AAU *Association of American Universities*
ACE *American Council on Education*
AAMC *Association of American Medical Colleges*
COGR *Council on Governmental Relations*

June 23, 2005

The Honorable Lamar Smith
Chairman
Judiciary Subcommittee
on Courts, the Internet
and Intellectual Property
U.S. House of Representatives
Washington, DC 20515

The Honorable Howard Berman
Ranking Member
Judiciary Subcommittee
on Courts, the Internet
and Intellectual Property
U.S. House of Representatives
Washington, DC 20515

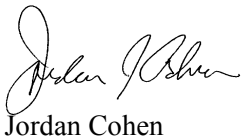
Dear Chairman Smith and Ranking Member Berman,

The Association of American Universities, the American Council on Education, the Association of American Medical Colleges, and the Council on Governmental Relations submit the enclosed comments on H.R. 2795, the "Patent Reform Act of 2005." Collectively, our associations represent the major universities and medical colleges that conduct most of the nation's basic research, leading to advances in knowledge that strengthen national security, increase the nation's economic competitiveness, and enrich the lives or our citizens. A significant portion of the societal benefits of university research is realized through technology transfer, and the U.S. patent system plays an important role in this process.

For our comments, we have drawn substantially from the thoughtful report of the National Research Council, *A Patent System for the 21st Century*. We share the NRC's view that, although the U.S. patent system is working well in many respects, important reforms are needed. Although we note a number of specific concerns with the bill in the attached comments, we believe that H.R. 2795 provides a strong start down the path of effective reform, and we commend you for the thorough and balanced process your Subcommittee has undertaken to begin this important reform effort.

We hope these comments are helpful, and we look forward to working with you and with other groups seeking to reform the U.S. patent system to strengthen its capacity to support innovation to the benefit of the nation.

Sincerely,



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Enclosure: AAU/ACE/AAMC/COGR Comments on H.R. 2795

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H.R. 2795, THE "PATENT ACT OF 2005"

COMMENTS BY THE ASSOCIATION OF AMERICAN UNIVERSITIES, THE AMERICAN COUNCIL ON EDUCATION, THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND THE COUNCIL ON GOVERNMENTAL RELATIONS

America's universities are the principal source of the basic research that expands the frontiers of knowledge and produces discoveries that enhance our national security, strengthen our economic competitiveness, and enrich the lives of our citizens. Although the principal means by which university research results are disseminated is through peer-reviewed publications, conferences, and other forms of open communication, the nation also benefits substantially from university research through technology transfer processes where fundamental discoveries are moved into the commercial sector for development into useful products. The landmark 1980 Bayh-Dole Act, which authorized universities and small businesses to retain patent and licensing rights to inventions resulting from federally funded research, has been an extraordinarily successful mechanism for facilitating the transfer of basic discoveries into the commercial sector for development. The patent system is an integral part of this process.

Universities play a critical role in the innovation process and have a strong interest in the means by which the patent system advances this process. Universities welcome the opportunity to examine the patent system and promote reforms that will enhance the capacity of that system to support invention, innovation, and development in the U.S. and worldwide.

Enhancing the capacity of the U.S. patent system to support innovation is the fundamental goal guiding the comments of our four associations on H.R. 2795, the "Patent Act of 2005." Our comments are also shaped in significant measure by the National Research Council's report, *A Patent System for the 21st Century*. We comment here only on those aspects of H.R. 2795 that bear directly on the capacity of universities to maintain and strengthen their role in the innovation process.

Section 3, First Inventor to File

The first inventor to file process specified in Section 3, which was recommended by the National Research Council's report, would harmonize U.S. patent law with that of other countries to a significant degree, would add greater clarity to the patent system by replacing the subjective determination of the first inventor with the objective identification of the first filer, and would reduce or eliminate the unpredictable and often substantial costs of interferences and litigation associated with determining the first inventor.

The associations do not oppose the U.S. patent system moving from a first to invent to a first inventor to file system. Such a move would provide significant benefits to the U.S. patent system as well as to

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universities, but it does raise concerns among some members of the university community about their ability to operate effectively in such a patent system.

University inventors typically are faculty members who first publish in academic journals and later consider whether to file to obtain a patent. Before filing a patent application, universities often need time to consider the potential commercial application of a basic research discovery, which may not be obvious at the point of discovery, and to assess the receptivity within the commercial sector to licensing any resultant patent for development. Moreover, the budgetary limitations on non-profit universities often constrain the resources they can devote to rapid filing of fully developed patent applications. All such practices are accommodated in a first to invent system but could be compromised in a first inventor to file system.

If Congress elects to move to a first inventor to file system, we believe it is imperative that U.S. patent law maintain three components of the current U.S. patent system: (1) the opportunity to file provisional applications, (2) the 12-month grace period for publishing articles containing a disclosure of the invention, and (3) the provision of current U.S. patent law requiring an applicant to sign an oath that he or she is an inventor of the claimed invention.

Provisional applications: H.R. 2795 preserves the provisional application procedure, and we simply note here the importance of preserving that procedure in any patent reform proposal that moves forward.

Grace period: We commend the inclusion in H.R. 2795 of Section 102 (a), which provides a 12-month grace period before the effective filing date of an invention, during which the publications or other disclosures made by the inventor, joint inventor or others who obtained the disclosed subject matter from the inventor or joint inventor are not treated as prior art. Such a provision encourages the early disclosure of basic research results by an inventor while permitting him or her to file up to a year later.

However, current US patent law provides a broader grace period covering the publications not only of the inventor but also of others carrying out research in the same area. We believe that such a provision facilitates research collaborations and encourages publication and other forms of disseminating research results in ways consistent with both the operation and objectives of the patent system.

We recommend that the Committee amend Section 102 (a) to restore the broader 12-month grace period of current law. In addition, we urge the committee to request the Administration to seek adoption by other countries of the current U.S. grace period, as recommended in the National Research Council's report.

Applicant oath: The requirement in current law that the individual filing an application, or on whose behalf an application is filed, must sign an oath asserting the belief that he or she is an inventor of the claimed invention is an important procedure underscoring the importance of a government grant of a property right. The same considerations should apply in a first inventor to file system, and we encourage the Committee to include the requirement for an applicant to sign an oath asserting inventor status.

The associations recognize the benefits of a first inventor to file system and do not oppose the proposed move to such a system. Three provisions of current U.S. patent law—provisional applications, a broad 12-month grace period, and the signing of an oath by the applicant—are important properties of patent law to be preserved for universities operating in a first inventor to file system.

Section 9, Post-Grant Opposition Procedure

The associations strongly support the creation of an administrative post-grant opposition procedure such as that proposed in H.R. 2795. An opposition procedure that is of finite, predictable duration and allows third parties to challenge a patent based on the full array of issues of patentability, utility, and adequacy of written descriptions would improve patent quality by providing a relatively low-cost alternative to litigation to establish patent validity.

Two modifications to the post-grant opposition procedure of H.R. 2795 would significantly improve this important new procedure:

- Identify all parties requesting an opposition: All persons requesting an opposition should be required to identify themselves and the real party in interest, if different. It is fair and appropriate that a patent holder should be able to know the identity of the party opposing the patent, and no useful purpose is served by withholding the identity of the opposer.

- Expand the timing of the opposition request: A 12-month, rather than 9-month, window could benefit smaller entities, which may need more time to identify and respond to patents about which they have concerns. The added three months would still keep the opposition procedure within the framework of a finite, predictable process.

It will be critical, however, for the United States Patent and Trademark Office (U.S. PTO) to receive the resources necessary to implement this additional administrative procedure. Failure to do so could cause significant increases in patent pendancy, undermining the considerable benefits that an effective post-grant opposition procedure could bring to the patent system.

Section 3, the CREATE Act

Section 102 (b)(2) of H.R. 2795 establishes a new Joint Research Agreement Exception designed to reinstate the CREATE Act, which was enacted into law last year under the leadership of the House Judiciary Subcommittee on Courts, the Internet and Intellectual Property. The CREATE Act was intended to facilitate research collaboration, and we appreciate the inclusion of the Joint Research Agreement Exception in H.R. 2795. However, the language as written does not contain the CREATE Act's effective

date or legislative history, and we urge adoption of modifications necessary to fully reinstate all aspects of the CREATE Act.

Section 8, Continuation Applications

Continuation applications serve important purposes for universities. Particularly in some research fields such as the life sciences, where the rapid pace of discovery runs ahead of the often unavoidably slow pace of U.S. PTO processing of patent applications, continuation applications are a valuable procedure for updating applications to reflect recent developments. We understand that continuation applications have been abused in the past by some patent applicants who attempt to extend patent applications through continuations until market conditions provide an opportunity for them to have a patent issue and file an infringement suit. However, there is some evidence[1] that the efficacy of "submarining" patents through continuation applications was substantially reduced by the enactment in 1999 of the requirement for publication of most applications after 18 months, and the 1995 change to a 20-year patent term measured from the date of filing rather than a 17-year term from the date of patent grant.

If Congress concludes that misuse of continuation applications is an ongoing problem that needs to be addressed, the proposal in H.R. 2795 to authorize the U.S. PTO to limit continuation applications by regulation may be an appropriate response, but we would be concerned if any such regulations would limit the legitimate use of continuations by universities or any other patent holder.

Section 9, Prior User Rights

The associations strongly oppose the expansion of prior user rights contained in Section 9 of H.R. 2795. As a practical matter, any assertion of prior user rights vitiates the value of patents. We understand the legitimacy of commercial entities choosing to develop products under trade secret procedures as opposed to a public patent process. However, expanding the prior user rights defense from a demonstration that an invention had been "commercially used" to a claim of "substantial preparations for commercial use" not only significantly weakens the value of patents but goes against the spirit of H.R. 2795 by introducing precisely the sort of subjectivity into the patent system that many elements of H.R. 2795 effectively eliminate. We recommend deleting Section 9 (b) DEFENSE TO INFRINGEMENT BASED ON EARLIER INVENTOR.

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[1] A recent Master's thesis which examined continuations of patent applications in molecular biological pathways found no evidence of submarining behavior in the applications examined after 1999, when the 18-month publication requirement for most applications was enacted. Eric M. Hoefer, An Analysis of the Effect of Patenting Research Tools on Innovation in Three Biological Research Domains: CTLA-4, NF-KB, and EGFR, Thesis for Masters in Public Policy, Duke University; on file with the author.

Section 7, Injunctions

The associations believe that injunctions are an important tool in the defense of patent rights. We recognize that there is considerable concern that injunctions are being abused, particularly in certain industry sectors, by some parties exploiting the issuance of injunctions by courts to extract unwarranted settlements from companies. However, the associations oppose statutory changes that would weaken patent rights by reducing the ability to defend those rights through the legitimate use of injunctions.

Section 9, 18-Month Publication

The associations support the requirement in H.R. 2795 that all applications be published 18 months after their effective filing date. Currently, patent applications are published after 18 months unless an applicant requests non-publication and is not intending to file in another country that has an 18-month publication rule. As noted earlier, there is some evidence that even the current, limited 18-month publication requirement has reduced the number of submarine patents. The H.R. 2795 requirement for publication of all patent applications after 18 months may well further discourage any abuse of continuation applications. But the strongest reason for requiring publication of all patent applications after 18 months is its congruity with a fundamental purpose of patent law to encourage disclosure in return for limited proprietary control over one's intellectual property. Such a requirement is fully consistent with the academic mission of full and open communication of research results at the earliest feasible opportunity.

Section 6, Damages

Section 6 (1) (B) appears essentially to codify current case law. Since judges have ample discretion under current law to assess the relative value of a patented technology in determining damages, we believe Section 6 (1)(B) is unnecessary, and the attempt to codify case law could have unintended negative consequences. Therefore, we encourage deletion of this subsection.

Section 10, Submissions by Third Parties

The associations support the Section 10 provision allowing preissuance submissions by third parties. This provision will promote patent quality and validity by assisting patent examiners to gather all relevant evidence in evaluating patent applications.

Experimental Research Exemption

We believe that the Committee should give careful consideration, in consultation with all parties with an interest in the patent system, to inclusion of an experimental research exemption in any patent reform bill that goes forward. Such an exemption should be carefully crafted to promote experimental research, while advancing the goals of the patent system and the larger society it serves, rather than any specific sector of society.

The exemption should at a minimum allow research on a patented product or process, research that specifically examines the nature of a patented invention—to determine whether it functions as claimed, to better understand its operation under various conditions, to discover something unknown about it, or, under appropriate circumstances, to improve upon it. A narrowly crafted exemption for research on the functioning of a patented invention could provide a fuller understanding of a patent without threatening the market for the patent, thereby advancing the fundamental goal of the patent system to promote innovation through a combination of disclosure and proprietary protection.

Crafting a research exemption that advances broad societal interests without intruding into the proprietary protections intended by the patent system is a difficult process, but we believe the potential benefits to society of an appropriately developed research exemption that is congruent with the goals of the patent system warrants thorough examination. We welcome the opportunity to work with the Committee and other appropriate parties to carry out such an examination.

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