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**From:** Todd Gillenwater (CHI) [mailto:gillenwater@chi.org]

**Sent:** Monday, May 01, 2006 1:06 PM

**To:** AB93Comments

**Cc:** Clarke, Robert

**Subject:** CHI Comments on Proposed Changes to Practice for Continuing Applications

Please find attached the formal comments of CHI - The California Healthcare Institute in response to proposed rule changes to the filing of Continuation, Continuation-in-Part, and Divisional applications and the filing of Requests for Continued Examination with the United States Patent and Trademark Office (PTO) published in the January 3, 2006 Federal Register.

Sincerely,

Todd Gillenwater  
Vice President - Public Policy  
California Healthcare Institute (CHI)  
1020 Prospect Street, Suite 310  
La Jolla, CA 92037  
www.chi.org  
O: 858-551-6677  
C: 858-395-7956

May 1, 2006

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 California Healthcare Institute (CHI) welcomes this opportunity to comment on the proposed rule changes to the filing of Continuation, Continuation-in-Part, and Divisional applications and the filing of Requests for Continued Examination (hereafter “continuation practice”) with the United States Patent and Trademark Office (PTO) published in the January 3, 2006 Federal Register. 1/

## **INTRODUCTION**

### **About CHI and the California Life Science Industry**

CHI represents the full biomedical sector of the California economy and unites more than 270 of California’s leading biomedical firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical research and development (“R&D”), with more than one-third of all U.S. biotechnology and medical device firms turning scientific discoveries into medical products at an unprecedented rate.

The California life sciences industry, employing nearly 250,000 workers, is responsible for many of the medical breakthroughs that allow doctors to now care for previously untreatable conditions as well as improving and extending the lives of millions here in the United States and around the world. In 2003, the state’s biomedical companies reported \$15.5 billion in private investment in R&D, with the average firm investing 48 percent of its revenues back into R&D. At the same time, over 700 spin-off companies, established through technology transfer and/or the establishment of new business by university alumni and researchers, have generated new jobs and billions of dollars in revenue.

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1/ 71 Fed. Reg. 48 (January 3, 2006).

## **Strong Patent Protection Is Especially Important To The Life Science Industry**

Life sciences research is extremely expensive, and attracting investment and other resources into companies, academic institutions and other R&D entities that are developing the next generation of treatments, therapies, and technologies depends fundamentally on the ability to develop strong patent and other intellectual property (“IP”) protections. Many of the smaller firms that comprise the majority of the life sciences industry have products and technologies that are still in the development and U.S. Food and Drug Administration (“FDA”) approval stages. Consequently, IP, particularly patents, are often their most valuable assets and the key to their funding. Without the ability to develop strong patent protections, many life-saving technologies may not see the light of day.

For example, a single invention disclosing a novel use of a technology (e.g., an energy source) and its application via a specific apparatus to treat a specific disease or condition can be improved by the original patent holder and/or spun out into new companies adapting the technology to treat entirely different conditions. All of this is enabled by the fact that patent coverage is available for the separate continuing inventions derived from the initial underlying technology. Absent the ability to protect derivative inventions via continuations, and thus to present a meaningful portfolio of underlying technology IP to potential investors, additional funding for the initial patent-holder and/or successor startup will likely not be available. Thus the stream of potentially beneficial new developments will be ended before their true value can be determined.

In the life sciences industry, “strong patent protection” often means the ability to obtain multiple patents that protect the many innovations and improvements that arise over the course of the lengthy R&D process. The FDA approval process, currently twelve to fifteen years on average for new drugs, and the attendant clinical trials that occur in the course of that process, also significantly contribute to the development of further innovations and improvements on an initial discovery. Therefore, it is extremely important for the life sciences industry that the patent application process is flexible and provides mechanisms for innovators to disclose and protect the new knowledge, discoveries and innovations gleaned through the lengthy R&D and FDA approval processes. To date, this critical flexibility has been supplied, in part, through the existing continuation practice.

The story of a California life sciences company that recently launched two new first-in-class medicines for the treatment of diabetes exemplifies the nature of the life science field and its need for the present continuation practice. Founded in 1987, the company did not receive its first drug approval until 2005. Without the flexibility and continuity that the present patent system provides, this company would have been severely hampered in its attempts to secure the venture capital necessary to keep it afloat as it researched and developed the two drugs that now provide unique therapeutic benefits to those battling diabetes. This company’s story is a success story. The company has grown to over 1000 employees and patients throughout the country currently benefit from its medicines everyday. Had the PTO’s proposed rule changes to continuation practice been in place at the time, however, the story would likely have ended much differently. The story of this company is not unique.

The bringing to market of ground breaking life sciences technologies involves long time lines and substantial capital investment. Without the flexibility that the current continuation practice provides, life sciences companies would be forced to enter capital markets relying on claims drafted many years before. This will make the already difficult task of securing funding even more difficult. The end result will be to hamper innovation and deprive U.S. citizens of all of the promise the biomedical industry has to offer.

**THE PROPOSED RULE CHANGES TO CONTINUATION PRACTICE WOULD NEGATIVELY AND DISPROPORTIONATELY AFFECT THE LIFE SCIENCES INDUSTRY AND LIFE SCIENCES INNOVATION**

The flexibility and ability to protect multiple innovations over time that is currently afforded by the long-standing continuation practice is essential to the life sciences industry. Merely by way of example, a patent application may disclose a new pharmaceutically active compound along with hundreds of chemical variants and varying dosage protocols or delivery method technology. As the R&D and FDA approval processes progress over the numerous years it takes to bring a product to market, only a small fraction of those initially disclosed compounds, dosage protocols, or delivery methods would be found safe and effective under FDA regulations. Thus, inventors must have the ability through an effective continuation process such as that currently in place to clarify and modify patent claims and to update patent applications throughout the R&D and FDA approval processes. The proposed continuation practice rule changes would, however, significantly limit inventors' ability to do so.

As described below, the proposed rule changes in continuation practice would discourage innovation by weakening patent protections and would discourage early disclosure that furthers development of the state of the art. The proposed rule changes, if enacted, would also ultimately result in the very increase in application backlog (due to a greater number of original applications being filed) and increase the lack of clarity in PTO communications the proposed rule changes are intended to avoid.

More specifically, a stated primary goal of the proposed rule change is to reduce the number of pending patent applications before the PTO in order to reduce current patent examination backlog. CHI lauds the PTO's goal of expediting the patent examination process, and supports increased resources to retain, hire, and train qualified examiners, especially in the life sciences field. CHI believes, however, that the proposed rule changes would have little benefit in reducing examiner caseloads. A continuation application is typically not a large burden to an examiner who is likely already familiar with the specification and claims through prior examination.

Instead, the proposed rule changes would very likely increase the caseload at the PTO because a natural response of patentees to these changes may likely be to file numerous parallel applications directed to various embodiments of the same invention. Because the proposed rules would limit inventors' ability to file continuation applications over the course of the regulatory approval process, the proposed rules would encourage, if not force, inventors at the outset of R&D activities to concurrently file numerous separate patent applications, each likely to have minimal or segregated disclosures. This necessity to file numerous early and separate patent

applications, before the clinical viability of any particular technology is recognized, would be especially burdensome on small businesses and non-profits due to their often-limited resources.

Rather than improving the dialogue between applicants and the PTO, it is believed that the proposed rule changes would also result in less meaningful, productive communications between applicants and the PTO. With the likely filing of multiple separate applications, the continuity of familiarity with applications would be lost since different cases on the same general area of technology would be likely assigned to different examiners. The rule changes would also limit the dialogue between applicants and the PTO because meaningful communications would effectively stop after a single action/amendment exchange, even where the dialog was constructive.

The proposed rule changes in continuation practice would also discourage innovation by weakening patent protections by essentially requiring applicants to accept narrower patent claims after the first action to avoid a final action since the proposed continuation practice rules would significantly limit applicants' response options to the final Action.

The proposed rule changes may further significantly stifle innovation by encouraging inventors to postpone the filing of patent applications. In particular, inventors with limited resources may opt to delay patent filings until after clinical testing or other refining of the invention. In the meanwhile, the inventors would keep the invention secret from the public, thus discouraging further research and development in the field by deterring the public disclosure of innovations through patent filings and the concurrent publication of articles.

Additionally, the proposed rule changes would likely shift the PTO's burden from the examination corps to the patent appeals process and undoubtedly result in a large increase in appeals to the Board of Patent Appeals and Interferences ("BPAI"). With limitations on continuation practice, applicants would increasingly rely on appeals to continue prosecution after final rejections to review the grounds for rejection and determinations on whether adequate grounds existed to file continuation applications. These appeals would be extensive time-consuming and expensive processes for both applicants and the PTO, and the issues for appeals often could have been easily resolved through further amendment.

Concurrent with the increase in the appeals, the proposed rule changes would cause applicants to increasingly request judicial review of the PTO determinations since applicants would have limited continuation practice options and since the proposed rule changes would add an additional ground for review. For that matter, limiting continuation applications will also shift the PTO's burden from the examination corps to subsequent litigation by adding additional grounds for dispute over appropriate PTO practice and procedures, including re-examination of provided bases for the necessity of continuation applications.

To better alleviate the concerns attempted to be addressed by the proposed rule changes, it would seem that alternative steps, such as introducing a deferred examination procedure or graduated filing fees depending on desired timing of examination, could address backlog concerns without so negatively affecting the life sciences industry. Expanding after-final practice or incentivising examiners to grant after-final interviews and/or to issue non-final

second office actions if progress is being made on an application would also better facilitate communications and movement of applications. For example, the PTO could remove disincentives and/or provide incentives to examiners for issuing second non-final actions, particularly if, in the Examiner's discretion, progress is being made in bringing the claims to allowance. This suggestion is consonant with European practice, which gives examiners substantial latitude in deciding whether to continue prosecution on the merits or issue a final action.

To better facilitate communications and movement of applications, the PTO could also implement rules changes to improve the usefulness of examiner interviews. For example, the PTO could allow pre-examination interviews after the examiner has reviewed the application but before issuance of a first office action on the merits to ensure that the examiner has fully understood applicant's disclosure. Similarly, the usefulness of examiner interviews would be improved if an interview with an examiner after a first action could include the examiner's supervisor, if desired by the applicant, and if after-final interviews would be granted as a matter of right.

Moreover, given that Congress has been considering in detail various patent reforms (and had, in fact, considered modifications to the continuation process), it may be that any proposed change to continuation practice should more efficiently and appropriately await action by Congress.

### CONCLUSION

For the reasons described above, CHI believes that the proposed rule changes to continuation practice before the PTO would negatively and disproportionately affect the life sciences industry, and urges the PTO to forgo the proposed limitations on continuation practice. CHI thanks the PTO for this opportunity to comment on the proposed changes to continuation patent practice. We look forward to working with the PTO in developing policy to better streamline and expedite the patent examination process. Please contact Todd Gillenwater, Vice President, Public Policy, at (858) 551-6677 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



David L. Gollaher, Ph.D.  
President and CEO