

March 16, 2016

The Honorable Michelle K. Lee
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Via email: 2014_interim_guidance@uspto.gov

RE: Request for Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility 79 Fed. Reg. 74618 (December 16, 2014)

Dear Under Secretary Lee:

The American Intellectual Property Law Association (AIPLA) is pleased to have the opportunity to present comments in response to the request from the United States Patent and Trademark Office (USPTO) in the notice “Request for Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility” (Eligibility Guidance). 79 Fed. Reg. 74618 (December 16, 2014).

AIPLA is a national bar association comprising approximately 15,000 members who are primarily lawyers in private and corporate practice, government service, and the academic community. AIPLA members represent a diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, unfair competition, and trade secret law, as well as other fields of law affecting intellectual property, in the United States and in jurisdictions throughout the world. Our members represent both owners and users of intellectual property.

Introduction

This current effort of developing examiner guidance on patent eligible subject matter began last year as a response to the Supreme Court’s decision in the *Mayo*, *Myriad* and *Alice* cases.¹ In March of 2014, the USPTO published on its website examiner guidance that addressed claims “reciting or involving” laws of nature, natural principles, natural phenomena, and/or natural products, focusing on the effects of the *Mayo* and *Myriad* decisions.² That was followed by a separate June 25, 2014, document providing examiner guidance on the ineligibility of patent

¹ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012); *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. ___, 133 S. Ct. 2107 (2013); *Alice Corp. v. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. ___, 134 S. Ct. 2347, 2354 (2014).

² “2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products,” available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

claims involving or reciting abstract ideas, focusing on the Supreme Court's *Alice* decision.³ On July 31, 2014, AIPLA filed separate comment letters on each of those documents.⁴

As stated in those comment letters, AIPLA believes that the USPTO properly issued prompt guidance to its Examiners to provide instruction on the Supreme Court's patent eligibility decisions. We continue to support any effort of the USPTO to improve patent examination, particularly with respect to compliance with the requirements of 35 U.S.C. §101. Despite improvements in the 2014 Interim Eligibility Guidance, the current version continues to suffer from fundamental flaws in both substance and process.

I. Improvements in 2014 Interim Eligibility Guidance

In a number of respects, the 2014 Interim Eligibility Guidance, together with the explanatory examples provided, contains important improvements over the initially issued guidelines.⁵ This version more faithfully reflects the *Mayo* decision holding that patent protection is available for claims that *recite* a law of nature so long as the overall effect of other features of the claim ensures that a law of nature is not monopolized. It also respects the rules that a process claim is not disqualified for patent protection simply because it *includes* a law of nature or a mathematical algorithm, and that a product claim is not disqualified for patent protection simply because it *contains* naturally occurring elements. In each instance, an invention is eligible for patent protection as long as it is "significantly more" than, or has "markedly different characteristics" from a law of nature, a natural phenomenon, or an abstract idea.

The previous version overextended these categories of ineligible subject matter to include any product or process that merely "involves" a law of nature or a natural product, whereas the revised version now limits those categories to claims "directed to" a product of nature or "reciting" a law of nature. In addition, the previous version advised examiners to look to only the structure of a nature-based product claimed in applications to find "markedly different characteristics" from the naturally-occurring product, whereas the revised version now expands the focus of that determination to the function and other properties of the claimed nature-based product.

The current version of the Eligibility Guidance also gives somewhat more attention to the requirement that patent eligibility determinations must be made with respect to the claim "as a

³ "Preliminary Examination Instructions in View of the Supreme Court Decision in *Alice Corporation Pty. Ltd. v. CLS Bank International, et al.*," available at http://www.uspto.gov/sites/default/files/patents/announce/alice_pec_25jun2014.pdf. Request for Comments and Extension of Comment Period on Examination Instruction and Guidance Pertaining to Patent-Eligible Subject Matter, 79 Fed. Reg. 36786 (June 30, 2014).

⁴ "AIPLA Comments on 'Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products (re: Myriad),' July 31, 2014, available at <http://www.aipla.org/advocacy/executive/Documents/AIPLA%20Comments%20on%20Myriad%20Guidance.pdf>; "AIPLA Response to 'Request for Comments and Extension of Comment Period on Examination Instruction and Guidance Pertaining to Patent Eligible Subject Matter (re: Alice),' July 31, 2014, available at [http://www.aipla.org/advocacy/executive/Documents/AIPLA%20Comments%20on%20Post-Alice %20Guidance.pdf](http://www.aipla.org/advocacy/executive/Documents/AIPLA%20Comments%20on%20Post-Alice%20Guidance.pdf).

⁵ "Request for Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility" (Examiner Guidance), 79 Fed. Reg. 74618, 74619 (December 16, 2014).

whole” rather than to separate elements dissected out of the claim. However, in practice and as discussed below, there still remains the opportunity under the current version for examiners to fall into the trap of parsing a claim and giving decisive weight to a single element or feature rather than making a judgment based on the claim as a whole.

II. The Guidance Flowchart Fails to Reflect the Instructions for Product of Nature Claims Ineligibility Determinations, as Recognized in the Guidance Text

Despite the improvements made to the initial versions of the Eligibility Guidance, the flowchart in the current version does not accurately reflect the instructions provided in the text for nature-based products, and we are concerned that the inconsistency between the flowchart and the text will impact the application of the guidelines. Following the *Mayo* two-step analysis, the flowchart asks (1) if the claim is to one of the statutory subject matter categories; (2) if so, does it recite one of the judicial exceptions, and (3) if so, does it recite additional elements that amount to “significantly more” than the judicial exception. It labels these three questions “Step 1,” “Step 2A,” and “Step 2B.”

As indicated in the first step, these questions are applied to all statutory subject matter categories and their corresponding claim types. However, the flowchart is not consistent with the text instructions for nature-based products. The text instructions for nature-based products distinguish the claimed product from the judicial exception for products of nature under the third step. The instruction in the flowchart’s third step (or Step 2B) that the examiner consider whether additional elements in the claim amount to “significantly more” reflects the standard applied to natural law and method cases. The Supreme Court, however, has been clear that a claim to a nature-based product does not impinge on the judicial exception for products of nature if it is “markedly different” from the naturally-occurring counterpart.⁶

Rather than incorporate nature-based product claims into the flowchart, they are referenced under the flowchart in a box with small type, entitled “Notable changes from prior guidance.” The failure to integrate into the flowchart this type of subject matter and the distinctive “markedly different” analysis for ineligibility decisions may confuse examiners into making decisions that do not consider the specific characteristics of the claimed nature-based product and the case law standards that apply to those considerations.

The decision-making process for deciding the ineligibility of nature-based product, as described in the text of the Guidance, should have been integrated into the flowchart in pursuit of the goals of consistency and efficiency, but not in the form described.

The questions posed by the flowchart, as published and as described above, have merit in that the examiner asks if the statutory categories are claimed, if exceptions are recited, and if other features of the claim mitigate the recitation of any recited exceptions. The analysis, however, is deficient in the last step by failing to recognize that any issues created by the recitation of subject matter exceptions are resolved differently for claims to nature-based products than for other product or process claims. The straightforward remedy for this problem is for the flowchart to

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

pose two alternative questions for determining if eligibility is supported by other elements of the claim:

- for a nature-based product, does the claimed product include markedly different structure, function, use, expansion of utility, or properties than its naturally occurring counterpart? and
- for other products and processes, does the claim recite additional elements that amount to significantly more than the judicial exception?

The text of the Guidance reflects this distinction, although it introduces other inconsistent analytical steps. The first question asked for claims to nature-based products is whether a “markedly different” analysis is needed, whereas the first question for claims to other products and processes is whether a judicial exception is recited. Thus, the “markedly different” analysis is used to determine if an exception is recited in the first instance, not whether the claim as a whole is eligible for patent protection. For this subject matter, the Guidance funnels a claim with no markedly different characteristics to the next question: do additional elements make the claim “significantly more” than the judicial exception.

It could be that the Guidance is trying to account for the circumstance it describes in the following sentence: “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.’”⁷ The authority given for this sentence is the first page of the *Myriad* decision, which states:

We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. 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, **but that cDNA is patent eligible because it is not naturally occurring.**

This may be a reference to a qualification of the *Myriad* ruling at the end of the opinion, where Justice Thomas states “except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.” It is a thin reed on which to base the proposed analysis.⁸

More generally, the attempt in this version of the Guidance to present a unitary, “comprehensive” document that combines and merges various analytical approaches into one creates more confusion than clarity. The only explanation provided for this approach is the statement that it “promotes examination efficiency and consistency across all technologies.”⁹ While efficiency and consistency are positive goals, in this instance they override both the realities of the subject matter listed in the statute and the corresponding Supreme Court analysis of that subject matter.

⁷ Examiner Guidance, 79 Fed. Reg. at 74623.

⁸ *Myriad*, 133 S. Ct. at 2119

⁹ Examiner Guidance, 79 Fed. Reg. at 74620.

The fact is that there are two distinct lines of Supreme Court cases presenting separate analytical approaches. The product of nature line of cases includes *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), *Chakrabarty*, and most recently *Myriad*, which made no substantive reference to any of its precedent analyzing process claims. The process claim line of cases includes *Gottschalk v. Benson*, 409 U.S. 63 (1972), *Parker v. Flook*, 437 U.S. 584 (1978), *Diamond v. Diehr*, 450 U.S. 175 (1981), and the more recent cases of *Mayo* and *Alice*. *Mayo* applied its two-step analysis to find ineligibility for a process claim that incorporated a law of nature—a naturally occurring correlation—without making any reference to the appropriate analysis for product claims. *Alice*, which involved process, system and readable media claims, applied *Mayo* only to find the process claim ineligible.

With respect to the system and media claims, the *Alice* Court pointed to the patentee's concession that those claims rise or fall with the method claims, essentially concluding they were mere surrogates for the ineligible method claims. "Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer, the system claims recite a handful of generic computer components configured to implement the same idea," Justice Thomas wrote.¹⁰ This is not a rationale for conflating the analysis for product of nature claims and process or other product claims. It is instead an application of the well-established rule that patent eligibility may not simply depend on the "draftsman's art."

While AIPLA does not believe that different industries should be treated differently, we respectfully suggest that unintended consequences can result from blurring the differences between these two distinct analyses and recommend that the Guidance clearly and unambiguously set forth separate analyses for them in both the text and the flowchart. The logic flow presented above for the product of nature inquiry tracks the approaches taken in the relevant Supreme Court decisions, none of which use the "*Mayo/Alice*" analytical approach.

We must also recognize the necessary and commendable addition of the "Streamlined Eligibility Analysis" at Part I.B.3 of the Guidance, and urge that it be included in any subsequent version of the Guidance flowchart. We believe that these additions will improve training and on-the-job use by Examiners and applicants.

III. Abstract Ideas: Where to Look and What to Look For

The Eligibility Guidance correctly instructs that the patent eligibility determination does not begin until the examiner has reviewed the entire application disclosure and construed the claims with a broadest reasonable interpretation to determine what the applicant invented. Once those steps are taken and "what the applicant invented" has been identified, the examiner is to determine whether the claim as a whole "is directed to" a judicial exception.

¹⁰ *Alice*, 134 S. Ct. at 2360.

The language from the courts on the judicial rules for excluding claims to abstract ideas, or other judicially excluded categories, complicates the effort to instruct examiners on applying those rules. As this process has demonstrated, even the three categories of excluded subject matter—laws of nature, natural phenomena, and abstract ideas—remain subject to debate.

Also subject to debate is where examiners should look for the excluded subject matter, and that question is not adequately resolved by the current version of the Examiner Guidance. The courts have given a high level instruction: no patent may be issued for a claim that, as a whole, is “directed to”¹¹ or “recites”¹² or “describes”¹³ or “involves”¹⁴ or “sets forth”¹⁵ or “claims”¹⁶ an abstract idea. The Examiner Guidance issued last March and last June was criticized for suggesting that claims that merely “involved” a judicial exception could be found ineligible, and this Interim version clarifies the point: the focus of the ineligibility inquiry is the claim that is “directed to” judicial exceptions.¹⁷ However, it then defines a claim “directed to” a judicial exception as one that “recites,” “sets forth,” or “describes” a judicial exception.¹⁸

While this language can be confusing, it can be understood as reflecting the “as a whole” analysis that an ineligibility determination requires, focusing not on a particular recitation in the patent but drawing conclusions from a flexible review of the totality of the circumstances. The consistent and never-repudiated theme of every court decision on these rules is that an ineligibility decision may not depend on a single element in the claim.

A decision of ineligibility must be based on considerations of context, whose significance is measured by this paramount consideration: does the claim as drafted threaten to tie up “the basic tools of scientific and technological work.”¹⁹ From this we understand that the disqualifying feature of a claim to one of the judicial exceptions is not the recitation of the exception itself, but rather the risk of a preemptive effect on the excluded subject matter.

¹¹ *Alice*, 134 S. Ct. at 2355 (“First, we determine whether the claims at issue are **directed to** one of those patent-ineligible concepts.” (Emphasis added.))

¹² *Mayo*, 132 S. Ct. at 1297 (“A patent, for example, could not simply **recite** a law of nature and then add the instruction “apply the law.” (Emphasis added.))

¹³ *Alice*, 134 S. Ct. at 2356 (“The claims at issue in *Bilski* **described** a method for hedging against the financial risk of price fluctuations.” (Emphasis added.))

¹⁴ *Mayo*, 132 S. Ct. at 1294 (“In particular, the steps in the claimed processes (apart from the natural laws themselves) **involve** well-understood, routine, conventional activity previously engaged in by researchers in the field.” (Emphasis added.))

¹⁵ *Mayo*, 132 S. Ct. at 1296 (“Prometheus’ patents **set forth** laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.” (Emphasis added.))

¹⁶ *Alice*, 134 S. Ct. at 2355 (“In *Mayo* ..., we set forth a framework for distinguishing patents that **claim** laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” (Emphasis added.))

¹⁷ Examiner Guidance, 79 Fed. Reg. at 74619, fn. 2.

¹⁸ *Id.* at 74624.

¹⁹ *Benson*, 409 U.S. at 67; *Mayo*, 132 S. Ct. at 1301; *Alice*, 134 S. Ct. at 2354.

For example, we know that a mathematical formula as such is ineligible for patent protection,²⁰ and that this principle may not be circumvented by limiting its use to a particular technological environment or insignificant post-solution activity.²¹ However, we also know that the ineligibility decision in *Flook* was not a reaction to claims that merely presented a mathematical formula and that the *Flook* claims did not cover every conceivable application of the formula. Instead, as explained in *Diehr*, the defect of the *Flook* patent application was that (1) it failed to explain how the variables used in the formula were selected, (2) it had no disclosures on the chemical processes at work, and (3) it had no disclosures on the means of setting off an alarm or adjusting the alarm limit.²² Without those limiting features, the risk of preemption was too high.

In the context of the process claim considered in *Mayo*, Justice Breyer explained that the claim's recitation of certain laws of nature and other conventional, routine steps, "when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."²³ The *Mayo* and *Alice* decisions, among others, call on these criteria as reflective of an "inventive concept" in order to make a qualitative comparison between the claim and the excluded subject matter.

The approach adopted by the current Eligibility Guidance, however, seizes on the "significantly more" and "markedly different" criteria to determine when a patent claim reciting a judicial exception has avoided ineligibility. It does so in a way that draws attention to discrete elements of the claim as opposed to the claim as a whole. While the Guidance correctly requires consideration of the elements of the claim, both individually and as an ordered combination, to identify an inventive concept, it strays from the literal language in *Mayo* and *Alice*. The Guidance says the object of the eligibility determination is "to ensure that the **claim as a whole** amounts to significantly more **than the exception** itself,"²⁴ whereas the Court has said the object is "to ensure that the **patent in practice** amounts to significantly more **than a patent upon the [ineligible concept]** itself."²⁵

The difference is significant because the Court's language suggests that an inventive concept protects against the risk that a "patent in practice" will tie up the judicial exception. The point is made elsewhere in *Mayo*, where Justice Breyer states that a process that focuses upon the use of a natural law must "also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."²⁶

²⁰ *Benson*, 409 U.S. at 71-72.

²¹ *Flook*, 437 U.S. at 590 (1978).

²² *Diehr*, 450 U.S. at 192, fn. 14 (1981).

²³ *Mayo* 132 S. Ct. at 1298.

²⁴ Examiner Guidance, 79 Fed. Reg. at 72624 (emphasis added).

²⁵ *Mayo*, 132 S. Ct. at 1294 (emphasis added); *see also Alice*, 134 S. Ct. at 2355.

²⁶ *Mayo*, 132 S. Ct. at 1294.

And like the other factors discussed here, an inventive concept is not claimed subject matter that is tested for novelty or non-obviousness, particularly because patents do not claim “concepts.”²⁷ Like the ultimate conclusion of patent eligibility, the inventive concept feature is ascertained from considering the claim as a whole. As explained by Justice Breyer in *Mayo*, even though the basic mathematical equation in *Diehr* was ineligible, “the overall process patent [was found] eligible because of the way the additional steps of the process integrated the equation into the process as a whole.”²⁸ The “overall process” continues to be required focus for eligibility decisions.

IV. Improvements Needed for Guidance on Abstract Idea Analysis

As with other Section 101 determinations, it is essential that the Guidance require examiners to support a determination of abstract idea ineligibility and lack of inventive concept with factual support. That determination must be objective, not subjective, and substantial evidence in the form of a reference showing that the identified idea is fundamental or that the limitations included are well-understood, routine, or conventional in the art. This standard is illustrated in the Supreme Court’s opinions in *Bilski* and *Alice*, which provided ample support for its conclusion that the underlying ideas of the claims were “fundamental” and “long prevalent.”²⁹

The Guidance also requires an express and conspicuous recognition that the *Mayo* and *Alice* decisions do not provide the exclusive analysis for Section 101 determinations. Inasmuch as different types of inventions will involve different technological features and considerations, more prominence should be given to the Supreme Court’s statement in *Bilski* that the presence of a machine or the transformation of an article is a “useful clue” to the patent-eligibility for a process claim.³⁰ Indeed, the ruling that the machine-or-transformation analysis is not the exclusive Section 101 test implies that there is no sole or exclusive test.

Importantly, examiners must be instructed to “tread carefully” in finding claims ineligible for patent protection for the same reasons that the Supreme Court has given that caution to the judiciary. Justice Breyer gave this admonishment in *Mayo*, pointing out that at some level “all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and that “too broad an interpretation of this exclusionary principle could eviscerate patent law.”³¹ If there is doubt, examiners should be instructed to resolve that doubt in favor of eligibility, not ineligibility.

²⁷ In a discussion of the difference between subject matter eligibility determinations and novelty/non-obviousness determinations, Justice Rehnquist in *Diehr* expressly cites Judge Rich’s statement that the case law requirement for “invention” was displaced by the non-obviousness requirement in the 1952 Patent Act. *Diehr*, 450 U.S. at 190, citing *In re Bergy*, 596 F.2d 952, 961 (CCPA 1979). On the very next page of *Bergy*, following the cited page, Judge Rich wrote: “Terms like ‘inventive application’ and ‘inventive concept’ no longer have any useful place in deciding questions under the 1952 Act, notwithstanding their universal use in cases from the last century and the first half of this one.” *Bergy*, 596 F.2d at 962.

²⁸ *Mayo*, 132 S. Ct. at 1298.

²⁹ *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010); *Alice*, 134 S. Ct. at 2356.

³⁰ *Bilski*, 130 S. Ct. at 3226.

³¹ *Mayo*, 132 S. Ct. at 1293.

Significantly, the Guidance fails to provide examiners any useful standard for identifying either the abstract idea that provokes the inquiry into ineligibility or the inventive concept that sustains eligibility. In effect, the Guidance encourages examiners to remove claim features until an abstract idea is uncovered and then to discount the removed claim features as not adding “substantially more” to the unearthed abstract idea. The approach which the Guidance extrapolates from the case law neglects the “as a whole” approach in the same way it was neglected under the *Freeman-Walter-Abele* methodology, which essentially required the examiner to subtract the excluded subject matter and make a decision on what was left.³² The Federal Circuit discarded that approach in the *State Street* decision, where Judge Rich wrote “[a]fter *Diehr* and *Chakrabarty*, the *Freeman-Walter-Abele* test has little, if any, applicability to determining the presence of statutory subject matter.”³³

More generally, the Guidance fails to provide a strict reading of the case law. For example, it states that courts have identified “certain methods of organizing human activities” as reciting abstract ideas,³⁴ citing the *Alice* opinion, but the cited page in the opinion reveals that the reference is simply taken from petitioner’s brief.³⁵ Elsewhere, the Guidance declares a blanket prohibition on using the “markedly different analysis” for process claims using nature-based products.³⁶ However, the supporting citation is instead to the statements in *Alice* that purely functional computer hardware cannot bootstrap the eligibility of method claims that recite an abstract idea. Similar flaws occur in the summaries of court decisions appearing at the end of the Guidance.³⁷ The list is also selective, omitting for example the *en banc* Federal Circuit’s important *Alappat* decision, holding that a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.³⁸

It is understandable that the latest Supreme Court decisions on these issues would attract the attention of the USPTO and the bar, but those decisions repeated the propositions of past cases and included a variety of disclaimers as to the scope of the rulings, evidencing an intent to retain the methodology of those past cases. The Guidance must instruct examiners that there is no single analysis required for all technologies and refrain from trying to fit all past rulings into a single framework for which such rulings are ill-suited. As written, it simply repeats the facts of an assortment of decisions as examples of abstract idea cases without providing any definition or standard for identifying the proscribed abstract idea claim. The approach dangerously encourages examiners to take liberties in their Section 101 decisions by treating those examples as bright-line categories, giving no attention to distinguishing features of the claims.

³² *In re Freeman*, 573 F.2d 1237 (CCPA 1978); *In re Walter*, 618 F.2d 758 (CCPA 1980); *In re Abele*, 684 F.2d 902, 214 USPQ 682 (CCPA 1982).

³³ *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368, 1374.

³⁴ Examiner Guidance, 79 Fed. Reg. at 74622.

³⁵ *Alice*, 134 S. Ct. at 2356.

³⁶ Examiner Guidance, 79 Fed. Reg. at 74623.

³⁷ Examiner Guidance, 79 Fed. Reg. at 74628-74632.

³⁸ *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994).

V. Natural Laws

There is a widespread sense of urgency among our membership regarding the need for Examiner Guidance that addresses claims that relate to or involve a law of nature or natural principle. While the Supreme Court has held that isolated genomic DNA may not be patent-eligible, it has also made clear that applications or methods of using the knowledge gained from determining its sequence may well be patent eligible.³⁹ We provide below some discussion to guide the delineation between patent ineligible method claims and those that are directed to patent eligible subject matter.

The first wave of challenges to diagnostic method claims has resulted in a trend: the challenged claims have been found ineligible where they recite steps related to the inventive concept with a degree of generality that is much broader than the embodiments described in the specification. However, more typical claims, such as those reciting the detection of a disease state with a specified assay have not been addressed by the courts in an analysis under 35 U.S.C. 101.

The Supreme Court has made it clear that methods applying laws of nature can be suitable subject matter for patenting. For example, in *Mayo*, the Court pointed out that applications of natural laws remain patent-eligible under *Diehr*. Justice Breyer explained that “the claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations.”⁴⁰ The Court contrasted the patent-eligible process in *Diehr*, based on the way the additional steps transformed the process into an inventive application of the formula, with the ineligible process in *Flook*, wherein the additional steps of the process did not limit the claim to a particular application. And in finding the Myriad product patents ineligible, the Court noted “this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes.”⁴¹ Judge Bryson's concurrence in the Federal Circuit Myriad decision aptly noted that, “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.”⁴²

AIPLA submits that where a claim is restricted to, for example, the sequence alterations disclosed in the specification, and to detection of the risk of certain disease states, the claimed method should be considered patent eligible and not claiming a natural law or an abstract idea. This is the approach recently followed in *University of Utah Research Foundation v. Ambry Genetics Corp.*, Fed. Cir., No. 2014-1361, 12/17/2014 (*Ambry*). In that decision, the court determined whether the claim is directed to an abstract idea/natural law by looking at the comparison step (comparing sequences and determining presence of alterations), and it noted that the comparison was not limited to any particular alterations, such as those described in the specification, or to the detection of any particular condition or even a particular type of cancer.

³⁹ *Myriad*, 133 S. Ct. at 2120.

⁴⁰ *Mayo*, 132 S. Ct. at 1297.

⁴¹ *Myriad*, 133 S. Ct. at 2120.

⁴² *Association for Molecular Pathology v. United States Patent and Trademark Office*, 689 F.3d 1303, 1349 (Fed. Cir. 2012).

It is only after concluding that the claim is directed to an abstract idea that the analysis moves on to considering whether additional steps recited in the claim, or particular mechanisms of comparison, add a further inventive concept. Care should be taken to ensure that examiners do not mistakenly proceed to look for "something more" if it has already been determined that the claim is not directed to the judicial exception.

For example, consider:

A method of detecting the presence of kidney cancer in a subject, comprising:

contacting a serum sample obtained from the subject with antibodies that specifically bind markers A, B, and C;

measuring the amount of specific antibody binding to A, B, and C;
comparing the amount of specific antibody binding to A, B, and C in the subject sample to a control amount of specific antibody binding to A, B, and C;

detecting the presence of kidney cancer when the amount of binding to A and C is increased relative to the control, and the amount of binding to B is decreased relative to the control.

These claims do not merely recite the abstract idea of comparing markers between subject and control samples; rather, they apply the idea to detection of a specified condition by measuring and comparing 3 specific markers in a specific combination, requiring a specific combination of differences between subject and normal (A & C increase; B decrease). As with the claims at issue in *Diehr*, these claims apply any abstract ideas relating to differential amounts of the markers to detection of a specific disease when specified conditions are met. Because it is more specific than the abstract idea (or high degree of generality) of comparing marker levels, it is not necessary to proceed to step two and analyze whether immunoassay steps are routine and conventional.

Even if one were to proceed to step two, it is important to consider the claim as a whole. Unlike the method steps recited in *Mayo*, which steps were already routinely practiced in the field of monitoring treatment of immune-mediated gastrointestinal disorders with 6-thioguanine, these method steps have not been routinely employed in the field of detecting kidney cancer. Examiners should be cautioned against improperly assuming that novel method steps or novel reagents are required in order for a method claim to be patent eligible.

The Guidance also should make it clear that examiners should not conflate "tying up a judicial exception" with claiming a particular application of the judicial exception. For example, in *Diehr*, the Supreme Court did not define the abstract idea as using the Arrhenius equation to determine when to open the rubber molding press. Rather, the Court found this step to be an eligible application of the ineligible abstract idea. This would be analogous to distinguishing between the ineligible natural correlation between a given protein expression level and cancer, and the eligible application of this correlation to using an immunoassay to measure antibody binding to the protein as a means to detect the cancer.

VI. Improvements of the Nature-Based Products Examples

We believe that the Nature-Based Products Examples are very helpful to Examiners and applicants. They demonstrate, in most instances, reasonable application of controlling precedent to new fact patterns. However, in the instances in which the analysis proceeds to Step 2B, the text should be corrected to explain that the proper approach is to determine whether the claimed product, viewed as a whole, possesses “markedly different characteristics” compared with specific Products of Nature. As stated above in Section II of these comments, it is not appropriate when a Product of Nature is the possible Judicial Exception to perform a Step 2B analysis by determining whether the claim “includes any additional features that could add significantly more to the exception.” Thus, we recommend that the description of the analysis pursuant to Step 2B in Examples 2 – 10 (Claim 1 in each case) and Example 9 (Claims 4 and 5) be amended to demonstrate the appropriate analysis when Products of Nature are involved, namely, determining whether the claimed product, viewed as a whole, possess “markedly different characteristics” compared with specific Products of Nature.

As stated above, we acknowledge the improvement of including the Streamlined Eligibility Analysis described in Part I.B.3 of the Guidance. It is noteworthy that Claims 7 and 8 of Example 3 (amazonic acid) are analyzed using the Streamlined Eligibility Analysis. We recommend that the text in the analysis for those claims be amended to expressly indicate the application of the Streamlined Eligibility Analysis and that reference be made to Part I.B.3 of the Guidance.

We furthermore suggest that at least Claim 1 of Example 1 (gunpowder), Claim 2 of Example 1 (fireworks), Claim 2 of Example 2 (beverage), Claims 2 – 6 of Example 3 (amazonic acid), Claims 2 – 4 of Example 7 (nucleic acids), Claims 2 – 5 of Example 8 (antibodies), and Claims 2 – 5 of Example 9 (cells) could be treated via the Streamlined Eligibility Analysis. So indicating such in the analysis descriptions for those Examples would facilitate learning and promote examining efficiency without sacrificing examining quality.

VII. Examiners Should Be Given Explicit Instructions on Making a §101 Rejection, Requiring Them To Make a Prima Facie Case To Support Such Rejection

In order to ensure an effective, efficient and transparent examination of claims, the USPTO should provide more detailed instruction to examiners as to how to handle a 101 rejection, consistent with the USPTO’s practices with prior art rejections. The current Guidance suggests that examiners must provide a *prima facie* basis for their 101 rejections.⁴³ However, in practice, examiners are making conclusory statements that shift the burden to the patent applicant to demonstrate why that statement is incorrect with no requirement that the examiner cite a reference

⁴³ See Fed. Reg. at 74624 (“In the rejection, identify the exception by referring to where it is recited, i.e., set forth or described, in the claim and explain why it is considered an exception. Then, if the claim includes additional elements, identify the elements in the rejection and explain why they do not add significantly more to the exception. *Also see* MPEP 2013 (VI) and 2106(III) for instructions on making rejections.”).

(or references) to support an assertion that a process is a law of nature or an idea is a “fundamental practice long prevalent in the field.”

In particular, the USPTO should expressly place a *prima facie* requirement on examiners to provide articulated reasoning concerning the specific claim limitations to support the legal conclusion of ineligibility. Importantly, prior comments from entities with very different and often conflicting perspectives (including AIPLA, ABA-IPL, BSA, IEEE and IPO as well as companies such as Microsoft, SAS and Trading Technologies) agreed on this recommendation in connection with their prior submission of comments. Under the Administrative Procedures Act and controlling federal case law, examiners must provide “substantial evidence” in support of all rejections.⁴⁴ Conjecture, conclusory statements, or personal opinions cannot meet this requirement.⁴⁵ Indeed, in connection with a Section 101 analysis of compositions of matter, the Supreme Court warned in footnote 8 of *Myriad*, “The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter unpatentable.”⁴⁶ (Emphasis in original).

To this end, examiners should be instructed to use claim language to identify the judicial exception and explain why it is considered an exception, citing to references to support their conclusions, using non-claim language and multiple different phrasings to describe the claimed invention results in an eligibility analysis that covers different concepts from the actual claimed invention. For rejections based on the “product of nature” and “law of nature” exceptions, the examiner should cite scientific literature and resources such as textbooks, journal articles, or databases to support the assertion that the claimed invention recites a product of nature or law of nature. For rejections based on the “abstract idea” exception, examiners should be required to cite specific authoritative literature to establish that the alleged abstract idea has been known in the industry and widely used for a long time and to clearly articulate the abstract idea, not the “category” of abstract idea. Indeed, in the *Alice* case, the Supreme Court cited to an 1896 reference to substantiate its finding that intermediated settlement is “a fundamental economic practice long prevalent in our system of commerce.”⁴⁷

The Guidance does not address how applicants may respond to such rejections nor how examiners are to evaluate such rebuttal arguments. Applicants should be able to rebut a rejection by submitting prior art that describes another use of the abstract idea or law of nature evidencing that the claimed invention does not risk “disproportionately tying up” the use of the underlying ideas.⁴⁸ Examiners should be instructed that if the applicant does so, the 101 rejection should be withdrawn.

⁴⁴ *In re Lee*, 61 USPQ 2d 1430 (Fed. Cir. 2002); *Dickinson v. Zurko*, 527 U.S. 150 (1999).

⁴⁵ See Administrative Procedure Act, 5 U.S.C. 500 *et seq.*; *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000); *In re Dembiczak*, 175 F.3d 994, 999-1000 (Fed. Cir. 1999) (broad conclusory statements about the teaching of references are not “substantial evidence”).

⁴⁶ *Myriad*, 133 S. Ct. at 2119.

⁴⁷ *Alice*, 134 S. Ct. at 2356.

⁴⁸ *Alice*, 134 S. Ct. at 2354-2355, quoting *Mayo*, 132 S. Ct. at 1294.

Finally, AIPLA requests that examiners be instructed to err on the side of finding eligible subject matter. This instruction, along with explicit guidance placing the burden of establishing a *prima facie* case of patent ineligibility, is consistent with the USPTO's general examination practices and the Administrative Procedure Act. It is also consistent with the language and spirit of the Supreme Court's recognition that courts must "tread carefully in construing this exclusionary principle lest it swallow all of patent law."⁴⁹

An interpretation of a judicial exception to patentable subject matter during the examination phase at the USPTO would likely deprive some inventors of their rights in their inventions forever. Recourse to a long and expensive appeal process is not an option for many small inventors, regardless of the ultimate value of their invention, who lack the resources to engage in many years of prosecution through appeal. Therefore, examiners should be instructed to err on the side of caution when considering whether any exception to the patentable subject matter is claimed by the applicant.

Conclusion

AIPLA appreciates the opportunity to comment in response to the Request. We would be pleased to answer any questions these comments may raise and look forward to participation in continuing efforts to enhance the examination process and help ensure that all inventions receive thorough examinations of the highest quality.

Sincerely,



Sharon A. Israel
President
American Intellectual Property Law Association

⁴⁹ *Id.*