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From: Anne Taylor [mailto:ataylor@cogr.edu]

Sent: Wednesday, May 03, 2006 3:48 PM

To: AB93Comments; AB94Comments

Subject: Changes to PTO Rules

Please disregard the initial transmittal of these comments. Formatting changes were visible.
Thank you.

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COGR

an organization of research universities

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Re: 71 *Fed. Reg.* 48 and 71 *Fed. Reg.* 61

Docket Nos.: 2005-P-066 and 067

JOANNE DE STEFANO
Cornell University

Dear Sir,

PETER DUNN
Purdue University

The Council on Governmental Relations (COGR) is an association of 170 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of government regulations, policies, and practices on the performance of research conducted at its member institutions. One of our principal areas of focus is to assure the continued ability of universities to successfully patent and license their inventions in order to transfer university technologies for use and benefit of the public. In the case of federally funded inventions, the Bayh-Dole Act (35 USC 200 *et seq.*) mandates universities to patent the inventions and to seek to commercialize them through appropriate licensing arrangements with the private sector.

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COGR appreciates the opportunity to submit comments in response to the referenced rule changes in patent practice that the Patent and Trademark Office (PTO) has proposed with regard to continuing applications, requests for continued examination and applications containing patentably indistinct claims (71 *Fed. Reg.* 48; P-066) and the examination of claims (71 *Fed. Reg.* 61; P-067).

NATALIE KRAWITZ
University of Missouri System

GUNTA LIDERS
University of Rochester

YOKE SAN REYNOLDS
University of Virginia

COGR appreciates PTO's concern for increasing efficiency in the patent examination process in order to promote innovation and improve patent quality. However, we are concerned that the proposed changes will not accomplish these goals, and will adversely affect universities and their ability to license new technologies to commercial partners, particularly in the pharmaceutical and biotechnology industries which predominate in university patents, and where patent applications tend to have a high number both of continuations and of claims. The proposed changes are particularly disadvantageous to smaller entities such as universities and other research institutions because they will increase the complexity, uncertainty and costs of obtaining patent protection.

JAMES SEVERSON
University of Washington

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ARA TAHMASSIAN
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President

Numerous studies have demonstrated that universities are significant drivers of U.S. technological innovation. University inventions usually consist of new cutting edge technologies for which strong patent protection is necessary to attract the industry investments needed to further develop the early stage technologies into commercial products that ultimately benefit the public. This is particularly true of new therapeutic products requiring approval of the Food and Drug Administration (FDA), which take an average of 12 years and significant industry investment to obtain FDA approval.

The ability to file continuations, continuations-in-part (C-I-Ps), and divisional applications are an important aspect of academic patenting practice. Academic incentives drive university researchers to publish their research discoveries early and often, which necessitates the filing of patent applications on early stage technologies for which additional experimentation is needed for further development. Continuations play a critical role in the ability of universities to present and protect claims covering the full scope of their inventions, in order to achieve technology transfer goals. We are aware of estimates that close to one-third of university patents are continuations or C-I-Ps. Limiting continuation practice as proposed in 71 *Fed. Reg.* 48 will negatively impact the ability of universities to pursue full and effective patent protection for their discoveries.

A key reason for filing continuations and requests for continuing examination (RCEs) is to give researchers and university technology transfer offices time to review and respond to PTO examiner actions, especially given academic pressures to publish early. Universities file continuations to better refine their patent claims in the course of the research and development process, not in response to developments in the commercial marketplace. Furthermore, given the cutting edge nature typical of university technologies, the claims may not be sufficiently understood by the examiner to be properly defined in only two examinations. We also note that the costs of filing continuations and RCEs already provide a deterrent to excessive use of these options, especially given typically limited university technology transfer office budgets.

C-I-Ps are a useful tool for universities to manage the cycle of filing a patent application, publishing on the invention claimed, then filing a second application on new results prior to publishing the new research findings. The proposed requirement to identify claims supported in a prior-filed application when filing a C-I-P will be burdensome and costly to universities. With respect to divisional applications, we understand that restriction requirements that divide a patent case into multiple claim sets are imposed with increasing frequency by PTO examiners. However, when combined with the proposal to force applicants to file all divisional applications simultaneously rather than serially as is the current practice, the result is a significant financial hardship for entities with limited budgets such as universities. This also may result in PTO receiving a significantly increased number of divisional applications from all applicant entities, since to avoid losing rights, applicants may file divisionals earlier in the process than they would have filed under the current system.

The proposed change in 71 *Fed. Reg.* 61 to limit applicants to ten representative claims unless the applicant also provides an examination support document also will have a negative effect on universities. While we note the relatively small percentages of such applications cited by PTO, our member institutions have informed us that rarely do university patent applications contain so few claims, especially given the nature of university technologies. We respectfully disagree with PTO's assertion that the proposed examination support document will not have a significant economic impact. It will require universities to conduct

extensive preexamination searches of U.S. and foreign patents and the scientific literature. This document will be time consuming and expensive for universities to prepare and submit.

We share PTO's concerns about pendency and the negative public perceptions of patent "trolls." However, we are not aware of any evidence that academic entities have abused current continuation or claim practice. As vigorous inventors and publishers of new technology, the academic community is far from the negative model of passive investor patent trolls. We are concerned that rather than addressing the real causes of increased pendency, which primarily involve the shortage of qualified examiners and workload management issues, the proposed rule changes will shift the burden to the applicant community in a flawed, unduly complex and burdensome way, disproportionately disadvantaging universities as compared to large for-profit entities with more substantial patent budgets. Rather than solving the problems, the pendency backlog and delays may increase, given the adoption of new and complex procedures, requirements and limitations.

Given these potentially serious negative effects, particularly for university inventions on which the U.S. depends for future economic innovations, we urge PTO to withdraw these proposed rule changes and to consider commissioning a pilot program or further study to test the assumptions on which the proposed changes are based. We would be happy to assist PTO in such efforts.

We appreciate the opportunity to comment.

Sincerely,

Anthony DeCrappeo
President