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

Dear Under Secretary Lee:

The American Civil Liberties Union (“ACLU”) submits these comments regarding the memoranda issued by the U.S. Patent & Trademark Office (“PTO”) 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, available at <http://www.uspto.gov/patents/announce/myriad-mayo.jsp> (“Guidance”), and “Preliminary Examination Instructions in view of the Supreme Court Decision in *Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*,” June 25, 2014, available at [http://www.uspto.gov/patents/announce/alice\\_pec\\_25jun2014.pdf](http://www.uspto.gov/patents/announce/alice_pec_25jun2014.pdf) (“Preliminary Instructions”). We appreciate this opportunity to share our thoughts with you.

The ACLU is a nationwide, nonprofit, nonpartisan organization with more than 500,000 members dedicated to protecting the rights guaranteed by the Constitution and the laws of the United States. The ACLU represented petitioners in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and filed amicus briefs in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2010) (supporting Mayo), and *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, No. 13-298 (S. Ct.) (supporting CLS Bank). Thus, the ACLU has a strong interest in how *Mayo*, *Myriad*, *Alice*, and other Section 101 cases are implemented by the PTO.

By way of preview, we offer two recommendations for amendments to the Guidance, which is the focus of this letter. We provide additional comments on the Preliminary Instructions, which we understand will be supplemented with more extensive guidance addressing abstract ideas.

- First, Section 101 patent eligibility as discussed in the Guidance must turn on both the structure and function of a claimed composition, while the Guidance now only focuses on the former;
- Second, we are concerned that the factor-weighting analysis laid out in the Guidance does not comport with the Supreme Court’s Section 101 decisions and will only confuse the analysis; and.

- In creating further guidance on abstract ideas in light of the decision in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, No. 13-298 (S. Ct. June 19, 2014) and other case law, the PTO should ensure that applications are not granted that claim mental thought and that they are subject to an in-depth examination of whether the abstract idea is sufficiently changed so that it no longer forecloses use of the underlying concept.

We commend the PTO for releasing guidance that synthesizes the Supreme Court case law on Section 101 of the Patent Act. This is an important and necessary effort to conform patent determinations with prevailing law. Given recent Supreme Court decisions invalidating patents issued by the PTO, it is imperative that patent examiners receive guidance explaining the Court's precedents and how to apply them when evaluating applications that may involve products and laws of nature, as well as abstract ideas. This will ensure that patent applications are decided in accordance with the Court's Section 101 doctrine, rather than on principles rejected by the Court. The Court has confirmed repeatedly that Section 101 determinations must be made based on the law, not in deference to past practices or industry expectations. *Myriad*, 133 S. Ct. at 2118-19; *Mayo*, 132 S. Ct. at 1304-05

Moreover, defining the boundaries of patent eligibility is vital to guarantee that all have access to products and laws of nature and abstract ideas—the “storehouse of knowledge of all men”—and that patent protection is given only to true inventions. 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 and impeding further innovation.

Guidance will also help prevent the issuance of patents that infringe Article I and the First Amendment of the Constitution. As the Court has said, “the Patent Clause [of the Constitution] itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’” *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 146 (1989). Section 101's prohibition on patenting laws and products of nature and abstract ideas is the primary mechanism through which the Court has resolved constitutional concerns about monopolies that block progress. *See Mayo*, 132 S. Ct. at 1293, 1303-04; *Bilski*, 130 S. Ct. at 3236-37.

The Guidance correctly recognizes that the PTO must apply the Supreme Court's decisions to all patent applications that may claim products and laws of nature. Guidance at 1. While *Myriad* 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.

Thus, we agree with the PTO's instruction to examiners that where there is any doubt about whether a Section 101 exception applies, the application must be scrutinized further. Furthermore, in order to heed the Court's warning that Section 101 cannot be satisfied through mere draftsmanship, *Mayo*, 132 S. Ct. at 1294, the PTO rightly warns examiners to assess applications independent of whether the claims include “magic words,” such as cDNA or primers. *See June Cohan, U.S. Patent & Trademark Off., Evaluating Subject Matter Eligibility under 35 USC § 101*, sl. 33 (Apr. 16, 2014).

The PTO is also correct in stating that a “discovery” does not satisfy Section 101. As noted, the Court in *Myriad* specifically found 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 PTO 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 occurring molecule,” that alone was insufficient to cross the Section 101 threshold. 133 S. Ct. at 2118.

We recommend that the PTO 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 claimed product, but a close reading of the 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. *Chakrabarty* specifically discussed the need for a “distinctive name, character, and use,” and the application of the markedly different characteristics standard in the Supreme Court’s cases confirms this. Thus, the *Funk Bros.* bacteria arguably had a different “character,” as the strains of bacteria did not appear together in nature. But the function—their ability to fix nitrogen without inhibiting each other—was not invented by the patentee. The fruit in *American Fruit Growers* had a different structure—borax in the rind—but not a different function; it was still intended for human consumption. *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 12 (“It remains a fresh orange, fit only for the same beneficial uses as theretofore.”). The *Chakrabarty* bacterium had both a markedly different structure and function than any found in nature. And the Court discussed the function of the isolated BRCA1 and BRCA2 DNA at issue in *Myriad*, noting that *Myriad* was “concerned primarily with the information contained in the genetic *sequence*”—i.e., the coding function of the gene.

Second, we are concerned that the factor-weighting 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 likelihood that a claim will meet several competing factors for or against eligibility and muddle the analysis. For example, factor e) in the Guidance provides that inclusion of a machine or transformation is one factor that weighs toward eligibility. Guidance at 4. While the Court has said that “machine or transformation” is a “useful and important clue,” it rejected reliance on that test. *Bilski v. Kappos*, 130 S. Ct. 3218, 3226-7 (2010). However, because machine or transformation is now an independent factor in the weighing analysis, it could be given undue weight when other factors mandate a finding of patent-ineligibility. To some extent, this played out in *Mayo*, where Prometheus’ claim arguably involved “transformation.” Clearer guidance should be provided as to the conclusions that must be drawn based on the overarching Section 101 standards set out by the Court.

Relatedly, factors b) and h) and some of the examples appear to unduly limit the preemption analysis engaged in by the Court. The Court specifically ruled in *Mayo* that “the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor.” 132 S. Ct. at 1303. While preemption of substantially all practical applications would demonstrate a lack of an invention, the analysis requires looking at what is preempted *in relation* to the contribution of the inventor. *Bilski* likewise noted that some of the claims that limited the use of the

abstract idea to specific markets, thus not preempting the use of the idea in all markets, still could not survive Section 101 under *Parker v. Flook*, 437 U.S. 584 (1978). 130 S. Ct. at 3231.

As the PTO revisits its guidance on abstract ideas, we provide some thoughts to help inform its analysis. First, we agree with the Preliminary Instructions that the Court’s case law does not set up different Section 101 standards for abstract ideas versus laws of nature (or products of nature). Indeed, *Mayo* involved both – a patient’s reaction to a drug (a law of nature) and the doctor’s mental consideration of the meaning of the metabolite levels (an abstract idea). *See Mayo*, 132 S. Ct. at 1302. It therefore is important that the PTO provides an integrated analysis of claims that may involve products of nature, laws of nature, and abstract ideas.

Second, guidance on abstract ideas should not permit any patents that claim mental thought or steps. Patents that claim abstract knowledge or thought are not only prohibited under Section 101, but are also forbidden under the First Amendment. *See Br. of the American Civil Liberties Union as Amicus Curiae in Support of Respondents, Alice Corp.*, at 14-20; *see also In re Bilski*, 545 F.3d 943, 1005 (Fed. Cir. 2008) (Mayer, J., dissenting) (discussing First Amendment implications of patents on methods of hedging), *aff’d but criticized sub nom. Bilski v. Kappos*, 130 S. Ct. at 3218.

Third, the Preliminary Instructions state that having determined whether the claim is directed to a category of invention, the examiner must then determine whether the claim is directed to a judicial exception. In explaining what “directed to” means in this context, the PTO should reinforce the need to broadly consider whether an exception is involved in the claim. MPEP 2106 incorrectly instructed patent examiners to determine whether a claim “wholly embraces a judicially recognized exception,” rather than the Court’s more nuanced examination of whether the abstract idea is sufficiently changed so that it no longer forecloses use of the underlying concept.

Fourth, the PTO should not rely on the inclusion of a machine in patent claims. The machine-or-transformation test was rejected as a sole test for patent eligibility by the Supreme Court and *Alice* states clearly that incorporation of a machine—or claiming the machine itself in the form of a computer system—will not suffice to cross the Section 101 threshold (fact that claim involves a physical computer “is beside the point,” because an “applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept”). *Alice*, Slip. Op. at 13-14.

In conclusion, we are pleased that the PTO is engaging in an ongoing dialogue with stakeholders on these important issues. As demonstrated by the diverse group of petitioners that brought the *Myriad* case and the many that filed amicus briefs, there are a wide range of communities directly impacted by the patents that are approved and denied by the PTO, beyond patentees and the patent bar. We encourage the PTO to engage in greater public outreach when considering patent policies that clearly impact the public interest in order to receive feedback from interested groups and individuals that do not regularly participate in PTO proceedings. Section 101 issues are of particular significance to the wider public as they are at the heart of the constitutional mandate that patents “promote the progress of Science and useful Arts,” rather than impede it. U.S. Const. Art. I, cl. 1. *See Laboratory Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (Breyer, J., dissenting).

Thank you for considering these comments. If you have any questions, please contact Sandra Park, Senior Staff Attorney, at (212) 519-7871 or [spark@aclu.org](mailto:spark@aclu.org).

Sincerely,

A handwritten signature in black ink, reading "Laura W. Murphy". The signature is written in a cursive style and is enclosed within a thin black rectangular border.

Laura W. Murphy  
Director, Washington Legislative Office

A handwritten signature in black ink, reading "Sandra Park". The signature is written in a cursive style.

Sandra Park  
Senior Staff Attorney  
ACLU Women's Rights Project