

March 13, 2015

Sent via email: 2014_interim_guidance@uspto.gov

Re: [Docket No. PTO-P-2014-0058] (79FedReg74618)

Higher Education Association Comments on USPTO Interim Eligibility Guidance

The Association of American Universities (AAU) is an association of 59 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research and advocacy organization of public research universities, land-grant institutions, and state university systems with member campuses in all 50 states, U.S. territories and the District of Columbia. The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 138 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, and 89 academic and scientific societies. The Council on Governmental Relations (COGR) is an association of 190 U.S. research universities and their affiliated academic medical centers and research institutes that 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. The Association of University Technology Managers (AUTM) is a nonprofit organization with more than 3200 members worldwide dedicated to supporting and enhancing the global academic technology transfer profession through education, professional development, partnering and advocacy.

We appreciate the good working relationship our associations have established with USPTO. We also appreciate USPTO's willingness to engage in dialogue with stakeholders as well as its responsiveness to concerns we had expressed about the previous (March) subject matter eligibility guidance. Our member institutions rely on the patent system to transfer their discoveries and inventions to commercial applications for public benefit, and have done so with considerable success. For example, data from the Association of University Technology Managers (AUTM) show that in 2013 U.S. universities received 5163 patents, executed 4590 licenses (and 1200 options), and initiated 747 startup companies.

Robert Hardy of the Council on Governmental Relations presented the views of our associations at the January 21 Public Forum. As Mr. Hardy stated, in our view the revised guidance is a significant improvement over the previous version, particularly in its recognition that with regard to eligibility of natural products, different characteristics can be expressed in terms of the product's structure, function and/or other properties. We think the flexibility inherent in the revised guidance will be helpful, and

particularly appreciate the flexible approach towards claim eligibility in the natural products claim examples on the PTO website.

However, as Mr. Hardy also indicated, there still appears to be a significant element of subjectivity in the analytic framework used for the subject matter eligibility test in the revised guidance. The Step 2A test for nature-based products uses a “markedly different characteristics” analysis. While this test may seem relatively straightforward, especially for composition claims when there are no naturally occurring counterparts as in some of the website examples, we still are concerned that this approach may lead to inconsistent outcomes. The recent Federal Circuit decision in the case of *University of Utah Research Fdn. et. al. v. Ambray Genetics* is a good example. In that case the Federal Circuit invalidated the primer claims on the grounds they were structurally identical to naturally-occurring DNA strands. The court also was not persuaded that there were significant functional differences. The case illustrates how courts may look at “markedly different characteristics” in different ways.

Assuming markedly different characteristics are not found, the USPTO eligibility analysis proceeds to Step 2B. This step requires “something more” than the nature-based product for eligibility, or the need for an “inventive concept.” We appreciate USPTO’s efforts to provide an affirmative example for natural product claims in Cell Claim #5 on the website. However, clearly the search for an “inventive concept” is by its nature fairly subjective. It also is taken from case law primarily dealing with eligibility of abstract ideas. The court in the *Ambray* case also applied this approach to the diagnostic claims at issue, finding that “something more” beyond routine techniques was lacking.

We appreciate that given the uncertainty inherent in the judicial exceptions (as the Supreme Court has said, at some level all inventions embody laws of nature, natural phenomena or abstract ideas), clear bright lines are difficult to draw with regard to the subject matter eligibility of claims directed to these judicial exceptions. This creates difficulties both for PTO and for patent applicants. As Mr. Hardy indicated at the Forum, USPTO has made a valiant effort in the revised guidance to comprehensively analyze and rationalize a maze of often seemingly contradictory court decisions on 101 subject matter eligibility going back over a century. Unfortunately, we fear that retrospective analyses of court decisions in this area, no matter how well done, may be of limited utility in determinations of 35 USC 101 subject matter eligibility going forward.

Given this uncertainty, we suggest that USPTO give more emphasis in the guidance to the concept of preemption. In our view the primary concern is whether the claim would wholly preempt new or different uses of the law of nature or natural phenomena or abstract idea. The guidance includes this concept in its streamlined eligibility analysis but it is not clear whether it is to be viewed as part of step 2A or a separate threshold analysis. In our view, the most important consideration is whether the claim seeks to tie up any judicial exceptions such that others cannot practice it. This is particularly important given the focus of our associations on scientific and technological progress. This approach looks back to a line of older Supreme Court cases (e.g. *Parker v. Flook*, *Diamond v. Diehr*) that focus on whether there are meaningful limits to claims in the areas of judicial exceptions to patentability. We recognize that recent cases have focused more on the concepts reflected in the USPTO guidance, but we believe these older cases represent a more consistent, coherent approach. If there is uncertainty about whether or not application of the claim would tie up the natural product or abstract idea, then the other concepts become more relevant. This approach is consistent both with the guidance and what we believe the Supreme Court has been seeking in its long line of decisions, although perhaps not always articulated precisely. We urge this inquiry be incorporated into the flow chart as step 1A. The existing 2A and 2B analysis would become relevant only if there is not a clear answer as to the preemption.

Given the conflicting and inconsistent case law in this area, no one approach is likely to completely satisfy the courts. However, more emphasis on the preemption approach would help reduce the subjectivity in the current analytic framework. Clearly the law and practice in this area will continue to evolve. We think the consultative process with the community is very important. We stand ready to assist USPTO and other patent stakeholders in thinking about ways to bring more clarity to this area, perhaps through workshops or task forces, as some suggested at the Forum. We look forward to continuing to participate with USPTO in this process.

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