July 31, 2014

Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
and Deputy Director of the United States Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313

Via email: myriad-mayo_2014@uspto.gov

Re: USPTO *Mayo-Myriad* Guidance

Dear Deputy Director Lee:

Intellectual Property Owners Association (IPO) submits the following comments on the United States Patent and Trademark Office's Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products and related published examiner training materials (Guidance). We appreciate the PTO providing us with this opportunity.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and more than 12,000 individuals who are involved in the association either through their companies or through other classes of membership.

IPO understands that the PTO trains examiners to examine patent applications consistent with governing statutory law as interpreted by judicial precedent. We applaud the PTO's extensive work associated with training examiners on patent-eligible subject matter and preparing the Guidance. We believe the Guidance, however, goes beyond the scope of relevant Supreme Court cases to create exceptions to the patent statute not articulated or envisioned by the court. The Guidance should reflect only the holdings of pertinent Supreme Court decisions. The PTO should use neither Supreme Court dicta, which can be subject to misinterpretation, nor extrapolation, to create additional "PTO exclusions" from the broad categories of patent-eligible subject matter specified in section 101 of Title 35. As the Supreme Court cautioned in its recent decision in *Alice Corp. v. CLS Bank Int'l 573 U.S. __ (2014)*, it is important to "tread carefully in construing this exclusionary principle lest it swallow all of patent law." That is, "[a]t some level, "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."

We are concerned that the Guidance as currently written does not conform to governing law and may chill investment in new technologies as well as cast doubt on the validity of vast numbers of existing patents covering many important inventions. We fear this will stunt developing technologies and damage the United States' strategic interests in spurring economic growth both inside and outside the U.S. Such a change to the patent landscape will directly impact entire industries in the U.S. and be felt throughout the rest of the world, particularly if other countries seek to adopt reciprocal approaches. We believe the PTO can ameliorate these harms by working with stakeholders to develop new guidelines that reflect the holdings of current Supreme Court decisions.

I. The Guidance is based on an overly-broad interpretation of Supreme Court precedent.

The Guidance expands the exceptions to patent-eligibility beyond relevant Supreme Court precedent. The new or amended guidelines should focus narrowly on the specific case holdings.

A. Supreme Court precedent does not support the "markedly different in structure" test for claims directed to compositions or manufactures.

The Guidance requires that an invention "involving" a law of nature, natural phenomenon, or product of nature be "markedly" or "significantly" different than the relevant "judicial exception." The 2013 *Myriad* case held that a naturally occurring segment of genomic DNA was not patent-eligible simply on the basis that it had been isolated from surrounding genetic material. However, the court also held that cDNA—encoding the same protein as the ineligible genomic DNA—"is patent eligible because it is not naturally occurring." The court never stated that cDNA satisfied, or needed to satisfy, the PTO's "markedly different" from nature standard to be patent-eligible. In fact, the court acknowledged that the cDNA sequence was "dictated by nature," but still held that cDNA was eligible because it was "new."

Diamond v. Chakrabarty, 447 U.S. 303 (1980), involving an invention of a genetically engineered bacterium, did not establish or require the "markedly different" standard. The holding in *Chakrabarty* was that Chakrabarty's "micro-organism plainly qualifie[d] as patentable subject matter" because it was "a nonnaturally occurring manufacture or composition of matter." Thus, a merely "nonnaturally occurring" composition was sufficient to be patent eligible. In *dicta*, the court observed that Chakrabarty's bacterium had "markedly different characteristics from any found in nature." However, this observation about "marked differences" only served to "underscore [the point] dramatically," not to articulate a test that must be met by future inventions.

The PTO has suggested that the court's 1948 *Funk Brothers* and 1931 *American Fruit Growers* decisions influenced the Guidance. IPO respectfully suggests that the PTO should exercise caution in relying on these cases to guide patent-eligibility determinations under §101 because both cases were decided before §101was enacted. The 1952 Patent Act separated the definition of patent-eligible subject matter (§101) from the conditions and requirements for patentability such as novelty (§102) and inventiveness/nonobviousness (§103). In both *Funk Brothers* and *American Fruit Growers*, the court discussed prior art in a manner indicating that

the patent claims in question failed the test for "invention" now embodied in §103. Moreover, the court did not state or apply a "markedly different" test in either case.

B. The importance of function in patent-eligibility analysis

A composition of matter or manufacture claimed in a manner that does not read upon matter as it is found in nature (e.g., because it is isolated or highly purified) has traditionally been viewed as patent-eligible if the claimed subject matter, viewed as a whole, has significantly different function or expanded utility compared to what is found in nature. *See,* for example, *Parke-Davis & Co. v. H.K. Mulford Co*., 189 F. 95 (C.C.S.D.N.Y. 1911) (Hand, J.), where the compound adrenaline was deemed to be patentable even if it were considered to be "merely an extracted product without change" because it had become "for every practical purpose a new thing commercially and therapeutically."

No Supreme Court decision states or implies that this longstanding analytical framework is *per se* incorrect. The *Myriad* case certainly did not. The holding makes this clear: "For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible ***merely because*** it has been isolated . . .. " (emphasis added) The conclusion contains the same limitation on the scope of the opinion: "We ***merely*** hold that genes and the information they encode are not patent eligible under §101 ***simply because*** they have been isolated from the surrounding genetic material." (emphasis added) The Supreme Court's holding does not rule out even a natural DNA segment from being patentable-eligible where there is an additional basis to support patentability, such as a meaningfully different function or use for an isolated composition.

Nor does *Funk Brothers* stand for the proposition that a structural difference is the *sine qua non* of patent eligibility for claims reciting natural products. Rather, the analysis in *Funk Brothers* demonstrates that the court considered each of the natural product components of the claimed inoculant, and considered whether any of the bacterial strains acquired a different use or an enlarged range of utility, exhibited any different effect, performed in any different way, or exhibited any improved functioning. It was only after determining that the claimed inoculant did not exhibit any of these different functions or uses that the court determined that the claims were not patentable. "No species acquires a different use. The combination of species produces … no enlargement of the range of their utility." In *American Fruit Growers*, the addition of borax to the rind of fruit "only protects the natural article" and did not produce a new article with "distinctive form, quality, or property." The court's decisions plainly considered whether inventions possessed new uses or properties that would weigh in favor of patent-eligibility, but the PTO Guidance did not address this factor.

When the analytical framework of *Funk Brothers* is followed, manufactures and compositions that include natural products would be patent-eligible as long as they differ in structure, function, or utility from natural products or individual natural product components. Thus, for example, a vaccine composition comprising an isolated or purified antigen and a pharmaceutically acceptable carrier would be eligible because the antigen has a different function and use in the context of the vaccine than it does in the host organism from which it was derived.

C. Method claims reciting natural products

Under the Guidance, method claims reciting the use of natural products are subject to the same analysis as method claims that recite a law of nature or natural phenomenon. However, no Supreme Court decision has held that the patent eligibility of a method claim is undermined simply because it recites the manipulation or use of a natural product. Quite to the contrary, in *Funk Brothers* and *Myriad* the Supreme Court made clear that method claims were not under consideration. Even in *Mayo*, the court distinguished the ineligible claims-at-issue from claims directed to "a new way of using an existing drug," which it acknowledged was a "typical" category of eligible subject matter. There, the claims did not call for a new way of using an existing drug or natural product, but attempted to claim a process applying a law of nature (a narrow window of therapeutic efficacy for an existing drug in an existing therapy), that otherwise involved only routine, conventional activity.

The method claims should not be subject to any patent-eligibility analysis beyond step one of the Guidance simply because they recite the use of a product of nature. Thus, method-of-manufacture claims and method-of-use claims (including method-of-treatment claims) should be patent-eligible regardless of whether the methods involve the use of natural products. How the claimed product was discovered or obtained should not abrogate the patent eligibility of using that product in a method claim.

D. Method claims involving laws of nature/natural phenomena

Under the Guidance, examiners are instructed to balance at least ten *Mayo* factors to evaluate patent-eligibility of a method claim involving a law of nature or natural phenomenon. The examiners are to use this test to reach a conclusion whether the claimed subject matter is "significantly more" than the law of nature or natural phenomenon. The PTO can presumably identify a phrase or paragraph in *Mayo* or another Supreme Court decision from which each "factor" was derived. These phrases, however, are not set forth in *Mayo* or any other decision as discrete "factors" to be "balanced." This stands in stark contrast to the "*Wands* factors" used to evaluate enabling disclosure, which the Federal Circuit explicitly listed as discrete factors to be weighed in a §112 analysis. No Supreme Court precedent supports an analytical framework that requires "weighing" multiple factors such as these, and in fact no court has ever "weighed" all these "factors" to determine patent eligibility.

Here, the PTO's balancing exercise pertains to evaluating a "judicial exception" to Section 101. The court has more than once cautioned that "courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Chakrabarty* at 308. As such, judicial exceptions should be construed narrowly. In the context of the "factors" identified in the Guidance, a judicial exception should not apply (and subject matter should be eligible) if any single "factor" points to patent-eligibility, or if *Mayo* can be distinguished on any other grounds.

Moreover, the Supreme Court has instructed that patent-eligibility be evaluated by looking at a claim as a whole. For example, in *Diamond v. Diehr*, 101 S.Ct. 1048, 1057-58 (1981), the court stated:

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

In *Alice Corp. v. CLS Bank*, the Supreme Court again confirmed the importance of considering all claim elements and reiterated the general rule that patent claims "must be considered as a whole," citing *Diamond v. Diehr* and *Parker v. Flook*. Although the Guidance correctly mentions the "claim as a whole" analysis, we are concerned that every factor that an examiner is instructed to apply involves dissecting claims into parts and evaluating the merits of individual "elements or steps."

The "factors" also make for a potentially dysfunctional test. Whereas the *Wands* factors are scientific in nature and/or can be elucidated with expert testimony or literature, the PTO's "*Mayo*" factors are generally highly subjective and expressed in relativistic terms (e.g., "meaningful" limits; "substantially" foreclosed; "nominally, insignificantly, or tangentially related"; "high level of generality"). These relativistic factors lend themselves to conclusory rejections rather than reasoned analysis. Further, whereas the *Wands* factors are distinct from each other, many of the Guidance factors are interrelated. The reality is that many of the factors, and the requirement for balancing them, obfuscate the core inquiry of whether a method claim is merely directed to a natural law/phenomenon, or to a patent-eligible practical application thereof.

The large number of factors to balance in the Guidance also increases the risk of misapplication. Even the examples provided in the Guidance misapply factors, such as the improper consideration given to the "machine or transformation" factor in assessing method claims. For example, the "flow cytometry" recited in the method claim of Example F indisputably invokes the use of a particular machine, yet the commentary states that no machine is recited. Additionally, claim 2 of Example E recites that the reaction conditions "allow the Taq polymerase to extend the primers," yet the commentary states that no transformation is recited. Claim 3 of Example B involves administering a drug to a patient, which results in transformation of the drug and the patient, yet the commentary states that no transformation is recited. The misapplication of the factors demonstrates the impracticality of the proposed test.

F. The cases used in the Guidance cannot be harmonized.

IPO agrees with the PTO's goal of harmonizing difficult Supreme Court decisions. Unfortunately, the unique facts of many of the cases do not merit harmonization. For instance, although *Funk Brothers*, *American Fruit Growers*, and *Mayo* are all viewed as "patent-eligible subject matter" cases, one should not lose sight of the fact that each case involved patent claims that should never have issued *in view of prior art*.

In *Funk Brothers*, which involved a mixture of bacterial inoculants, "[i]t was the general practice, prior to the Bond patent, to manufacture and sell inoculants," and the patented mixture was criticized because the combination/mixture produced no change in the component parts and no enlargement of their use. The court stated, "Their use in combination [did] not improve in any way their natural functioning." In *American Fruit Growers*, the invention involved treating fruit with borax to retard mold growth, but "the underlying conception had been adequately revealed" in a prior patent more than twenty years earlier. In *Mayo*, the invention involved measuring a drug metabolite to evaluate the proper dose, but the drug, the metabolite, and the use of the metabolite to evaluate safety and efficacy all were known in the prior art.

The *Mayo* and *Funk Brothers* cases also involved claims that would be defective under today's standards for 35 U.S.C. §112. In his concurring opinion in *Funk Bros.*, Justice Frankfurter observed that the patent in question was claiming the inoculant by function rather than defining the actual components, making the claims suspect on written description or enablement grounds. In *Mayo*, the claims were directed to a method of optimizing therapeutic efficacy for treatment of a disorder, but the method was incomplete insofar as it lacked steps to optimize efficacy.

Regarding unusual fact patterns, the patent eligibility questions in *Chakrabarty* and *Myriad* were further complicated by political and philosophical questions about whether patent laws should be extended to cover novel life forms created by mankind or permit patent "ownership" of human genes.

The cases at issue involved unique and difficult fact situations, and/or patents that should never have issued in view of prior art or faulty claiming. In each of the cases, the Supreme Court could have promulgated a test like the one proposed in the Guidance. But the court did not. The Supreme Court refrained from articulating broad rules or tests for application of its judicial exceptions. The PTO should follow the Supreme Court's example and refrain from attempting to articulate criteria that the court has not explicitly expressed.

II. Gunpowder, amazonic acid, and the potential damaging effects of the Guidance on pharmaceutical and biotechnology industries.

Although the PTO aims to avoid bright line or *per se* rules, the Guidance draws two clear lines that are particularly troubling: one pertaining to a requirement for markedly different structure in composition inventions made from multiple components, and another categorically refusing patent protection for any isolated, purified, or concentrated compound or composition that might exist in any amount in nature.

The former is exemplified in Example IIIC of the Guidance, which suggests that gunpowder would not have been patent-eligible because it is "not markedly different from what exists in nature." Guidance, pp. 9-10. In Example IIIC, the Factor A analysis states that gunpowder, a mixture of the naturally occurring saltpeter, sulfur, and charcoal, is "not markedly different than what occurs in nature." Assuming that the "broadest reasonable interpretation" of "gunpowder" is defined to include its components in admixture, in ratios that are only non-naturally occurring, then the claimed gunpowder is non-naturally occurring and has a functional property, explosiveness, that is markedly different from any naturally occurring combination of the gunpowder components. Because the claimed subject matter, taken as a whole, is non-

naturally occurring (structurally different from any naturally occurring combination) and has a new function and property resulting from the structural difference of the combination, gunpowder should be eligible subject matter. No Supreme Court case requires a different analysis.

The Guidance explained that gunpowder is naturally occurring because, in its simplest form, it is a combination of potassium nitrate, sulfur and charcoal, and the structure of none of these components is changed in combination. This analysis ignores the fact that when these three components are combined into gunpowder, the result is a composition that is physically different, with new properties. That the individual components might be capable of being separated (*at which point they would not constitute gunpowder*) should not mean that the combination that qualifies as gunpowder is any less deserving of patent protection. This would lead to results such as a pencil being patent ineligible because it merely contains graphite and wood, both of which are found in nature and easily separated from one another. But gun powder and pencils are exactly the type of advancement that the patent system was created to encourage.

The Guidance relies on the *Myriad, Chakrabarty, and Funk Brothers* decisions to support the conclusion that a novel combination of naturally occurring components is patent-ineligible if no individual components are modified. However, none of these cases requires such a conclusion. As noted above, *Funk Brothers* and *Myriad* did not hold that a novel combination with a new function was patent-ineligible, but that the subject matter was patent-ineligible because it did not have a new function. As noted in the *Funk Brothers* quotation cited in the Guidance, "[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their activity." (*Funk Brothers*, 333 U.S. 127, 131 (1948)).

Many commercially valuable and transformative pharmaceutical and biotechnology inventions are analogous to gunpowder insofar as they are often made up of components that have a counterpart in nature, but when formulated exhibit novel functions, properties, and/or uses. We are troubled by the Guidance suggesting that such compositions will only be patent-eligible if a component is chemically changed. If followed in its present form, the Guidance may damage industries engaged in new drug research and development and harm consumers who rely on future drug development. Denying patent protection on these compositions removes much of the incentive to invest the time and money required for drug development.

A second bright line in the Guidance concerns apparent ineligibility of any isolated composition of matter: the Guidance clearly dictates that a claim to a "purified" naturally occurring compound, without more, must be patent-ineligible because it does not include any elements other than the natural product. This is evinced by Example B, which concludes that a claim to "purified amazonic acid" would be patent ineligible because it would not be structurally different from the same compound as it exists in the Amazonian cherry tree. Such a conclusion, however, goes beyond the holding of *Myriad*. The *Myriad* decision concerned "genetic information" and not chemical compounds. It should not be read as creating a *per se* rule against claims to purified compounds.

In *Myriad*, the Supreme Court stated that the claims at issue "focus[ed] on the genetic information encoded in the BRCA1 and BRCA2 genes," and "not with the specific chemical composition of a particular molecule." As such, the court left open the question whether purified

compounds other than human genomic DNA could be patent eligible. The Supreme Court did not hold that a purified compound with a markedly different function or utility from what exists in nature can never be patent eligible.

Example B posits that a patient would need to eat an *impossible* amount of a natural plant (30 pounds of the leaves per day for at least four weeks) to obtain a therapeutic effect, and that "[m]any [before the patent applicant] have tried and failed to isolate the cancer-fighting chemical from the leaves." The inventor in Example B successfully isolated the therapeutic moiety such that a single teaspoonful was therapeutic. If the inventor's purified version of the compound provides a more realistic treatment regime (or the only realistic treatment regime), then it should be patent-eligible.

III. The PTO should solicit public input prior to adopting significant guidelines in the future.

IPO appreciates that the PTO provided a forum for public discussion and the opportunity for public comment on the Guidance. We believe the Guidance would have benefited from public discussion and comments earlier in the process. As part of preparing future significant examiner guidance it would be ideal if sufficient time could be reserved to consider the impact on businesses and gather viewpoints of industry or legal professionals on the merits. Preparing significant examiner guidance is a task of such complexity and with such far reaching consequences for the entire patent system as to warrant early and substantial public input.

IV. The Guidance could harm business and innovation.

The Guidance may create uncertainty for innovators across a broad swath of industries, with inventions in the pharmaceutical, biotechnology, and personalized medicine industries being particularly affected. The Guidance raises serious questions as to whether key aspects of the innovative products and processes from those industries are even patent-eligible. This threat to patent protection unnecessarily puts U.S. innovation at risk. For example, to expand the narrow holding in *Myriad* beyond isolated nucleic acids or to require marked differences from products found in nature could threaten meaningful patent protection for new generations of drugs like protein therapeutics as well as existing therapies like therapeutic antibodies, proteins, and nucleic acid molecules that are now on market and being used to effectively treat patients.

The potential negative impact on the U.S. pharmaceutical industry can hardly be stated. A significant percentage of drugs approved in the last 30 years have been derived from natural constituents. All of these drugs require extensive testing to obtain FDA approval, typically 10-15 years and about $1.5 billion per commercialized drug. Without the promise of meaningful patent protection, no company will make these investments and fewer life-saving and life-improving therapies will be available to the public.

Similarly, vaccines, which are a vital part of preventative healthcare, are often engineered or designed from naturally occurring sources and are thus threatened under the Guidance. The possibility that real and meaningful research and development work in preventing human disease could be removed from patent-eligible subject matter raises serious concerns about the future of pharmaceutical innovation in the United States.

The Guidance's impact on the diagnostics industry could be similarly alarming, and arguably has already begun due to application of the Office's interim 2012 *Mayo* Memorandum. Examiners may interpret Example F in the 2014 Guidance (or Example 2 in the 2012 *Mayo* Memorandum) as creating a rule that patent-eligibility of a diagnostic method is contingent upon development of a patent-eligible diagnostic reagent ("antibody XYZ" in the example). Restricting patent protection for diagnostic inventions in this manner, as an overaggressive extrapolation of *Mayo*, will create a disincentive for investors to invest in, or for industry to develop, novel prognostic and diagnostic processes that will help caregivers prevent disease, detect disease earlier, and select precision treatments with more favorable patient outcomes. The disincentive to innovate in this area will result in less favorable outcomes and less successful treatments.

V. Specific Suggestions for Improving the Guidance

IPO suggests the PTO consider the following steps for improving the Guidance:

- Eliminate the "markedly different" criteria and associated factors. Weighing the quality of differences should be the province of §§ 102 and 103 of the patent statute, not § 101.
- Accept a "meaningfully different function or use for an isolated composition" as sufficient for patent eligibility (even in circumstances where no structural novelty exists relative to subject matter that exists in impure trace amounts in nature).
- Remove method claims for processes involving new ways of using a natural product from any patent eligibility analysis beyond step one of the Guidance (i.e., determining that such a process is being claimed).
- Emphasize that patent examiners must analyze a claim as a whole, including the interrelationship of all limitations, when evaluating patent eligibility.

IPO thanks the USPTO for considering these comments and would welcome any further dialogue or opportunity to provide additional information to assist in the Office's efforts on this issue.

Sincerely,

Herbert C. Wamsley
Executive Director