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From: Joyce Morrison [mailto:jmorrison@xencor.com]
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To: AB93Comments
Subject: Comments on proposed USPTO Rules Changes on Continuations etc.

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To: Robert W. Bahr, USPTO

From: Joyce L. Morrison

Re: PTO's Proposed Rules on Continuations and Claims

Background

The United States Patent and Trademark Office's (USPTO) proposed rules published on January 3, 2006 would limit the filing of continuing applications and the number of claims that can be examined in a single application. Both of these rules, if adopted, would limit a biotechnology company's ability to provide information and data to convince the USPTO of the merits of an invention thereby diminishing the scope of patent protection. I believe that the USPTO's proposals will disproportionately impact the biotechnology sector because of the nature of biotechnology applications and will ultimately stifle biotech innovation.

In its rationale for proposing the rules, the USPTO points to a small number of cases where applicants "game" the system by prolonging patent prosecution until a competitor commercializes a product that is covered by the patent application. The USPTO also points to the large number of backlogged cases pending before the USPTO and concerns about patent quality. I disagree with these rationales and maintain that the proposed rules packages will not only lead to an increase in the number of application filings. These rule changes do nothing to address the quality concerns of the USPTO. In the biotechnology sector the need for multiple continuations is legitimate business practice and is not a "bad actor" issue.

Discussion

Promulgation of the USPTO's rules would result in piecemeal protection of biotechnology inventions. Because of the complexity of biotechnology inventions, it can sometime take years and multiple rounds of communication with the USPTO convince the agency of the merits of the invention. Without this opportunity, 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 by paying significantly more in filing and prosecution costs. Resource-limited biotechnology companies would be disproportionately impacted, as they would be forced to choose between filing additional applications and funding R&D. Without proper patent coverage, biotechnology companies could suffer significant setbacks in obtaining venture capital, as investors would likely not invest in technologies that are not fully protected.

Promulgation of the USPTO's rules would diminish the ability of biotechnology companies to protect the full breadth of their invention to which they are entitled. It can take decades to develop and commercialize a biotechnology product and biotechnology applications are filed very early in the R&D process. 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. The USPTO 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. Without the ability to file continuations, a company may be forced to limit the protection of the commercial product to use in animals.

Limits on filing continuations would make it difficult for small biotechnology companies to secure investment and financial support from potential partners or investors. During the course of patent prosecution, some companies change the commercial aspect of their invention over time based on the needs of its financial partners. As an example, a small company working on a licensing agreement with a

licensee may change the direction of the invention based on the needs of the licensee, what would most likely secure the support of the investment community. Also as an 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 filing. This ability to obtain support may well depend upon the existence of a continuation application, one in which claims sought by the investor or potential partner can be crafted.

The inability to fully protect biotechnology inventions will likely hinder the development of promising technologies. Some resource limited biotechnology companies may be forced to put their inventions in to 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. Many biotechnology inventions must go through a rigorous regulatory approval process which requires tens of millions to hundreds of millions of dollars to complete. Investors will not invest the vast amount of resources necessary to develop a promising technology that is not patent protected and can be copied by competitors.

The USPTO's rules do not address the concerns about the USPTO's application backlog and "abuses" of the system. Since the passage of the American Inventor Protection Act of 1999, the US has been subject to a 20-year from-filing patent term. An applicant that filed an application after 1999 would only be limited to 20 years of patent term from the date of filing, thus it benefits an applicant if the applicant is granted a patent sooner than later. So if an applicant filed in 1999 and did "stall" until 2006, as the USPTO alleges, the applicant would be entitled to only 13 years of patent protection plus any administrative delay by the USPTO beyond three years. With respect to the USPTO's backlog, I believe that promulgation of these rules would increase rather than decrease the backlog.

The USPTO's proposed rules permit the filing of single continuation from an original application unless the applicant makes a showing for filing a continuation. Applicants who would normally not file continuations would be forced to file multiple similar applications on the same date in order to be able file a single continuation on each original application. The USPTO has not provided any guidance on what kind of reasons will permit the filing of additional continuation applications after the first continuation.

If there are true "abuses" of the system, the USPTO should focus on addressing those abuses and abusers, rather than hinder the vast majority of applicants who are not "gaming" the system and only looking to obtain appropriate patent protection for their innovations.

There are alternative means for addressing the USPTO's challenges and concerns. I am a former Examiner at the USPTO. I believe that the USPTO should consider alternatives such as a deferred/ accelerated examination system, changes in the USPTO examiner production system (which has been in place and unchanged since the mid-70s); implementation of a substantive and responsive after final practice, increased examiner education (on the law and in their technology area), modifications to restriction practice, and improved cooperation with other patent offices among others.

The nature of the current examiner production system encourages the filing of multiple continuations because there is no real after final practice and it benefits the examiner's production goals. Essentially, if the applicant doesn't get it right in their first substantive response, an after final response will not generally result in an allowance since the examiner is not encouraged to work with the Applicant, as evidenced by the check off boxes on an Advisory Action. While it is to the advantage to the examiner to encourage a refilling to restart prosecution, to their credit, there are some examiners who will work with Applicants who are trying to address open issues.

The rule changes will encourage significantly more appeals to the BPAI. The Board is already overloaded, it taking about 2 years for an opinion on an appeal. The backlog will increase significantly since many applicants will have no alternative but to file an appeal, since a continuation will not be available. The end result will be a significant increase in the time to an opinion from the BPAI.

In addition to the appeals backlog, there will be significant increases in petitions regarding restriction practice. Restriction practice in the biotechnology area is currently a disaster. Many examiners' do not understand the MPEP rules and generate inappropriate restriction requirements. In addition, in many cases, the restriction requirement severely limits the ability of the applicant to actually capture the scope of the invention. Prior to implementing limitations on continuations and divisional practice, the USPTO should address the numerous problems in its restriction practice first. As discussed above, due to the restriction practice that results in 70 way restrictions (or more), many biotechnology companies do not have the resources to pursue divisional filings on this many restrictions.

The key to resolving the backlog of applications is to not only focus on hiring quality employees but retaining them. If the USPTO can retain experienced examiners, the productivity of the Office would be increased and the experienced examiners can serve as mentors to the junior examiners. Retention of the experienced examiners would also begin to address the quality concerns of the USPTO and their stakeholders.

Conclusion

I oppose the USPTO's recently proposed rules because the rules would have a disproportionate negative impact on biotechnology applications. In addition, I do not believe that the proposals address the concerns of the USPTO, e.g. backlog and abuses. I also believe that the USPTO has not followed the appropriate procedure for promulgating these rules. I believe that such sweeping patent office changes should be the subject of public hearings and advance notices of proposed rules.