

# **EXHIBIT B**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
National Institutes of Health

Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

May 3, 2006

**VIA ELECTRONIC MAIL**

John J. Doll  
Commissioner for Patents  
Mail Stop Comments-Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, Virginia, 22313-1450

Attn: Robert W. Bahr

Dear Commissioner Doll:

The written remarks presented herein are directed to the request for comments to the Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims published at 71 Fed. Reg. 48 (January 3, 2006). These comments represent the views of the National Institutes of Health (NIH). NIH is the lead agency within the Department of Health and Human Services (HHS) in matters of technology transfer. In addition to providing patent and licensing services to all Institutes and Centers within NIH and the U.S. Food and Drug Administration (FDA), it is the lead agency responsible for coordinating and facilitating technology transfer policy functions for NIH, FDA, and Centers for Disease Control and Prevention (CDC). Finally, NIH appreciates the USPTO's efforts to streamline and improve the patent prosecution process. As such, the comments herein are offered to further this process.

**Introduction and Background to Federal Technology Transfer**

**Legislative Mandate for Federal Technology Transfer**

The Bayh-Dole Act of 1980, (Pub. L. No. 96-517, 94 Stat. 3015, as amended) permits recipients of federal grants and contracts to retain title to their inventions developed under such federal funding. In October 1986, Congress also enacted the Federal Technology Transfer Act (FTTA, Pub. L. 99-502, 100 Stat. 1785), which amended the Stevenson-Wydler Innovation Act of 1980. The FTTA, as amended, stimulates transfer of Government-owned technology by offering incentives to both federal laboratories/scientists and collaborating partners in universities, foundations, and private industry.

NIH Advancement of the Technology Transfer Mandate via Patent Procurement

The NIH supports a balanced approach to intellectual property. In instances where further developmental efforts and private sector investment are needed to realize the potential of a basic research observation, the availability of the exclusivity provided by the patent system serves to foster private sector investment. This is balanced against the widespread public benefit that is garnered by public disclosure and widespread availability. See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (the “NIH’s Research Tools policy”), 64 Fed. Reg. 72090 (December 23, 1999).

**I. General Comments to Proposed Regulations**

NIH recognizes that the proposed changes to continuation practice rules provide that one continuation application is always available as of right, whether in the form of a continuation application, or a request for continued examination, subject to certain limitations for divisional and continuation-in-part applications. However, in the pharmaceutical, biotechnology, and related arts, continuation applications are more widely used than in other art units. Anecdotal reports suggest that the continuation filing rate may be twice that in other technology areas. This trend may be attributed to the nature of the development cycle of innovative drugs and therapies, rather than a gaming of the system to improperly delay issuance. NIH expresses concern that the proposed regulations may disproportionately affect the arts that most directly impact public health, in at least the following two ways:

First, the practice of filing multiple continuation applications is related, at least in part, to the nature of the development of new drugs (both small molecule and biologics), therapies, and products. Many of these innovations are subject to regulatory review by the FDA. As such, pharmaceutical and biotechnology innovators are subject to two-pronged administrative requirements: (a) filing and prosecuting applications before the USPTO; and (b) preparing submissions to the FDA, such as Investigative New Drug Applications and New Drug Applications. While the US patent system favors prompt disclosure, necessitating the filing of applications early in the research and development process, innovators concurrently pursuing FDA regulatory approval are also gathering additional data that may be relevant to pending applications. Therefore, information derived from experiments initiated on or before the time an initial application was filed may only become available to the innovator at a later time.

Given the unpredictable nature of pharmacologic research, especially research involving biologics, patent applications in these technology areas often have prophetic disclosures that garner rejections under 35 USC 112, ¶1, that are not dismissed until pharmacologic data are available. However, obtaining such data requires both time and significant

financial investment. The latter is often only available when either (a) intellectual property rights have been obtained (i.e., a patent) or (b) when potential rights in the form of patent applications are present. By imposing additional requirements on continuation application practice rules, the USPTO may be limiting the ability of pharmaceutical and biotechnology innovators to provide evidence incorporating new data supporting the patentability of the claimed subject matter. Similarly, additional clinical trials and studies may reveal follow-on drugs, therapeutics, and products, otherwise supported by the initial application's specification. However, under the proposed regulations – in the absence of a mechanism to recapture co-pendency – these “second generation,” and potentially superior, products may be denied the benefit of the initial application's filing date[s].

Second, the NIH expresses concern as to the effect of the proposed regulations in connection with Markush practice. Under the USPTO's guidelines published at 63 Fed. Reg. 47000 (September 3, 1998), which issued following In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994), the patentability of a species over a genus is highly fact-dependent. A pharmaceutical or biotechnology innovator often begins a chain of applications to a new family of promising pharmacologies by filing an application disclosing a broad Markush group. As the innovation cycle progress, a particular member of the group may become the focus of investigation. For example, data may become available related to a member of the Markush group that is pharmaceutically superior to either representatives of the broad genus originally disclosed or to the specific members initially targeted for late-stage clinical trials. Under the proposed regulations, the innovator may be unable to claim the benefit of the initial filing date. While some innovators may have the funding capabilities to file multiple applications for each sub-genus in the Markush group so as to allow for this contingency, publicly-funded institutions, small research incubators, start-up companies, and many biotechnology companies may have more limited financial resources that are better spent on experimentation rather than legal expenses.

## II. Comment to Proposed Section §1.78(d)(1)(iv)

Section 1.78(d)(1)(iv) provides, in relevant part, that where an applicant seeks to file a second or subsequent continuation application, the applicant must file a petition accompanied by the fee set forth in 1.17(f) and “a showing to the satisfaction of the Director that the amendment, argument, or evidence *could not have been submitted* during the prosecution of the prior-filed application.” (Emphasis added). The proposed regulations, however, do not provide concrete examples of showings sufficient to allow the filing of the second or subsequent applications, thereby creating uncertainty as to the scope and impact of the proposed regulations. The standard, “could not have been submitted during the prosecution of the prior-filed application,” may be open to several interpretations by different applicants based on the technology area encompassed by the claimed invention.

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NIH proposes that the USPTO prior to implementation of the proposed regulations publish more specific guidance, with the opportunity for comment, related to the types of showings sufficient to permit the filing of a second or subsequent continuation application. Such guidance should include a non-exclusive set of examples of the types of information required to meet the requirements under § 1.78(d)(1)(iv) for different technology art groups. The NIH acknowledges that the USPTO cannot provide examples for each and every technology group and that the examples provided should not be used by applicants as justification for permitting each and every request for a second or subsequent continuation application. Rather, NIH proposes the publication of the additional guidance to provide further clarification to applicants how to proceed under the proposed regulations.

In conclusion, NIH thanks the USPTO for the opportunity to present our views. Please feel free to contact us, if we can be of further assistance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mark L. Rohrbaugh".

Mark L. Rohrbaugh, Ph.D., J.D.  
Director, Office of Technology Transfer

**Chang, Joni**

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**From:** Stanton, Brian (NIH/OD) [E] [stantonb@od.nih.gov]  
**Sent:** Wednesday, May 03, 2006 4:28 PM  
**To:** AB93Comments  
**Subject:** FW: NIH's Comments to Proposed USPTO Rule Changes to Continuation Practice  
**Importance:** High

May 3, 2006

Attn: Robert W. Bahr

On behalf of Mark L. Rohrbaugh, Director, Office of Technology Transfer, National Institutes of Health (NIH), attached please find NIH's comments (in PDF format) to the USPTO's Proposed Rule Changes to Continuation Practice, published at 71 Fed. Reg. 48 (January 3, 2006).

Should you have any difficult viewing the attached document, please do not hesitate to contact me at [stantonb@mail.nih.gov](mailto:stantonb@mail.nih.gov) and/or 301-435-4074. Thank you for the opportunity to submit comments.

Sincerely,  
Brian Stanton

Brian R. Stanton, Ph.D.  
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