant would be required to elect a single protein, single nucleic acid, or single method utilizing one such protein or nucleic acid for examination. Applying the proposed rules to this example, the company would need to file, in addition to the first nonprovisional application, eleven divisional applications within the pendency of the first nonprovisional application to protect all of these molecules and their respective methods of use. However, it may be many years before sufficient information is available to determine which protein (or nucleic acid) candidate, if any, might be approved by the FDA for public sale for use in treating a particular disease or condition.[2]

[2] The U.S. Supreme Court observed recently that a company might not know which specific drug candidate it might ultimately proceed with until late in development and might need to proceed with a different candidate than originally selected for reasons that could not have been anticipated. *See Merck KGAA v. Integra Life Sciences I, Ltd.*, 125 S. Ct. 2372, 2382-2383 (2005).

The requirement that all divisional applications during pendency of the first nonprovisional application would place a huge upfront financial burden on such an applicant – long before it could be determined whether which particular drug candidate might be approved for sale. Many biopharmaceutical companies, particularly small companies, would not be able to file all divisional applications within the prescribed period and would lose the ability to obtain patent protection on the actual commercial embodiment of the invention.

On the other hand, a biopharmaceutical applicant who could afford to do so (e.g., large company) would likely file all divisional applications directed to the restricted inventions during pendency of the first filed nonprovisional application in order to obtain the same early filing date for each invention. The overall number of divisional applications filed by such an applicant would likely be far greater than the number such applicant would file under the current rules which allow for time to make tactical and considered decisions as to which inventions to pursue. The effect would be to increase the PTO's patent application backlog.

The proposed rules are also problematic because they do not take into account the (not uncommon) situation in which an Examiner makes a further (second) restriction of claims in a divisional application that should or could have been made in the parent application. The claims in any further divisional application filed from the first divisional application should be entitled to the priority date of the parent application in which the initial restriction was made. Under the proposed rules, this does not appear to be the case.

The proposed rule changes to divisional practice present additional concerns. Under the proposed rules, if a divisional application directed to a restricted invention (e.g., a particular protein sequence) is not filed during pendency of the first nonprovisional application, but is filed subsequently, it would be entitled only to the filing date of then-pending application. This may have severe consequences. For example, given that a patent application typically publishes 18 months after its priority date, if a divisional application is not filed during pendency of the first nonprovisional application and is filed more than one year after publication of the first nonprovisional application, the published first nonprovisional application would serve as 102(b) prior art against a later-filed divisional application, thereby effectively barring patent protection for the invention claimed in the divisional application.

In addition, the proposed definitions do not appear to have been carefully considered. For example, proposed rule 1.78(a)(3) defines a "divisional application" as a continuing application as defined in rule 1.78(a)(1) that "discloses and claims only an invention or inventions that were disclosed and claimed in the prior-filed application, but were subject to a requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. § 121 and not elected for examination in the prior-filed application." *See* proposed 37 C.F.R. § 1.78(a)(3) (emphasis added). It is not clear whether dependent claims that were not presented in the prior-filed application could be presented subsequently in the divisional application, or whether the restricted claims could be amended prior to submission in a divisional application.

The proposed rules might also have the undesirable effect of limiting an applicant's disclosure, because an applicant might be reluctant to file a comprehensive application that is inclusive of all embodiments and may prefer to file an application that is narrower or limited in disclosure. Such outcome would be contrary to public interest, as the applicant would likely keep such advancements as trade secrets, thereby limiting the information available to the public. Alternatively, an applicant might file multiple applications, with each limited to a separate (and perhaps distinct) embodiment, thereby increasing the total number of application filings and defeating the PTO's stated goals and intentions in promulgating the proposed rules.

We strongly recommend that the current rules governing divisional application practice be maintained. Under the current rules, divisional applications may be filed in succession while still retaining the priority date of the first nonprovisional application.[3] Because an applicant is permitted to file divisional applications successively, without losing the priority date, applicants are not pressured to file divisional applications prematurely, but need only file those divisional applications directed to potential products(s). The current rules give applicants the opportunity to make more selective and strategic business decisions regarding which invention(s) to pursue based upon later-acquired information and financial resources. Thus, for example, biopharmaceutical applicants can make informed decisions regarding which drug-related inventions to proceed with much more easily later in the development and/or regulatory review phases.

Rules Affecting Claim Examination Practice

I. Alternative approaches to facilitate claim examination without the requirement that an applicant submit an Examination Support Document should be considered.

Under the proposed rules, only up to 10 representative claims will be initially examined. Representative claims include all of the independent claims and only those dependent claims that are expressly designated by the applicant for initial examination. If an applicant submits more than 10 independent claims in an application, or designates more that 10 representative claims for initial examination, the applicant will be required to submit a burdensome and onerous Examination Support Document (ESD). The applicant may avoid having to submit an Examination Support Document by (1) canceling any independent claims over the limit of 10, (2) rescinding designation of enough dependent claims so the total number of representative claims is no greater than 10, or (3) submitting a proposed restriction requirement with an election without traverse of an invention to which there are drawn 10 or fewer representative claims.

[3] Under 35 U.S.C. § 121, the bar against double patenting rejection pertains to the situation when a divisional application is filed during the pendency of the nonprovisional application containing the restriction requirement. However, an applicant should be able to benefit from this provision in successive divisional application filings if all of the non-elected claims are filed in each subsequently-filed divisional application (assuming the Examiner restricts the non-elected claims into the same groups in the same manner as in the first application). In this way, a restriction requirement would again be applied to the all of the non-elected claims in the divisional application, and an applicant could elect the claims directed to one such restricted invention.

There are significant dangers and problems with these proposed rules. First, the requirements of the ESD are not only burdensome, but also increase the applicant's legal risk and may have the effect of placing some level of doubt or uncertainty on the validity of claims ultimately allowed. The required statements and showings could invite legal challenges to any subsequently issued patent, including almost certainly assertions of inequitable conduct. At least one commentator has astutely noted that such statements could be "attacked in litigation as fully equivalent sworn statements made under penalty of perjury under existing 37 C.F.R. § 10.18 of the PTO Disciplinary Rules." *See* Anonymous, "Major USPTO Prosecution Proposals for Spring 2006," March 8, 2006, available at http://patentlyo.com. For example, a challenger in patent litigation could argue, based on the ESD, that a sufficient search was not conducted, that a document identified in the search was intentionally not disclosed to the Office, that a sufficient explanation as to where each claim limitation was disclosed by a cited reference was not provided, and/or that the search of each limitation in a dependent claim was not sufficiently independent or separate from the search of each limitation in an independent claim. Overall, the ESD approach would likely have the consequence of increasing patent litigation, increasing the costs of patent litigations, and increasing the uncertainty of the result in any patent litigation. These outcomes would not strengthen the U.S. patent system.

If the proposed rules are adopted in their present form, in an effort to avoid having to submit the ESD, an applicant may feel obliged to limit the scope of the invention, and may feel that he or she has no choice but to forego the full patent protection the invention merits.

Moreover, the proposed rules relating to the ESD do not appear to have been well thought out. *See* proposed 37 C.F.R. § 1.261(1)-(6). For example, the proposed rules provide no standards for properly assessing whether an ESD or a pre-examination search is sufficient. Examiners could thus apply arbitrary, subjective, and/or inconsistent standards. In addition, the proposed rules do not give an applicant sufficient opportunity to rebut or contest a position taken by the Examiner with regard to the ESD submission. For example, if the Examiner concludes that an ESD or pre-examination search is insufficient[4] or that the claims have been amended such that the ESD no longer covers each designated claim, the Examiner can issue a notice with a non-extendable one-month time period within which applicant must file a corrected or supplemental ESD to avoid abandonment. If an applicant believes an Examiner's findings are incorrect or misplaced, the applicant would have little time to contest or rebut those findings. Further, if the Examiner finds an applicant's subsequent submission to be insufficient or non-responsive, it appears the application may be (inadvertently) abandoned.

Additionally, the proposed rules would, impracticably, require that the search must encompass any disclosed features that may at some point be claimed. Thus, prior to any examination, an applicant would be required to anticipate which features disclosed in the application may at some point be included in an (newly added or amended) independent claim or designated claim and to ensure those features are included in the search. An applicant would also be required to include in a search those features he or she may want to include at some point

[4] The proposed rules do not provide any standards for making this determination and offer no examples of an insufficient ESD submission.

in a dependent claim that has not been designated or even in a new dependent claim that has not yet been drafted.

The PTO has recognized the problems posed by an ESD and proposes a means to avoid such submission. However, the "alternative" is as problematical as the ESD. Specifically, the PTO proposes that an applicant could avoid having to submit an ESD by submitting instead a proposed restriction requirement with an election without traverse of an invention to which there are drawn 10 or fewer representative claims. But the proposed rules give no indication as to what would happen if an Examiner were to reject the proposed restriction, and given that the election would have been made without traverse, the applicant presumably would have no recourse. Given that the PTO's current restriction practice is complex and that restriction standards are not applied consistently by Examiners (particularly in the biotechnology and pharmaceutical arts), this proposal is not viable.

Applicants have the right to define and claim their invention as they wish. *In re Weber*, 580 F.2d 455, 458-459, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978). Some applicants, especially those with complex or multi-faceted inventions, may need more that 10 independent claims (or 10 claims total) to define and protect sufficiently all aspects and embodiments of an invention. A biopharmaceutical applicant, for example, often needs more than 10 independent claims (and more than 10 claims total) to protect complex and multi-faceted inventions. A patent application may cover several potential drug candidates, such as several protein therapeutic drug candidates and nucleic acids encoding those proteins, or several small molecule therapeutic candidates. In addition, the application may cover various forms, derivatives, and/or variants of the drug candidates, various compositions, and formulations thereof, methods for making the drug candidates, dosing regimens employing the drug candidate, therapeutic and/or prophylactic methods of using the drug candidates, diagnostic or screening methods utilizing the drug candidates, antibodies induced by the drug candidates, etc.

The PTO states that it is concerned that the examination of applications containing many claims requires an inordinate amount of resources. Based on these concerns, the PTO proposes to: (1) limit the number of independent claims that can be presented in an application to 10 independent claims; and (2) limit the number of representative claims that will be initially (and fully) examined to 10 claims. However, the PTO admits that only 1.2% of all nonprovisional applications filed during fiscal year 2005 contained more than 10 independent claims. Moreover, the recent increases in fees for more than three independent claims and each claim over 20 claims have cut down the number of applications presenting large numbers of claims for examination. Thus, the "solution" proposed does not seem suited to the issues actually facing the PTO.

In any event, having more than 10 claims to examine does not necessarily burden Examiners or prevent the Office from conducting more reliable and thorough examinations. For example, narrower claims that more particularly define embodiments of a complex invention often serve to assist an examiner in understanding more rapidly the general subject matter of the invention.

We understand the PTO's concerns, but believe that the limit of 10 claims is too restrictive and would significantly negatively impact the ability of biopharmaceutical companies to adequately protect all aspects of an invention. We believe that alternative measures can be used to enhance examination efficiency without limiting applicant's right and ability to define his/her invention and obtain protection on all of its various aspects. For example, we believe that the PTO's concerns could be addressed by further increasing claim fees for initial examination of more than 10 designated claims in an application. Appropriate fee increases should sufficiently discourage applicants from submitting more than 10 representative claims and adequately compensate Examiners for the increased time needed to examine to a larger number of claims. In this way, an applicant's ability to define and protect all aspects of the invention as he/she feels best would not be compromised, and an applicant would at least have the opportunity to have more independent claims and more representative claims initially examined.

If necessary, a higher limit on the number of claims initially and fully examined could be permitted. For example, we propose that at least 40 claims should be permitted for initial examination.

The need to file an ESD could be alleviated by permitting or even requiring an interview(s) prior to the first Office Action. Furthermore, the Office could require that an applicant submit an information disclosure statement with a list of all documents known to applicant (or his agents or representatives) prior to such interview. An early interview would give an applicant the opportunity to explain the invention and how the independent and dependent claims define the invention and would allow the Examiner to ask questions to alleviate any confusion. With a better understanding of the invention and how the claims define the invention, the Examiner's search of the prior art could be better focused.

Furthermore, submission of a search report(s) from a foreign patent office should be allowed in lieu of the proposed ESD requirement. Most biopharmaceutical applicants (and applicants in other arts whose inventions that have global commercial value) file U.S. and foreign applications covering their inventions. The US and foreign patent applications are usually identical or nearly so. If a deferred examination procedure were implemented, the search report from a foreign patent office would likely be available prior to the deadline for requesting examination. If such report were available, it should satisfy the requirement for the ESD in a U.S. application if the claims searched in the foreign application are of the same or similar scope to the claims in the U.S. application.

We believe flexible approaches to the number of claims initially examined are needed – without requiring an applicant to take legally dangerous actions that could ultimately foster additional legal challenges in the PTO or in federal courts. Such approaches would facilitate an applicant's ability to protect multiple or various embodiments of the invention, while still addressing the PTO's concerns with application backlog and examination efficiency.

II. A terminal disclaimer alone should be sufficient to overcome any presumption of obviousness-type double patenting between two separate applications containing patentably indistinct claims. No additional showing should be necessary.

The proposed limitations on the number of claims that would be initially examined in an application are exacerbated by the proposed rules that seek to require elimination of patentably indistinct claims from all but one of an application's nonprovisional applications. The proposed limitations on terminal disclaimer practice significantly compound the problem and effectively prevent an applicant from protecting alternative or different aspects of the invention.

Under the proposed rules, all nonprovisional applications having the same effective filing date that are commonly owned (or subject to an obligation of assignment to the same person), have at least one inventor in common and contain substantial overlapping disclosure will be presumed to have patentably indistinct claims – no matter how different the claims actually are in such applications. In addition, an applicant would have a duty to disclose all such applications to the PTO that have filing dates that differ by less than two months.

Further, under the proposed rules, if a nonprovisional application contains at least one claim that is patentably indistinct from at least one claim in one or more other nonprovisional applications or patents, and if such one or more other nonprovisional applications or patents and the first nonprovisional application are commonly owned (or subject to an obligation of assignment to the same person) and the patentably indistinct claim has 35 U.S.C. § 112, first paragraph support in the earliest of such one or more nonprovisional applications or patents, the PTO may require elimination of the patentably indistinct claims from all but one of the applications. *See* proposed 37 C.F.R. § 1.75(b)(4). If the patentably indistinct claims are not eliminated from all but one of the nonprovisional applications, the PTO will treat the designated claims in the first nonprovisional application and in each of the other nonprovisional applications or patents as present in each of the nonprovisional applications for the purposes of determining whether an ESD must be submitted. Thus, in effect, patentably indistinct claims in such separate, but related, applications would be collectively considered as being in one application, and the limitations on the number of claims that would be examined would apply.

These rule changes, if adopted, would further limit the total number of claims (and variedly claimed embodiments) that would be examined initially and fully without the need to submit an ESD. An applicant's ability to effectively protect his invention through multiple applications containing claims of varied scope would be severely limited. These proposed rules discriminate against applicants whose applications containing complex and/or multi-faceted inventions and applicants who need to modify claims over time in response to changes in law, clinical trial results, FDA concerns, business decision, commercial considerations, etc.

Moreover, under the proposed rules, the filing of a terminal disclaimer alone would not be sufficient to overcome the presumption of patentably indistinct claims. An applicant would also need to provide a "good and sufficient reason" that, to the satisfaction of the Director, justifies why there are two or more pending nonprovisional applications (naming at least one inventor in common, owned by the same person or subject to an obligation of assignment to the same person, and having same effective filing date) containing patentably indistinct claims. *See* proposed 37 C.F.R. §§ 1.78(f)(2) and 1.78(f)(3). No guidelines are given or suggested as to what constitutes "substantial overlapping disclosure." No standards are provided for evaluating

whether a submitted reason is "good and sufficient." No examples of "good and sufficient" reasons are presented. Nor do the proposed rules provide any mechanism by which to appeal or contest a decision by the Director that a good and sufficient reason has not been provided. As proposed, the rules are vague, indefinite, and likely to lead to arbitrary decisions.

Furthermore, they are confusing and would tend to increase the burden on the PTO. The PTO has indicated that any "issues" with more than 10 representative claims will be resolved prior to forwarding the application to the Examiner for initial examination. *See* "Notice of Proposed Rule Making, Changes to Practice for the Examiner of Claims in Patent Application, Los Angeles Intellectual Property Law Association, 'Washington and the West' Conference," January 25, 2006, p. 25. The Examiner would then consider all representative claims and whether a restriction is appropriate. *Id.* A restriction would be based on all pending claims in the application. *Id.* However, it is unclear from the proposed rules who, if not the Examiner, would decide issues associated with more than 10 representative claims.

For example, suppose two nonprovisional applications having common assignee and a common invention are filed, and each application contains one independent claim and 9 dependent claims. Suppose the applicant expressly designates the 9 dependent claims in each application for initial examination. If an Examination Support Document is not also filed, who would determine whether at least one claim in each application is patentably indistinct from at least one claim of the other application and whether such patentably indistinct claims have § 112, first paragraph, support in the earlier-filed application? Who would determine if each application contained more than 10 claims designated for initial examination (i.e., 20 claims) due to the alleged presence of at least one patentably indistinct claim in each application? Would the applicant be advised as to which claim(s) is alleged to be patentably indistinct from a claim in the other application? Would the applicant have the ability to contest this decision? If the PTO decided to treat each application as having 20 designated claims, it appears the applicant would have to cancel the appropriate number of claims (to have no more than 10 designated claims total for initial examination) or file an ESD. Furthermore, it appears the Examiner (upon examination) could also issue an obviousness-type double-patenting rejection, forcing applicant to cancel claims so only patentably distinct claims remain, rebut the presumption by explaining to the satisfaction of the Director how the applications contain only patentably distinct claims or submit a terminal disclaimer and satisfactorily explain why two applications with patentably indistinct claims should be maintained.

In our view, the filing of a terminal disclaimer alone should be sufficient to overcome any presumption of obviousness-type double patenting. No additional showing should be necessary. An applicant should not be required to provide, in addition, reasons or explanations as to why there are two or more pending, related nonprovisional applications containing patentably indistinct claims. An applicant should be permitted to have two or more applications pending that contain patentably indistinct claims if a terminal disclaimer is submitted – without any further showing. In addition, the claims in such applications should not be treated as if they are present in one application, and an applicant should not be forced to submit an ESD to request such treatment. One application should not be treated as having more claims that it actually has, simply because a related application contains patentably indistinct claims. However, the

proposed rules would effectively serve to consolidate such claims from two or more pending applications into one application.

For example, if an applicant files a second continuation or CIP and the Office believes the claims of the second continuation or CIP are patentability indistinct from the claims of the pending application from which priority is claimed, not only would the applicant need to provide a "good and sufficient reason" that satisfies the Director (a decision for which no standards are provided) for maintaining the multiple applications, but would also be required to limit the combined number of independent claims or designated claims from both applications to a total of 10 unless an ESD were submitted. These rules more negatively impact applicants whose inventions are multi-faceted and/or complex and who utilize continuation and CIP applications to cover alternative or varied embodiments of their inventions – embodiments to which they are entitled.

As noted above, there are alternative solutions to assisting an Examiner with examination of multiple applications, including those containing patentably indistinct claims – without the need for an ESD.

III. All of the limitations of undesignated (and initially unexamined) dependent claims should be examined fully and independently in view of all prior art.

The proposed rules indicate that unless a dependent claim has been designated for initial examination prior to the application being taken up for examination, the examination of such dependent claim will be held in abeyance until the application is in condition for allowance. *See* proposed 37 C.F.R. §§ 1.75(b) and 1.104(b). At that time, dependent claims that depend from an allowable claim(s) may be examined for formal requirements and allowed in the application. The PTO has suggested in at least two public presentations (February 2006 presentation in Chicago, IL and April 2006 PTO presentation at Sc[i][3] in Sunnyvale, CA) that if the designated claims are found allowable, the remaining undesignated dependent claims will be examined for only compliance with 35 UCS §§ 101 and 112 (i.e., only for formal matters). The PTO's rationale appear to be that because the PTO will recognize only an "proper" dependent claim (one that incorporates all limitations of the claim(s) from which it depends), if the base claim(s) from which the dependent claim depends is found allowable over the prior art, then such dependent claim is by operation of law patentable under §§ 102 and 103 over the prior art (since the dependent claim must add a limitation in order to be a "proper" dependent claim). Under this procedure, the only basis for the PTO to reject the claim would be under §§ 101 and 112.

However, this suggested examination procedure for undesignated dependent claims may raise concerns regarding the presumption of validity afforded such a dependent claim, if issued, and could pose issues in subsequent proceedings regarding validity. The PTO's suggestion that it would review an undesignated dependent claim only for formal matters under §§ 112 and 101 would appear to be an admission that the claim was not reviewed independently and fully (including under §§ 102 and 103), and, furthermore, that the undesignated dependent claim was reviewed under an examination standard different from that applied to an initially designated dependent claim. Although it's not clear from the proposed rules, one would presume that as part

of an initial examination of 10 designated claims, the PTO would a search of all of the features of a designated dependent claim separately, in addition to conducting a search of all of the features of the claim(s) from which the dependent claim depends. However, it appears that the PTO would not similarly search all of the features of an initially undesignated claim that is subsequently "examined" after the designated claims are found allowable. If that is the case, the standards for examination of an initially undesignated claim (after the designated claims are found allowable) would appear to be different from (and effectively less than) those examination standards applied when examining a designated dependent claim.

IV. The PTO's two proposals regarding Markush claims are not consistent with current standards and law. Any proposal to count each alternative in a Markush group in a single claim as a separate claim should be consistent with current law.

A Markush-type claim specifies alternatives in a format such as "selected from the group consisting of A, B, and C." The PTO has requested comments on whether the PTO should: (1) count each alternative in a Markush claim as a separate claim for purposes of proposed 37 C.F.R. § 1.75(b)(1); or (2) count each alternative in the claim as a separate claim unless the applicant shows that each alternative in the claim contains a common core structure and common core property or activity, in which the common core structure constitutes a structurally distinctive portion in view of existing prior art and is essential to the common core property or activity. We note that the PTO's second proposal refers to the PCT rules governing Markush practice in international applications (citing MPEP § 1850).

We recommend against the PTO's proposals because they specify a showing regarding whether alternatives in a Markush group are properly grouped together that is inconsistent with – and more restrictive than – that employed in current Markush practice in either the U.S. or the PCT. The current law and standards applied to examination of Markush claims should be maintained.

Conclusion

We understand the PTO's concerns and agree that improvements to the patenting system are needed. However, any changes to the patent system should be made with great care, since they may have an enormous effect on U.S. research and development, investment in U.S. business, and ultimately the U.S. economy. We strongly urge the PTO to re-consider not only these rules, but also its procedure for implementing any such changes to the practices and procedures of the PTO. We further recommend that the PTO submit the suggestions and comments it receives on its proposed rule changes to a group comprising representatives from various industries, including practitioners, PTO management, academics, and innovators, to study any proposed changes and suggestions in a considered and thorough manner. Further, public hearings should be held on any recommendations made by such group.

Thank you for your consideration of these comments.