

October 15, 2014

Transmitted via email to Michelle.Lee@uspto.gov

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce and
Deputy Director, U.S. Patent and Trademark Office

Subject: Supplemental Comments on the USPTO Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products

Dear Deputy Director Lee:

The university community looks forward to the final guidance that the U.S. Patent and Trademark Office (USPTO) will issue to address the subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, and natural products. Four higher education associations – the Council on Governmental Relations (COGR), Association of University Technology Managers (AUTM), Association of Public and Land-grant Universities (APLU), and Association of American Universities (AAU) – provided comments on July 28, 2014, in response to the USPTO federal register notice regarding the guidance memorandum published on March 4, 2014 (“March Guidance”). The four associations on behalf of the university community expressed concern about the March Guidance being overly broad, extending well beyond Supreme Court rulings in recent patent-eligibility cases. We are also joined in these latest comments by the Association of American Medical Colleges, and the American Council on Education.

We understand that USPTO officials have suggested during recent public events that elements of the March Guidance will be revised and included in the final Guidance. Because it appears that the revisions may include substantive changes to the previous version, we are writing this letter to request the USPTO to re-issue the revised Guidance in draft form to allow the patent community and the public to comment on any significant proposed changes to the criteria used to determine patent eligibility or to the patent prosecution process. Any revised Guidance will have a profound impact on the life sciences community in the United States, including universities and their licensees, and the university mission to translate important discoveries into products that treat or cure diseases. The March Guidance would impede start-up companies that are exploring innovative approaches to drug development driven by campus-based research, as well as established companies that are commercializing early-stage university technology in the form of new, useful products.

When preparing the revised Guidance, we urge the USPTO to consider carefully the effect that the revisions will have on applications that are currently in progress, which we believe should not be

adversely impacted or penalized by the shifting rules. Applicants who received a first rejection under the March Guidance should be allowed to respond to rejections under the revised Guidance as if they are responding to new grounds of rejection.

Our concern about the impact on life science innovation is especially acute due to the increased pressure on universities from federal and state governments to enhance programs that transfer technologies from university laboratories to industry to grow the United States economy and enrich the nation's innovative capacity. The effect of USPTO Guidance on universities' ability to secure patent protection will have a direct bearing on our ability to fulfill our commitment to the Commerce Office of Innovation and Entrepreneurship to ensure the success of university innovation and technology commercialization programs as part of the Administration's Strategy for American Innovation. We hope that the USPTO will continue to reach out to the patent stakeholder community and the end users of new technologies so that the final Guidance will benefit from as much thoughtful input as possible and will be implemented in a way that ensures that the U.S. patent system continues to support the universities and industries that are essential to our nation's health and economic vitality. For these reasons we urge the USPTO to provide an additional opportunity for public comment prior to implementing the revised Guidance.

Thank you for your consideration of our request.



Hunter R. Rawlings III
President
Association of American Universities



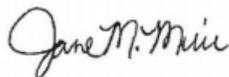
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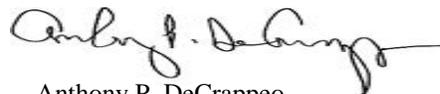
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