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July 31, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
And Deputy Director of the United States Patent and Trademark Office
401 Delaney St.
Alexandria, VA 22314

Sent via the Guidance Mailbox (myriad-mayo_2014@uspto.gov)

Re: Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products

Dear Under Secretary Lee:

AARP is pleased to have the opportunity to submit comments in response to the memorandum issued by the U.S. Patent & Trademark Office (USPTO) titled "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products," March 4, 2014, http://www.uspto.gov/patents/announce/myriad-mayo.jsp. We appreciate the USPTO's efforts in releasing guidance that synthesizes the Supreme Court case law on Section 101 of the Patent Act. This is an important and necessary effort to improve patent determinations.

AARP is a nonprofit, nonpartisan organization, with a membership of nearly 38 million, that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse. AARP is concerned about the impact of improperly granted patents on the cost of healthcare. When patents are improperly granted, competition in the marketplace is foreclosed and the public is forced to pay higher prices. Access to affordable healthcare is particularly important to the older population, which has higher rates of chronic and serious health conditions.

AARP filed amicus briefs in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132

S. Ct. 1289 (2010) and *Bilski v. Kappos,* 130 S. Ct. 3218 (2010). Therefore AARP has a strong interest in how *Mayo, Myriad* and other Section 101 cases are implemented by the USPTO.

As we have seen, patents that are invalid under Section 101 (such as those at issue in *Myriad* and *Mayo*) can have harmful consequences to the scientific, medical, and patient communities by tying up the use of natural phenomena. The patenting of medical correlations (i.e., that an overly high or low level of some chemical in the body correlates to an unhealthy condition) led to severe restraint on the provision of medical care and greatly increased cost and reduced availability of vital medical services. *See* Br. of AARP and Public Patent Foundation in Support of Petitioners, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,*No. 10-1150 (S.Ct Mar. 20, 2012). Medical correlation patents were rejected as expressions of laws of nature in *Mayo.* Patents on medical correlations between genetic mutations and predisposition for disease were likewise rejected in *Myriad.*[1]

The *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (Guidance)* correctly recognizes that the USPTO must apply the Supreme Court's decisions to all patent applications that may claim products and laws of nature. *Guidance* at 1. While *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013), examined nucleic acids, the reasoning of the Court was not limited to nucleic acids. The Court relied heavily on the standards it previously articulated in *Diamond v. Chakrabarty,* 447 U.S. 303 (1980) and *Funk Bros. Seed. Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948) – namely, that the claimed composition must have "a distinctive name, character, and use," "markedly different characteristics from any found in nature," and that the "invention" must be more than "the discovery of the natural principle itself." *Myriad*, 133 S. Ct. at 2116-18. Moreover, the body of Supreme Court case law on Section 101 must be examined together, as each case often relies on and further elaborates on earlier cases. *See e.g.,* Brief of Fifteen Law Professors As Amici Curiae Supporting Petitioners, *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S. Ct. 2107 (2013) (No. 12-398); Brief of Eleven Law Professors and AARP as Amici Supporting Respondent, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010)(No. 08-964).

The USPTO is correct in stating that a mere "discovery" does not satisfy Section 101. As noted, the Court in *Myriad* specifically stated that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the Section 101 inquiry." *Myriad*, 133 S. Ct. at 2117. This principle ensures that scientists, researchers, and others can use natural phenomena and innovate with it, rather than face barriers due to others' exclusive rights following discovery. The USPTO further rightly acknowledges that "isolation" or "purification" does not automatically confer patent-eligibility, contrary to its earlier practice. *Myriad* found that although isolating DNA "creates a nonnaturally

[1] The requirement in Section 101 of "new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof" precludes non-inventive, piecemeal incursions on the public domain of science, nature, and ideas, even though the claimed applications may be new.

occurring molecule," that alone was insufficient to cross the Section 101 threshold. 133 S. Ct. at 2118.

We recommend that the USPTO make two amendments to the guidance. First, Section 101 patent eligibility must turn on both the structure and function of a claimed composition. The Guidance examines only the structure of a product claim and suggests that "a functional difference is not necessary" (*Guidance* at 8). In contrast, the *Myriad* decision recognized that isolated DNA was structurally different from genomic DNA in that it had been excised from a longer strand and that it possessed different functional properties -- in that it could be manipulated in ways that genomic DNA could not -- and it was nevertheless found ineligible as a product of nature. A close reading of the Supreme Court's decisions lays out the requirement that the composition must have markedly different characteristics from any found in nature in both structure and function. In short, in order for patents to be granted there needs to be ***both*** a marked structural and marked functional difference from what can be found in nature.

Secondly, we are concerned that the factor-weighing analysis laid out in the *Guidance* does not comport with the Supreme Court's Section 101 decisions and will only confuse the analysis. The Court generally makes its Section 101 determinations by evaluating whether what is claimed has markedly different characteristics from any found in nature, or whether there is an inventive concept. There may be different components to each of these evaluations, but they should not be parsed out as individual elements of the Section 101 question. Weighing multiple factors on each side of the Section 101 threshold introduces the possibility that a claim might meet several competing factors for or against eligibility and muddle the analysis. The factors should not be "balanced" but determined separately. For example, if any one of the listed factors weighing against eligibility in the Guidance applies, the claim should be held invalid.[2] Patent claims that attempt to assert ownership over natural products, natural laws/principles of nature should be presumptively ineligible for patenting under 35 U.S.C. § 101. Specifically, the USPTO should make it clear that applications that attempt to claim the associations between genetic changes and physical characteristics or physiological effects, whether through process claims that in effect claim these natural relationships, or through claims on the gene sequences themselves, are directed toward patent ineligible subject matter, *Myriad* 133 S. Ct. 2107; *Mayo,* 132 S. Ct. 1289.

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[2]The *Guidance* lists the following factors as weighting against eligibility:
g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products. h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered. i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s) j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field. k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s). l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use" *Guidance,* pp. 4-5.

AARP appreciates the opportunity to provide comments on this important issue. If you have any questions, please feel free to contact me, or have your staff contact KJ Hertz on our Government Affairs staff at khertz@aarp.org or 202-434-3770.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs