March 16, 2015

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United States Patent and Trademark Office
401 Delaney St.
Alexandria, VA 22314

Sent via email: 2014_interim_guidance@uspto.gov

Re: 2014 Interim Guidance on Patent Subject Matter Eligibility

Dear Mr. Tamayo and Mr. Cygan:

The American Civil Liberties Union ("ACLU"), Association for Molecular Pathology, Breast Cancer Action, the College of American Pathologists, and Ellen T. Matloff submit these comments regarding documents issued by the U.S. Patent & Trademark Office ("PTO") on December 16, 2014, titled "2014 Interim Guidance on Patent Subject Matter Eligibility" ("Interim Guidance") and "Nature-Based Products" ("Nature Examples"), *available at* http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0. We appreciate this opportunity to share our thoughts with you, as well as the PTO's ongoing efforts to provide guidance on Section 101 of the Patent Act.

The ACLU is a nationwide, nonprofit, nonpartisan organization with more than a million members, activists, and supporters dedicated to protecting the rights guaranteed by the Constitution and the laws of the United States. The ACLU represented petitioners in *Ass'n 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 (2012) (supporting Mayo), and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (supporting CLS Bank). Thus, the ACLU has a strong interest in how the rulings in *Mayo*, *Myriad*, *Alice*, and other Section 101 cases are implemented by the PTO.

The Association for Molecular Pathology is an international not-for-profit scientific society that advances the clinical practice, science, and excellence of molecular and genomic laboratory medicine with more than 2,300 members. AMP was the first-named plaintiff in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), and filed an amicus brief in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (supporting Mayo). Thus, AMP has a strong interest in how the rulings in *Mayo, Myriad* and other Section 101 cases are implemented by the PTO.

Breast Cancer Action (BCAction) is a national education and activist non-profit whose mission is to achieve health justice for all women at risk of and living with breast cancer. BCAction focuses on systemic interventions that address the root causes of the disease and produce broad public health benefits. BCAction joined other women's health groups, individual women, researchers, genetic counselors, and scientific organizations in challenging the legality of Myriad's patent on the BRCA genes, specifically the BRCA 1 and 2 genes, better known as the "breast cancer genes." BCAction was the only national breast cancer organization named as a plaintiff in the case.

The College of American Pathologists is a medical society representing more than 18,000 physician members and the global laboratory community. It is the world's largest association composed exclusively of board-certified pathologists and is the worldwide leader in quality assurance. The College believes 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. The College was thus, amongst the petitioners in the *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*. suit.

Ellen T. Matloff is a genetic counselor with 19 years of experience in cancer genetic counseling. She founded and directed the Cancer Genetic Counseling Program at Yale School of Medicine for 18 years and served as a plaintiff in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). She experienced the fallout from the BRCA patents and has written and lectured extensively about how these patents have harmed patients, clinical care and clinical research.

These comments make a number of recommendations regarding the Interim Guidance and Examples:

- The PTO must ensure that patents do not issue on products of nature, laws of nature, or abstract ideas, because such patents interfere with scientific and medical advancement and innovation.
- Products of Nature
    - Nature-based products must be examined to determine whether there is a marked difference in structure *and* function from nature; if the subject matter does not have a markedly different structure and function, it is a patent-ineligible product of nature.
    - The Interim Guidance should be amended to state that Step 2B is inapplicable to claims on products of nature, because a product claim that does not have markedly different characteristics from any found in nature is invalid under Section 101.
    - The Interim Guidance must consistently explain that a claim on subject matter that does not have markedly different characteristics from any found in nature is patent-ineligible.
    - The Interim Guidance should not implement streamlined eligibility analysis, or at a minimum, significantly amend how it is done.

- For clarity, the Quick Reference Sheet should be amended to include "products of nature" in Step 2A.
- The *Funk Bros.* case should be discussed as a key product example. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

- Abstract Ideas
  - Examiners should be specifically instructed that patents that claim mental thought cannot be approved.
  - Examiners must be directed that Section 101 is not satisfied solely by the inclusion of a machine in patent claims.
- Nature-Based Product Examples
  - Guidance should include an example of patent claims on primers.
  - In many patents where the subject matter is not a product of nature, it must be analyzed for whether it impermissibly claims a law of nature.

Comments on Interim Guidance

A. The PTO must ensure that patents do not issue on products of nature, laws of nature, or abstract ideas, because such patents interfere with scientific and medical advancement and innovation.

Patents on products of nature, laws of nature, and natural phenomena present serious barriers to scientific and medical advancement and innovation. While patents can and often do spur progress, patents on products and laws of nature impermissibly lock up fundamental building blocks. *Mayo*, 132 S. Ct. at 1301-03. The damaging effects of such patents were seen in *Association for Molecular Pathology v. Myriad Genetics* and *Mayo v. Prometheus*. Myriad's patents on isolated DNA and any and all methods of analyzing the BRCA1 and BRCA2 genetic sequences authorized one laboratory to monopolize all genetic testing of the two genes, *Ass'n for Molecular Pathology*, 133 S. Ct. at 2113-14, impeding the development and offering of more comprehensive, lower cost, and confirmatory genetic testing. Similarly, Prometheus' patents prevented Mayo from developing its own diagnostic test that would use higher metabolite levels to determine drug efficacy. *Mayo*, 132 S. Ct. at 1295-96.

Because of the harms posed by these types of patents, for over a century, the U.S. Supreme Court has recognized that laws of nature, natural phenomena, products of nature, and abstract ideas are not patent-eligible. "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Mayo*, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). The Court has explained repeatedly that "[s]uch discoveries are 'manifestations of laws of nature, free to all men and reserved exclusively to none.'" *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Otherwise, "there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them." *Mayo*, 132 S. Ct. at 1301.

Since the *Myriad* decision, we have seen how the lifting of patents on products of nature benefits the public. Many more laboratories now offer genetic testing of the BRCA1 and BRCA2 genes, often in combination with testing other genes connected to cancer risk and at lower cost. Robert Cook-Deegan & Annie Niehaus, *After Myriad: Genetic Testing in the Wake of Recent Supreme Court Decisions about Gene Patents* 227-39, Current Genetic Med. Rep. (Sept. 11, 2014), *available at* http://link.springer.com/article/10.1007/s40142-014-0055-5. This has provided more options to patients and clinicians. In addition, with the diversity of laboratories now offering testing, Myriad can no longer control all data regarding the BRCA1 and BRCA2 genes. Other laboratories have committed to sharing data regarding variants with the scientific community, in line with recommendations issued by the American Medical Association. American Med. Ass'n, *Policy D-460.971 Genome Analysis and Variant Identification* (encouraging laboratories to place all clinical variants and the clinical data that was used to assess the clinical significance of these results into the public domain, which would allow appropriate interpretation and surveillance for these variations that can impact the public's health).

B. Comments Relating to Products of Nature

1. Nature-based products must be examined to determine whether there is a marked difference in structure *and* function from nature; if the subject matter does not have a markedly different structure and function, it is a patent-ineligible product of nature.

The Interim Guidance contradicts prevailing case law by providing that an application must only established marked difference in structure *or* function. 79 Fed. Reg. at 74,623. For example, the Interim Guidance states: "Markedly different characteristics can be expressed as the product's structure, function, and/or other properties." *Id.* It also provides a list of characteristics, any of which can be used to determine whether there is a marked difference: "biological or pharmacological functions or activities; chemical and physical properties; phenotype, including functional and structural characteristics; and structure and form, whether chemical genetic or physical." *Id.* (citations omitted). Once a markedly different characteristic in the product is shown, whether in structure or function, the Section 101 inquiry is satisfied. *Id.* at 74,624.

By allowing applicants to establish eligibility based on structure or function, the PTO has relaxed the standard provided in its "2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products" ("March 2014 Procedure"), which required applicants to demonstrate that a product had a markedly different structure from that in nature. Now an applicant may satisfy Section 101 by showing marked differences in either structure or function and need not prove that the subject matter has a marked difference in structure.

While we agree that function also must be considered in determining the patent-eligibility of a nature-based product, Section 101 requires markedly different characteristics from any found in nature in both structure and function, not in just one or the other. The Supreme Court's cases mandate this standard. *Chakrabarty* specifically discussed the need for a "distinctive name, character, *and* use," *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980) (quoting

Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)) (emphasis added), and the application of the markedly different characteristics standard in the Supreme Court's cases confirms this. Had markedly different structure *or* function been the test, the patents at issue in in *Myriad*, *Funk Bros*., and *American Fruit Growers* would have been upheld.

- In *Myriad*, the Court noted that isolated DNA was different in structure, but not in function. "[I]solating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." 133 S. Ct. at 2118. But the function of the isolated BRCA1 and BRCA2 DNA was not markedly different: Myriad was "concerned primarily with the information contained in the genetic *sequence*"—i.e., the naturally-occurring coding function of the gene. *Id.*
- The *Funk Bros.* bacteria had a different structure, 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. *Funk Bros.*, 333 U.S. 127 at 130-31.
- 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 (1931) ("It remains a fresh orange, fit only for the same beneficial uses as theretofore.").
- The *Chakrabarty* bacterium satisfied this standard because it had both a markedly different structure (after the insertion of plasmids) and function (could be used to clean oil spills) than any found in nature. *Chakrabarty*, 447 U.S. at 303, 305, 310. The Court discussed structure and function

Given this line of cases, it is vital that the PTO require that nature-based products have markedly different characteristics in both structure and function. Otherwise, patents on products of nature will be issued and we will again face a situation as we did with gene patents, where exclusive rights on nature were exercised to harm the public interest and stand in the way of scientific and medical advancement.

2. The Interim Guidance should be amended to state that Step 2B is inapplicable to claims on products of nature, because a product claim that does not have markedly different characteristics from any found in nature is invalid under Section 101.

For nature-based product claims, the Interim Guidance instructs examiners 1) to determine whether the claim is on a product of nature employing the markedly different characteristics analysis (Step 2A), and if there are no markedly different characteristics, 2) to determine whether the claim recites additional elements that amount to significantly more than the judicial exception (Step 2B). However, once an examiner determines that a claimed product has no markedly different characteristics from any found in nature, the examiner should be directed to conclude that the subject matter is patent-ineligible. The Supreme Court has never searched for "additional elements that amount to significantly more than the judicial exception" as part of its Section 101 inquiry for product claims that do not have markedly different characteristics from any found in nature. That is because, as the PTO rightly notes, the nature-based product claim must be analyzed as a whole for markedly different characteristics. In

Myriad, the Court's inquiry focused on whether the subject matter is "a product of human ingenuity 'having a distinctive name, character [and] use'" and whether it has "markedly different characteristics from any found in nature." *Myriad*, 133 S. Ct. at 2117. Once a product is found not to have markedly different characteristics from any found in nature, it is unpatentable under Section 101.

The Interim Guidance confuses the analysis, by providing that a product that does not have markedly different characteristics from any found in nature can nonetheless have additional elements that amount to significantly more than the judicial exception. While it may be difficult to imagine how something that is a product of nature (because it does not have markedly different characteristics) could satisfy Step 2B, the Interim Guidance requires examiners to proceed to Step 2B. This is problematic as it permits applicants to argue that a claim on a product of nature can still satisfy the Section 101 threshold. The Interim Guidance should be revised to eliminate Step 2B for claims on nature-based products that do not have markedly different characteristics from any found in nature – i.e., patent-ineligible products of nature.

3. The Interim Guidance must consistently explain that a patent that claims subject matter that does not have markedly different characteristics from any found in nature is patent-ineligible.

The Interim Guidance does not always articulate the standard set out by the Supreme Court. Section I.A.3. states: "Courts have held that naturally occurring products and some man-made products that are *essentially no different from a naturally occurring product* are 'products of nature' that fall under the laws of nature or natural phenomena exception." 79 Fed. Reg. at 74,623 (emphasis added). But the Court has not held that the subject matter is patentable so long as it is "essentially no different" from a naturally occurring product – the standard requires more scrutiny. Subject matter is only patentable when it has "markedly different characteristics from any found in nature." *Chakrabarty*, 447 U.S. at 310.

4. The Interim Guidance should not implement streamlined eligibility analysis, or at a minimum, significantly amend how it is done.

Section I.B.3. of the Interim Guidance provides a streamlined eligibility analysis. "For purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it. Such claims do not need to proceed through the full analysis herein . . ." 79 Fed. Reg. at 74,625.

While we appreciate the need to streamline patent examinations where possible, we urge the PTO to revisit this provision. Section 101 is a threshold legal determination, one that cannot be bypassed. *See Mayo*, 132 S. Ct. at 1303-04. Moreover, the Interim Guidance significantly changes how Section 101 questions must be analyzed, including the more nuanced examination mandated by case law. Examiners should be required to engage in this analysis to ensure that the law is being applied appropriately. In addition, the streamlined eligibility analysis encourages applicants to write complex claims that on their face may not appear to tie up any judicial exception, but that ultimately claim a product or law of nature or abstract idea. To allow

examiners to skip the full analysis invites the issuance of patents that are invalid under Section 101.

If the PTO decides to retain the streamlined eligibility analysis, at a minimum it should require examiners to specifically explain why there is *absolutely no doubt* that the claim does not seek to tie up *each of the Section 101 exceptions*. While we contend that Section 101 should be fully examined for each application, articulating why there is no doubt that the claim will not tie up each of the exceptions, separately, will provide some assurance that the threshold has been met.

5. For clarity, the Quick Reference Sheet should be amended to include "products of nature" in Step 2A.

Currently, the inquiry in Step 2A does not include products of nature among the exceptions, although they are referred to in the box at the bottom of the page. Given that the analysis is triggered when a claim involves a nature-based product, we recommend that "product of nature" be included in the list, along with law of nature, a natural phenomenon, or an abstract idea. Inclusion of product of nature would ensure that the product of nature analysis is understood to be a central and integral part of the patent eligibility determination.

6. *Funk Bros.* should be discussed as a key product example.

Guidance on Section 101 should also incorporate *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), which is not included as an example or Supreme Court decision in the Interim Guidance. *Funk Bros.* is a significant opinion on nature-based products, products of nature, and laws of nature, one that has been discussed and cited repeatedly by the Supreme Court in Section 101 cases, including *Chakrabarty*, *Mayo*, and *Myriad*.

Yet, the Interim Guidance mentions it only in footnotes 28-30. As noted above, *Funk Bros.* provides valuable guidance on the necessity of establishing marked differences in structure and function and thus should be a case studied by examiners in making Section 101 determinations on nature-based products.

C. Comments Relating to Abstract Ideas

7. Examiners must be specifically instructed that patents that claim mental thought cannot be approved.

Patents that claim abstract knowledge or thought are prohibited under Section 101. Recent cases considered by the Supreme Court involved claims on a thought process. *See, e.g.*, *Mayo*, 132 S. Ct. at1302 (invalidating claims for method of determining drug efficacy because they "tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations."); *see also Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 136 (2006) (Breyer, J., dissenting from dismissal of writ of certiorari) (arguing that the patent claim for correlating metabolite levels with vitamin deficiency

is invalid under Section 101 because the claim simply "instructs the user to (1) obtain test results and (2) think about them"). In addition, the Federal Circuit invalidated method claims relating to analyzing genetic sequences in the *Myriad* litigation because the claim "recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences." *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1334 (Fed. Cir. 2012) *aff'd in part, rev'd in part sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

Given these cases, examiners should be directed to examine whether a claim is on a mental thought. If they do, they should be deemed invalid as claiming abstract ideas under Section 101.

This conclusion is also compelled by the First Amendment. The structure of intellectual property that is created by Article I, section 8, clause 8 of the Constitution is limited by the First Amendment. There can be little doubt that patents giving control over intellectual concepts and abstract knowledge or ideas – and thus limiting free thought – would violate the First Amendment. The ability to think without constraint is an essential attribute of human autonomy and a cornerstone of the First Amendment. *See* Laurence Tribe, *American Constitutional Law* § 12-1 (2d ed. 1988); Thomas Emerson, *The System of Freedom of Expression* 6 (1970). In Justice Harlan's words, "No other approach would comport with the premise of individual dignity." *Cohen v. California*, 403 U.S. 15, 24 (1971). Or, as Justice Brandeis famously stated in an opinion joined by Justice Holmes, the First Amendment protects the "freedom to think as you will and to speak as you think." *Whitney v. California*, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring). Echoing that theme, *Palko v. State of Connecticut*, 302 U.S. 319, 326-27, (1937) *overruled by Benton v. Maryland*, 395 U.S. 784 (1969) , described "freedom of thought and speech" as "the matrix, the indispensable condition, of nearly every other form of freedom." And the Court in *Griswold v. Connecticut* said, "The right of freedom of speech … includes not only the right to utter or to print, but the right to … freedom of inquiry, freedom of thought …." 381 U.S. 479, 482 (1965). *See also United States v. Reidel*, 402 U.S. 351, 355-56 (1971); *Stanley v. Georgia*, 394 U.S. 557, 564-66 (1969). The unhindered potential to consider ideas, intellectual concepts, and abstract knowledge is necessary for freedom of thought and speech.

The vast majority of patents do not directly target thought or speech, and for that reason, courts generally have not needed to examine the First Amendment implications of patent law. *Cf. In re Bilski*, 545 F.3d 943, 1005-06 (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. 3218 (2010). However, all patents should be scrutinized for whether they explicitly claim mental thought as part of the Section 101 inquiry.

8. Examiners must be directed that Section 101 is not satisfied solely by the inclusion of a machine in patent claims.

The Interim Guidance notes that "applying the judicial exception with, or by use of, a particular machine" may be enough to qualify as "significantly more" for purposes of Step 2B of the analysis. 79 Fed. Reg. at 74,624. While it is possible that a "particular machine" might qualify as significantly more – *e.g.*, when the applicant creates an improved the use of the machine – it must be made clear that inclusion of a machine in a patent claim should not carry the weight it once did in the Section 101 analysis.

In *Bilski*, the Court rejected the machine-or-transformation test as a sole test for patent eligibility, stating that it could be a useful clue. *Bilski v. Kappos*, 561 U.S. 593, 604 (2010) . More recently, in *Alice*, the Court stated 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 Corp. Pty. Ltd.*, 134 S. Ct. at 2358-59. Thus, using a machine, in of itself, does not render a claim patent-eligible; the focus must be on how applicants have changed the machine through the application of their inventive concept.

Comments on Nature-Based Products Examples

9. Guidance should include an example of patent claims on primers.

The March 2014 Procedure included an example regarding the patent-ineligibility of primers that was omitted from the Interim Guidance. This example should be added in light of the recent decision by the U.S. Court of Appeals for the Federal Circuit in *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014) ("Myriad II"). *Myriad II* held that primers based on naturally-occurring DNA, including primer pairs, are patent-ineligible under Section 101. *Id.* at 755, 757. This example should be provided to examiners in the future as instructive on how to consider claims involving DNA derived from naturally-occurring DNA, whether as single DNA molecules or combinations of molecules.

10. In many patents where the subject matter is not a product of nature, it must be analyzed for whether it impermissibly claims a law of nature.

The Nature Examples appear to assume that when a nature-based claim is not a product of nature, it is patent-eligible. However, it is important to emphasize that such claims must also be analyzed for whether they claim laws of nature, such as in *Mayo*. *E.g.*, For the amazonic acid example, the analysis of claims states that claims 7 and 8 do not require a full eligibility analysis because the claims do not seek to tie up all practical uses of the nature-based products. That is incorrect. These claims should be analyzed for whether they tie up laws of nature, such as those at issue in *Mayo*. Claim 8 in particular ties up a law of nature: amazonic acid's ability to treat breast or colon cancer. While the patentee could seek a patent on a new composition of matter based on amazonic acid, the method claim monopolizes the law of nature because it excludes all others from administering amounts of amazonic acid to treat breast or colon cancer, without even specifying the dosages effective for each type of cancer. Others thus are excluded from using what the PTO considers to be unpatentable subject matter (purified amazonic acid) to determine how the body naturally responds.

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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.

Sincerely,

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