

From: Norton, Leah [redacted]

Sent: Friday, November 19, 2010 3:10 PM

To: HumanitarianProgram

Subject: Comments to PTO - Docket No. PTO-P-2010-0066 the from Association of American Universities (AAU) and the Council on Governmental Relations (COGR)

Below (and attached) you will find the Association of American Universities and the Council on Governmental Relations response the Federal Register request for comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System [Docket No. PTO-P-2010-0066].

November 19, 2010

Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
HumanitarianProgram@uspto.gov
Attn: Joni Y. Chang

Re: Docket No. PTO-2010-0066 (75FR57261)

The Association of American Universities (AAU) is an association of 61 U.S. and two Canadian research universities distinguished by the breadth and quality of their programs of research and education. The association works to develop and implement effective national policies supporting research and scholarship, graduate and undergraduate education; and the AAU provides a forum for discussion and development of institutional policies that advance the missions of the member institutions. The Council on Governmental Relations (COGR) is an association of more than 180 U.S. research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research and other sponsored activities conducted at its member institutions.

We read with great interest USPTO's request for comments on a proposed fast-track *ex parte* reexamination voucher program to create incentives for technologies and licensing behavior that address humanitarian needs. Members of the AAU staff and the AAU Council on Federal Relations as well as the COGR Contracts and Intellectual Property Committee greatly appreciated the opportunity to participate in the university stakeholders meeting convened by USPTO to discuss the proposal on October 27.

The university community strongly supports the goal of USPTO to explore strategies that would use the patent system to incentivize activity addressing humanitarian needs, and encourages USPTO to pursue a pilot program as proposed in the Federal Register notice. Universities and

university associations are committed to seeking to develop and license technologies and innovations that will benefit underserved populations to the widest extent possible. For example, a large number of U.S. universities and university associations including AAU and COGR have endorsed the Nine Points to Consider in Licensing University Technology. Point 9 calls for considering including provisions in licensing agreements that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world. In addition, a number of universities have signed a Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies, and the Association of University Technology Managers (AUTM) has launched a Global Health Initiative (www.autm.net/home.htm).

While we support the goals of the USPTO proposal, we are concerned that some aspects may need to be carefully considered to avoid unintended consequences and potential exploitation. We believe that USPTO should consider instituting a competitive review process for voucher issuance to assure quality and effectiveness. We also suggest that the number of vouchers issued on an annual basis be substantially limited, at least until the results of the pilot program are known. While possible transferability of the reexamination vouchers on the open market would substantially enhance their value, auctioning the vouchers off to the highest bidder could lead to negative public perceptions and questions about public vs. private benefit. We urge USPTO to consider whether the enhanced value offsets these possible negative consequences.

Our comments on the numbered questions raised in the proposal are set forth below.

1. While developing new treatments for neglected tropical diseases unquestionably should be a high priority, we do not believe that an automatic reexamination voucher necessarily should be awarded. This more properly should be considered as a significant factor in the competitive evaluation process.
2. As noted, free transferability undoubtedly would greatly enhance the value of the vouchers. However, there could be significant concerns about who is receiving the greatest benefit. For universities, direct sales of such vouchers may raise policy and tax issues. The greatest value for universities might lie in including such vouchers in license agreements, as an incentive for licensees. We think that rather than allowing outright sale, enabling patent holders to use the vouchers as incentives for encouraging humanitarian use or research in license agreements would be more advisable.
3. We believe that while technologies patented by universities may serve needs in developing countries, they also could be of use to disadvantaged populations in the U.S. We urge USPTO not to limit the voucher program to humanitarian activities directed only to developing countries.
4. We suggest the USPTO ask patent holders to demonstrate other examples where they have facilitated use of patented technologies for humanitarian purposes or cite

examples of similar technologies that have proved beneficial. This could be an element considered in the competitive review process. In addition, patent holders might commit to including clauses in licensing agreements that address this issue should a previously undetermined use arise.

5. We strongly urge USPTO to consider a competitive review process for award of the vouchers. Third party expertise, either from organizations or individuals familiar with science and technology as well as needs of underserved populations, could be very helpful in this process. If applicants wish to provide third party statements, this should be allowed but not required.
6. We do not think qualifying humanitarian criteria should be defined narrowly through use of lists as stated, although such lists could provide helpful guidance.
7. Universities typically address this type of issue through milestones included in license agreements. The 9 Points document referenced in the second paragraph above may provide some suggestions as to the type of efforts and evidence that would be helpful in addressing this question from a university perspective.
8. While a process and means for determining significance and deterring abuses is important, flexibility also is necessary to determine the nature and degree of research needed. Seeking to quantify this effort through minimum thresholds may not be advisable. Similarly, new or innovative uses of patented technology should not be discouraged through “but...for” requirements as suggested in the question. We suggest that the burden be placed on the voucher applicant to make the case for how the patented technology in question will advance humanitarian research, and the credibility of the arguments presented would then be judged through the competitive review process we are proposing.
9. As indicated above, it is likely that for universities the greatest use of the proposed voucher would be as an incentive for licensees. We expect that universities would retain the rights over the research results, and that terms of use as well as milestones for increasing access would be set forth in license agreements.
10. This should be addressed through the competitive review process we are suggesting.
11. Universities are unlikely to be direct users of *ex parte* reexamination vouchers. They might more readily take advantage of vouchers for initial examination. While as discussed above we believe there could be value in the reexamination vouchers if transferable to our licensees, in the case of universities initial examination vouchers might offer greater incentives.
12. While valuable and important, non-monetary prizes and awards are not as likely to encourage greater investment as incentives tied more directly to financial rewards.

We again applaud USPTO for considering this initiative, and hope that our comments will be helpful. We encourage USTPO to proceed with the initiative, and would be pleased to discuss the proposal further.

Sincerely,

Robert Berdahl
President
Association of American Universities

Anthony DeCrappeo
President
Council on Governmental

Relations