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Subject: AUTM, COGR, AAU, APLU Comments

Please see the attached comments on the USPTO's ***Guidance Memorandum for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products*** submitted by the Association of University Technology Managers, Council on Governmental Relations, Association of American Universities and the Association of Public and Land-Grant Universities.

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Comments on the USPTO's *Guidance Memorandum for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products.*

The Association of University Technology Managers (AUTM) is a nonprofit organization with more than 3,000 members from more than 300 universities, research institutions and teaching hospitals as well as numerous businesses and government organizations. AUTM is the leader in education and benchmarking data and statistics for the technology transfer profession. 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 American Universities is an association of 60 U.S. and two Canadian research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and professional education, undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization representing 234 public research universities, land-grant institutions, state university systems, and affiliated organizations, dedicated to advancing learning, discovery, and engagement.

Our associations are informed and well positioned to advise on matters of public policy affecting the profession and appreciate the opportunity to submit comments on the USPTO's *Guidance Memorandum for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products.*

The majority of AUTM members and the entire COGR, AAU and APLU memberships represent nonprofit research institutions that do not directly commercialize their discoveries and intellectual property but are dependent on the private sector to invest in, develop and market products and services based on university-created technology. In 2012, U.S. universities filed over 14,000 new patent applications, launched over 700 new high-technology companies and completed 5,100 license agreements with existing for-profit companies or startups. With over $36 billion in net sales of products based on inventions made at institutions represented by our associations, it has been estimated that academic technology transfer generates $80 billion dollars in economic activity annually in the U.S. In critical industries such as biotechnology and biomedicine where America is highly competitive, the continued involvement of our members in early stage innovation is a key success factor.

With this in mind, AUTM, COGR, AAU, and APLU are deeply concerned about the PTO Guidance Memorandum and its unwarranted, as well as legally inconsistent broad changes in examination practice. The ability of our members to bring the benefits of research to the public is significantly decreased if patents on valuable and meritorious university technology cannot be obtained. Secure and predictable protection is a prerequisite for our licensees to justify substantial investments in commercializing university discoveries. The Guidance adversely and unnecessarily impacts our ability not only to license and commercialize future discoveries and inventions, but also the validity of many existing patents for products, particularly in life science areas which make up the majority of university patents. Our associations are concerned about several aspects of the Guidance.

Primary concern: We believe that the Guidance is overly broad and contravenes the Supreme Court's own warning in *Mayo* against over-interpreting its holdings in a way that might stifle innovation, the very kinds of innovation to which U.S. universities contribute. AUTM, COGR, AAU, and APLU agree with others who have criticized the emphasis on structure rather than the functional characteristics of a product.

Impact on Life Science Innovation- two major flaws:

1) An inappropriate and legally questionable interpretation of *Myriad* would adversely impact commercialization of important life science products. Previously, the PTO granted patents on natural products with practical utility. To patent a product (e.g., a drug) purified from a natural source under the new Guidance, the claimed product must be both structurally and functionally different from its natural state, a position not supported by case law, including Supreme Court case law such as *Mayo*, *Myriad*, and especially *Diamond v. Chakrabarty*. In fact, the holding in the recent *Myriad* case is focused on isolated segments of naturally occurring DNA, not other products derived by the "hand of man" from natural sources. Instead, earlier cases emphasized functionality rather than the need for a significant modification from their natural form.

2) Misinterpretation of *Mayo* could seriously harm the diagnostics industry and patients relying on its products. The Guidance implies simple diagnostic assays might no longer be patentable if characterized as natural phenomena discovered rather than invented. The claimed diagnostic now must contain significantly more than the correlation between the marker and the condition, but it is unclear what that "something more" must be. The examples provided in the Guidance are unclear, ambiguous, and raise more questions than they answer. We believe this position comes from a strained and overreaching interpretation of *Mayo v. Prometheus* which is not required by the Supreme Court's holding in that case which only considered a claim to measuring levels of metabolites of a known drug to see if they fell within the optimal range.

PTO's actions: By drafting and releasing this Guidance, the PTO is assuming a judicial authority that is not properly PTO's to assume by erroneously re-interpreting Supreme Court case law, with no opportunity for

public comment. In recent public comments at the May 9th Open Forum, the Biotechnology Industry Organization (BIO) stated: "Expanding *Myriad's* holding to all claims to isolated or purified natural molecules like antibiotics and other medicinal substances, and combinations thereof, and fermentation or distillation products or bacterial enzymes, will not only prospectively block inventors from acquiring commercially meaningful protection for products that were never even mentioned by the Supreme Court [but] also casts a shadow over thousands of issued patents that the PTO now says would never be issued if they were examined today and--implicitly-- should never have been issued in the first place." Numerous AUTM, COGR, AAU, and APLU members, many of whom have licensed or will in the future license the kinds of inventions to which BIO is referring, find the Guidance unsettling because it could improperly prevent universities from patenting valuable and potentially life-saving technology and effectively block these technologies from ever reaching the public. It could also create grave uncertainty about pending and issued university patents and remove the incentive for companies to license them and create innovative products and services that will benefit society.

In summary, AUTM, COGR, AAU and APLU leadership believe that the Guidance has gone far beyond what the Supreme Court actually ruled in recent-patent eligibility cases. The Court has been direct in limiting the scope of its decisions to the cases at hand and has cautioned against over-interpreting its holdings. By crafting such absolute, categorical prohibitions contained in the Guidance, the PTO has overreached its authority in ways both unnecessary and inconsistent with the Supreme Court's more measured approach. We urge the PTO to carefully consider the foregoing objections, and revise the Guidance appropriately in a way that directly addresses and is clearly consistent with the narrow rulings of the Supreme Court and supports the business community and economic development in the various States. Doing so will help ensure that the many benefits of research performed at our universities and non-profit research institutions reach the American public and stimulate the U.S. economy. Failing to do so will eviscerate the benefits of that research by unnecessarily denying patent protection to promising technologies, stifle innovation in academia, seriously harm the ability of companies to develop products that will help the American public, and significantly, adversely impact job growth in America.

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