

From: Sharon West (s)

Sent: Tuesday, July 22, 2014 9:41 AM

To: myriad-mayo_2014

Subject: Comments on Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products ("Guidance")

Attached please find comments from the College of American Pathologists (CAP) in response to the USPTO memo issued March 4, 2014 containing the revised subject matter eligibility Guidance. The CAP is a medical society serving more than 18,000 physician member pathologists and the global laboratory community and the world's largest association composed of exclusively board-certified pathologists.

CAP was moved to participate as a plaintiff in the *Myriad* suit for a variety of strong and long held policy reasons. As such, we particularly welcomed the opportunity to commend USPTO for its revised guidance and to comment on the guidance in general and more specifically incorporating some suggested revisions.

If you have questions or need additional information regarding the attached, please feel free to contact me.

Thanks. Sharon

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July 22, 2014

Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
and Deputy Director of the USPTO
United States Patent and Trademark Office
401 Delaney Street
Alexandria, Virginia 22314

RE: Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products ("Guidance")

Dear Under Secretary Lee,

The College of American Pathologists ("CAP") appreciates the opportunity to comment in response to the United States Patent and Trademark Office ("USPTO") memo issued March 4, 2014 containing the revised subject matter eligibility Guidance. The CAP is a medical society serving more than 18,000 physician members and the global laboratory community. The CAP is the world's largest association composed exclusively of board-certified pathologists and the worldwide leader in quality assurance. The CAP advocates for accountable, high-quality, and cost-effective patient care. The CAP's Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide.

CAP was moved to participate as a plaintiff in the *Myriad*¹ suit because of the CAP's policy on gene patents in place for over a decade that these patents prevent physicians and clinical laboratories from providing gene-based diagnostic test services, limit access to medical care, jeopardize its quality, and raise its cost. Also motivating the CAP's participation in the suit was its long-held belief that limiting gene-sequence based test services to a single provider is not in the public interest as doing so interferes with medical training, practice, and research, the advancement of medical knowledge, and enhancement of the public's health. Invalidating Myriad Genetics' patents on BRCA1 and BRCA2 was therefore, a huge victory for patients allowing women to receive life saving, state-of-the art genetic tests without being forced to trust one laboratory performing a single test to secure a diagnosis or inform treatment. The CAP also believes that genomic medicine will be the cornerstone of diagnostic testing and treatment and that pathologists are the key to genomic test selection, interpretation and clinical integration.

USPTO Guidance -- CAP commends the USPTO for its revised Guidance issued March 2014 replacing previous guidance on process and product claims in light of the *Mayo*² ruling involving process claims on laws of nature and the *Myriad* ruling involving natural product claims on nucleic acids. As USPTO indicated in its training materials, the new Guidance uses the same essential approach to subject matter eligibility under 35 U.S.C. §101 as the previous guidance. The Guidance, though, is important and necessary to improve patent determinations by providing clarity and effective

¹ *Association for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. ___, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013).

² *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 566 U.S. ___, 132 S. Ct. 1289, 1010 USPQ2d 1961 (2012).

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illustrations that take into account both *Mayo* and *Myriad* and the precedent on which they rely. Clear guidance for patent examiners on how to evaluate patent applications that may involve natural products and laws of nature is critical. Effectively defining the boundaries of subject matter eligibility is essential so that access to products and laws of nature is ensured and at the same time, patent protection is only extended to true inventions. As conveyed above, the CAP was compelled to become a party in the *Myriad* case having seen firsthand patents found to be invalid under Section 101 (such as those that were at issue in *Myriad* and *Mayo*) can be exceedingly detrimental to medical and scientific advancements and most importantly, to patient access to care by tying up the use of natural phenomena.

Scope of Guidance

The Guidance was clearly needed to fully address the impact of *Myriad* on the Supreme Court's long-standing rule against patents on naturally occurring things. The Guidance is correctly crafted broadly enough to ensure the PTO applies the Supreme Court's decisions to all patent applications that may claim laws of nature and products. The Guidance also correctly includes natural products that are not nucleic acids to take into account the Court's reasoning extending beyond nucleic acids as well as earlier Supreme Court precedent on which the *Myriad* decision relied. The body of Supreme Court rulings on Section 101 relied upon heavily, even centrally, in the *Myriad* decision must be considered together rather than in a vacuum. The Guidance, therefore, correctly considers *Myriad* in the context of other applicable Supreme Court decisions including those upon which the *Myriad* decision relied.

The Guidance correctly handles the issue of "discovery" and the ineligibility of a mere "discovery" of nature's handiwork under Section 101. As the Supreme Court indicated in *Myriad*, not even groundbreaking, innovative, or brilliant discoveries by themselves satisfy the Section 101 inquiry. This principle set forth in *Myriad* and applicable precedent and clarified in the Guidance enables the use of natural phenomena and innovation unhampered by the exclusive rights of others following discovery.

Isolation

The Guidance also very effectively addresses that not every change to a product will result in a marked difference from what exists in nature, and that despite prior USPTO practice, the mere recitation of particular words such as "isolated" in the claim does not automatically confer eligibility. Just as the Supreme Court made clear in *Myriad* although isolating DNA creates a non-naturally occurring molecule, this alone is not enough for eligibility. As the Guidance accurately conveyed, isolation or purification are not "magic words" and do not automatically confer patent-eligibility regardless of any prior USPTO practice. Eligibility indeed requires the creation of something not naturally occurring and markedly different from what exists in nature.

Suggestions – As helpful as we find the Guidance, we would like to suggest the following two amendments:

- 1) *Weighting Factors* – We are concerned that the flexibility USPTO intended to confer to under the Guidance to accommodate all technologies and for examiners to consider relevant factors, related evidence, and the claim as a whole, may in fact, serve to confuse examiners' analyses. We also question whether the factor-weighting analysis comports with the Supreme Court's Section 101 decisions.

While the new Guidance follows the common theme from previous guidance of evaluating factors that weigh for, or against eligibility, with nothing headed toward a brighter line rule

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and no one factor controlling, though, we fear the result will be muddled analyses. Potentially a claim could meet several competing factors weighing both for and against eligibility with no clear conclusion. The well-intended flexibility to balance the totality of the relevant factors could result in murkiness and confusion at best, and an incorrect conclusion, at worst.

As to consistency with the Supreme Court's previous Section 101 decisions, the Court has made its determinations based on whether the claim presented has markedly different characteristics from what exists in nature or whether there is an inventive concept. While the determinations may have taken into account different components, they were not considered for the purposes of their being parsed out as individual elements to decide whether Section 101 is satisfied.

For the above reasons, we recommend clearer guidance on the conclusions that examiners must draw based on the overarching Section 101 standards set out by the Supreme Court.

- 2) *Structure and Function* – Section 101 patent eligibility under the Guidance expressly turns on marked differences in structure of a product claim, in both its instructions and supporting example provided. A close reading of the Supreme Court's decisions, though, lays out the requirement that the composition have markedly different characteristics from any found in nature in both structure and function. The Supreme Court in *Myriad* discussed the function of the isolated BRCA1 and BRCA2 DNA at issue. In the *Chakrabarty*³ case, the Supreme Court expressly discussed the need for a “distinctive name, character, and use” of a claimed composition. The Court has consistently applied this markedly different characteristics standard in other cases.

As such, we recommend Section 101 patent eligibility turn on both structure and function of a claimed composition.

Thank you for considering our comments. We greatly appreciate the opportunity to provide the USPTO with input on its Guidance. We do believe the Guidance with the recommended revisions above, should assist USPTO patent examiners to address changes in the law in light of *Myriad* that CAP in becoming a party, believes resulted in a significant victory most importantly for patients, but also for medical practice, public health, and the public interest overall. If you have questions or need additional information, please contact Sharon L. West, J.D. at swest@cap.org.

³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).