



March 16, 2015

Hon. 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
Alexandria, VA 22313
Attention: Raul Tamayo

Via email: 2014\_interim\_guidance@PTO.gov

Re: Comments on Section 101 Interim Eligibility Guidance

Dear Deputy Director Lee:

Intellectual Property Owners Association (IPO) submits the following comments on the United States Patent and Trademark Office’s 2014 Interim Guidance on Patent Subject Matter Eligibility.

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.

On July 31, 2014, IPO sent a letter to the PTO commenting on the PTO’s Mayo-Myriad Guidance and a letter commenting on the Preliminary Examination Instructions in view of the Supreme Court decision in Alice Corp. v. CLS Bank Int’l. IPO appreciates the changes made by the PTO in the Interim Eligibility Guidance. In particular, IPO applauds the PTO for its efforts to provide guidance to examiners and the IP community – especially guidance in the form of training examples to identify types of “nature-based products” and inventions involving “abstract ideas” that continue to be patent-eligible.

However, the PTO can improve the Interim Eligibility Guidance and accompanying examples, as outlined below.

I. General Comments and Recommendations

U.S. companies in high technology, healthcare, and other sectors invest hundreds of billions of dollars annually into the U.S. economy.1 The primary protection for this R&D investment, particularly in such technology-driven areas as the computing/software and medicine/

1 “Highlights from the 2013 Global Innovation 1000 Study: Navigating the Digital Future.” Booz & Company (http://www.strategyand.pwc.com/media/file/Strategyand\_2013-Global-Innovation-1000-Study-Navigating-the-Digital-Future\_Media-Report.pdf).

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biotechnology fields, is the U.S. patent system. Clear and accurate guidance on § 101 is critical to protect these R&D investments. Any weakening of patent protection, or uncertainty as to the scope of protectable subject matter, could discourage investment in these fields, potentially harming the U.S. economy and costing U.S. jobs.<sup>2</sup>

Accordingly, the PTO's guidance must strive to clearly articulate types and examples of inventions that remain patent-eligible, and provide examiners with thorough and accurate instructions for analyzing claims under § 101 based on the current state of the case law. Mindful that most cases involving ineligible subject matter have created *fact-specific* judicial exceptions<sup>3</sup> to the plain wording of a statute, the PTO's guidance cannot overreach by extending the conclusions found in the limited number of cases decided to date beyond their actual findings.

### A. The PTO Should Clarify the Evidentiary Burden for Examiners in § 101 Rejections

The Interim Eligibility Guidance can be improved by emphasizing that examiners are required to make a detailed *prima facie* showing on all elements of a rejection under § 101. The PTO guidelines for taking Official Notice<sup>4</sup> or rejecting a claim for *prima facie* obviousness<sup>5</sup> embody this principle and serve as a model for defining an examiner's burden for making a rejection under § 101.

In rejecting any claim on review of the prior art or on any other ground, the PTO bears the initial burden of presenting a *prima facie* case supported by substantial evidence.<sup>6</sup> In explaining the substantial evidence standard, the Federal Circuit has held that an "assessment of basic knowledge and common sense not based on any evidence in the record" fails to meet this standard.<sup>7</sup> The Federal Circuit has also held that "it is important to require the PTO to adequately explain the shortcomings it perceives so that the applicant is properly notified and able to respond."<sup>8</sup>

For example, in Step 2A of the § 101 analysis, Examiners should be instructed that they need to provide documentary evidence or a "clear and unmistakable technical line of reasoning" to support an assertion that a claim recites "a law of nature, natural phenomenon, or an abstract idea."<sup>9</sup> As none of these exceptions has ever been defined by the Court, examiners should be required to articulate any alleged judicial exception, to permit Applicant rebuttal with reasoning or evidence. For instance, if an Examiner asserts that a claim recites "a fundamental economic practice,"

<sup>2</sup> [http://www.uspto.gov/about/stratplan/ar/2011/mda\\_01.html](http://www.uspto.gov/about/stratplan/ar/2011/mda_01.html) ("As the clearinghouse for U.S. patent rights, the USPTO is an important catalyst for U.S. economic growth as it plays a key role in fostering the innovation that drives job creation, investment in new technology, and economic recovery.")

<sup>3</sup> Strictly speaking, "judicial exceptions" are judicial interpretations of section 101.

<sup>4</sup> "Procedures for Relying on Facts Which are Not of Record as Common Knowledge or for Taking Official Notice," February 21, 2002, (<http://www.uspto.gov/web/offices/pac/dapp/opla/documents/offnotice.pdf>) (now incorporated into MPEP § 2144.03) ("Official Notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well known. \*\*\* If Official Notice is taken of a fact, unsupported by documentary evidence, the technical line of reasoning underlying a decision to take such notice must be clear and unmistakable.") (where the facts are not capable of instant and unquestionable demonstration as being well-known, "it would not be appropriate for the examiner to take official notice of facts without citing a prior art reference.")

<sup>5</sup> MPEP § 2143 ("It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly.")

<sup>6</sup> See *In Re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

<sup>7</sup> See *In Re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001).

<sup>8</sup> See *Hyatt v. Dudas*, 492 F. 3d 1365, 1369 (Fed Cir. 2007).

<sup>9</sup> See U.S. Patent & Trademark Office Memo on "Procedures for Relying on Facts Which are Not of Record as Common Knowledge or for Taking Official Notice," February 21, 2002, (<http://www.uspto.gov/web/offices/pac/dapp/opla/documents/offnotice.pdf>) (hereinafter, "PTO Official Notice Memo").

“longstanding commercial practice,” or other allegedly “long prevalent” concept, as such rejections amount to the examiner taking Official Notice. The Supreme Court and Federal Circuit reasoning in recent cases underscores the need for documentary evidence, as these courts have cited textbooks and other references when analyzing claims under Step 1 of the § 101 analysis.<sup>10</sup> The mere assertion that a claim recites a judicial exception, and nothing “significantly more,” is inadequate, and requires the applicant to prove a negative – that the elements beyond the identified abstract idea are not routine or are unconventional.<sup>11</sup>

Similarly, in Step 2B of the § 101 analysis, Examiners should be instructed that when they determine whether a claim recites additional elements that amount to “significantly more” than the judicial exception – such as whether claimed elements are “well-understood, routine, [and] conventional” to scientists who work in the field of the invention<sup>12</sup> – they should provide documentary evidence or a “clear and unmistakable technical line of reasoning”<sup>13</sup> to support any rejection. The Examiners should also be instructed that they must account for all recited features.

Rejections consisting of boilerplate language that lack specific evidence or analysis violate the PTO’s notice obligations and are very difficult, if not impossible, to respond to. Examiners should be instructed that conclusory assertions are insufficient, and that any conclusions should be supported with reasoned logic rather than general statements parroting language from stock rejections. Further, examiners should be trained to realize that if they cannot articulate such reasoned logic, it is a strong indication that there is no eligibility issue. The vast majority of inventions are patent-eligible – examiners should be reminded of this – and other statutes exist (e.g., §§ 102, 103, and 112) for a complete examination for patentability.

Importantly, the PTO must also train examiners to fairly weigh reasoning or evidence in rebuttal, filed by Applicants, when reconsidering any rejection under § 101.

## **B. No Single Test Is Dispositive**

The Supreme Court has rejected the notion that a single, bright line test exists for eligibility. (*See, e.g., Bilski v. Kappos*, characterizing the machine-or-transformation test as an important test, but rejecting the notion that it was a definitive test). In fact, the Supreme Court in *Alice* consistently used the word “framework” to describe its analysis, avoiding the term “test.” Although remarks below discuss the PTO’s “two part test,” the PTO’s eligibility guidance should be revised to make clear that satisfaction of this “test” is not necessarily the only means for demonstrating patent-eligibility. For example, evidence that a claim does not preempt all uses of a “judicial exception” should be dispositive that the claim is patent-eligible. Preemption is a central theme of the

<sup>10</sup> *See, e.g., Bilski v. Kappos*, 561 U.S. 593 (2010) (citing three textbooks on finance in demonstrating that “hedging is a fundamental economic practice”); *Alice Corp. v. CLS Bank Int’l*, 573 U.S. \_\_\_, 34 S. Ct. 2347 (2014) (citing a textbook from 1896 in demonstrating that “the concept of intermediated settlement is ‘a fundamental economic practice long prevalent’”); and *BuySafe, Inc. v. Google, Inc.*, \_\_\_ F.3d \_\_\_, 112 USPQ2d 1093 (Fed. Cir. 2014) (citing a history textbook from 1927 in demonstrating that “creating a contractual relationship” is “beyond question of ancient lineage.”)

<sup>11</sup> To the PTO’s credit, we note that the Interim Eligibility Guidance includes a discussion of the reasoning that an examiner should include in a rejection. However, this discussion is located in the final paragraph of Section (B)(1), where it is likely to be missed by both examiners and applicants. Moreover, the heading of Section (B)(1) is “Significantly More,” but the paragraph addresses the examiner’s burden of production under both Steps 2A and 2B. In the next iteration of eligibility guidance, the final paragraph of Section (B)(1) should be moved into an introductory section, or into a new Section (C) that may be titled “Establishing A Prima Facie Case Of Ineligibility.” This section should address the need for more than conclusory statements and indicate that factual findings are necessary to support findings that features are “well-known,” “conventional,” or “routine,” as discussed above.

<sup>12</sup> *Mayo Collaborative Serv. v. Prometheus Labs, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289 (2012).

<sup>13</sup> PTO Official Notice Memo at 2.

Supreme Court cases on patent eligibility, and is in fact a justification for creating exceptions to the plain language of the statute.<sup>14</sup> The final guidance should require a preemption analysis, and not merely characterize preemption as a side effect of an ineligible claim.

### C. Applying the Two-Part Test

The Interim Eligibility Guidance properly indicates that only claims “directed to” a judicial exception should be subject to scrutiny under § 101 in Step 2A. However, the meaning of “directed to” requires further clarification. In particular, the Interim Eligibility Guidance states that a “claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is *recited* (i.e., *set forth or described*) in the claim.” If the “directed to” requirement is meant to be narrower than the “involves” analysis used in the *Mayo-Myriad* Guidance, then having “directed to” encompass all claims that “set forth or describe” an exception does not serve that purpose.

In the patent community, a claim “recites” a word when that word is expressly written in the claim. In contrast, “describe” can encompass concepts that are not expressly written in claim language. The final guidance should clarify whether a judicial exception must be expressly recited in a claim (as opposed to implied) for the claim to be “directed to” the judicial exception, and whether all claims that expressly recite a judicial exception are “directed to” the judicial exception.

One way to avoid any misunderstanding of what “recited (i.e., set forth or described)” means is to give *Alice* credit for clarifying the *Mayo* framework, and state that Step 2A of the PTO’s eligibility test asks for the focus of the claim to be identified. The focus of a claim is the central concept of the claim, and, thus, the judicial exception must be the focus of what is being claimed. We certainly understand that the PTO may be struggling with the shift away from the PTO’s prior interpretation of *Mayo* when *Alice* introduced the “directed to” description of the first prong of the *Mayo* framework. While *Mayo* had already implied that the first part of its two-part evaluation included an implicit determination that the judicial exception was the focus of the invalidated claims (“[the Court’s precedents] insist that a process that *focuses* upon the use of a natural law also contain other elements or a combination of elements.”), *Alice* makes this implication clear (“[f]irst, we determine whether the claims at issue are directed to one of those patent-ineligible concepts”). The PTO should include this reasoning in the final guidance.

The final guidance should also better instruct examiners regarding application of the “insignificant extra-solution activity” analysis to determine whether a claim is directed to “significantly more” than a judicial exception in Step 2B. The Interim Eligibility Guidance states that one example limitation which is not “significantly more” is “[a]dding insignificant extrasolution activity to the judicial exception, e.g., mere data gathering in conjunction with a law of nature or abstract idea.” This statement is inconsistent with the fact that in the underlying cases from which it came (*Mayo* and *Flook*), the Supreme Court was implicitly asserting that the offending judicial exceptions were the “focuses” of the respective claims in question. Thus, if the PTO wants to cast a wide Step 2A net, the final guidance should clarify that “insignificant extrasolution activity” should only be an available tool for disqualifying additional subject matter if the judicial exception under scrutiny is the focus of the claim.

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<sup>14</sup> The recent Federal Circuit decision in *DDR Holdings* emphasizes that considering whether a claim preempts every application of an idea is important to a § 101 analysis. In *DDR Holdings*, the Federal Circuit found that “a specific way” of performing steps “to solve a problem” weighs in favor of patent eligibility because there is no concern over preemption of a judicial exception.

## **D. Streamlined Eligibility Analysis**

As part of the Streamlined Eligibility Analysis, the Interim Eligibility Guidance provides example claims that are “clearly not an attempt to tie up” use of an abstract idea. These example claims are not subjected to rigorous § 101 analysis. As the Interim Eligibility Guidance recognizes, if a “robotic arm assembly having a control system” is modified so that the “control system . . . operates using certain mathematic relationships,” this is clearly not an attempt to tie up use of the mathematical relationships” in the field of use of robotic arm assemblies. Further examples of claims that would wind up in different art units, but will nevertheless result in a streamlined § 101 eligibility analysis, would be helpful.

## **II. Issues Relating to High Technology**

IPO applauds the PTO for promptly providing examiners with examples of what does and does not constitute an abstract idea in conjunction with the Interim Eligibility Guidance. We appreciate the PTO’s recognition that *Alice* neither creates a *per se* excluded category of subject matter, such as software or business methods, nor imposes any special requirements for eligibility of software or business methods. The Interim Eligibility Guidance correctly establishes that the same analysis should be used for all types of so-called “judicial exceptions” to the statutory categories of patentable subject matter and all categories of claims (e.g., product and process). However, as explained below, some confusion may arise over certain aspects of the Interim Eligibility Guidance that are specific to software and business methods.

### **A. The PTO Should Provide Additional Technical Examples to Clarify the § 101 Analysis**

The examples of abstract ideas do not shed light on a number of significant technology areas. For example, Art Unit 2140 is tasked with examining graphical user interface (“GUI”) focused inventions. Yet none of the examples provide conclusions or guidance regarding how GUI-focused claims will be examined under § 101. As another example, Technology Center 3600 includes many art units that examine applications involving business methods. The examples do not provide any scenario where a claim is found to be directed to a business method, but still amounts to significantly more than the abstract idea of the business method. From *Bilski* and *Alice*, we know that methods of executing software and business methods are not *per se* ineligible. Consequently, it would be helpful if the PTO would provide additional examples that address the issues faced by examiners and applicants in these areas.

Many examiners have also indicated that they are waiting for an example closer to their art unit technology before they are comfortable indicating that a claim passes muster under the new § 101 guidance. Examiners routinely explain that they more easily understand practical examples than generic instructions, so it is of paramount importance for consistency of examination and adequacy of examiner training that additional examples be prepared addressing GUI and business method-focused claims.

### **B. Step 2A of the § 101 Analysis**

IPO recommends that the PTO clarify some specific examples provided in the Interim Eligibility Guidance. For example, the Interim Eligibility Guidance provides the following examples of concepts that are described as abstract ideas:

- “organizing information through mathematical correlations (*Digitech*)”; and
- “a mathematical procedure for converting one form of numerical representation to another (*Benson*).”

However, both the Interim Eligibility Guidance and MPEP § 2106<sup>15</sup> recognize that the machine-or-transformation of a particular article may be used to overcome a § 101 rejection. As the Interim Eligibility Guidance is currently written, there is potential that examiners may miscategorize software and computing solutions as an abstract idea, when in fact they relate to transformation of electronic data sufficient to change its function or use. This is particularly true for claims with a calculation or data processing aspect.

The expansive nature of the examples in the Interim Eligibility Guidance introduces potential rejections related to, for example, cryptography and information security, which are building blocks of the U.S. technological economy and U.S. national security. In addition, techniques for digital data processing (e.g., images, video, and scientific analysis) that are relevant to communications, media, and industrial applications may be improperly interpreted by Examiners to fall under the categories listed above. Accordingly, IPO suggests that the PTO clarify the examples provided under Step 2A of the Interim Eligibility Guidance, especially for data processing solutions.

### C. Step 2B of the § 101 Analysis

The Interim Eligibility Guidance states that an example of “significantly more” includes “improvements to the functioning of the computer itself.” It would be helpful for the PTO to provide examples of “improvements to the functioning of the computer” that would qualify, including, for example:

- improved security, such as protection against hacker attacks;
- improved battery life through reduced power consumption;
- enhanced speed of processing operations; and
- graphical user interfaces.

The Interim Eligibility Guidance also states that “significantly more” may include “applying the judicial exception with, or by use of, a particular machine.” It would be helpful for the PTO to give examples of subject matter that would qualify under this category, such as:

- a cloud-hosted service running on a virtual machine in a data-center;
- a standard phone or tablet configured for a particular function through an application;
- a programmable hardware device, such as a processor or function implemented through programmable logic gates; and
- a fixed-function non-programmable hardware circuit.

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<sup>15</sup> See MPEP § 2106 (stating that “[a]n article can also be electronic data that represents a physical object or substance” and “transformation of electronic data has been found when the nature of the data has been changed such that it has a different function or is suitable for a different use.”)

#### **D. Conventional Computers and Hardware Can Amount to Significantly More**

Certain statements in the Interim Eligibility Guidance may be used to reject every claim directed to an abstract idea that includes a generic (or conventional) computer or other hardware, including, for example, a mobile device, a depth camera, an image sensor, or a global positioning system receiver. In particular, the Interim Eligibility Guidance states that “[s]imply appending well-understood, routine and conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception” is insufficient to qualify as “significantly more.” Such broad-brush statements, even if taken from court opinions, should not be presented divorced of context. For instance, many examiners have interpreted this sweeping characterization to incorrectly imply that conventional computers or hardware are never significant to the claim as a whole, and should be avoided. Moreover, if this statement is to remain emphasized in the final guidance, it should be accompanied by an explanation of the accompanying phrase “previously known to the industry,” a requirement that is glossed over in the Interim Eligibility Guidance.

Examiners should not use the recitation of conventional hardware as a basis to reject every claim that is directed to an abstract idea, such as a mathematical formula. On this issue, the third and fourth examples provided in the PTO’s abstract idea examples are instructive. The digital image processing example is directed to a mathematical formula. Even though the steps are carried out on a conventional computer, the PTO acknowledges that the claims amount to “significantly more” than the mathematical formula. In the global positioning system processing example, the PTO again recognizes that the claims amount to “significantly more” than a mathematical formula despite being carried out on a conventional server and a mobile device using a GPS receiver. Accordingly, we encourage the PTO to clarify that conventional computer and hardware technology is often significant to the claim as a whole and can be elements illustrating “significantly more” than a judicial exception.

#### **E. Methods of Organizing Human Activity**

The Interim Eligibility Guidance incorrectly implies that all methods of organizing human activity are, *per se*, abstract. In particular, the Interim Eligibility Guidance states that “abstract ideas have been identified by the courts by way of example, including fundamental economic practices, certain methods of organizing human activities, . . .” While this statement is technically true, the implication is that claimed concepts have been identified as abstract ideas because they are methods of organizing human activities, which does not accurately reflect the case law. Rather the question is whether they are directed to a “fundamental economic practice.”

In *Alice*, the Court never stated that all methods of organizing human activity were abstract. When the *Alice* Court discussed methods of organizing human activity, the Court merely pointed out that *Bilski*’s and *Alice*’s claims were methods of organizing human activities, as opposed to pre-existing truths about the world. The Court found that *Alice*’s and *Bilski*’s claims were abstract ideas because they were directed to a fundamental economic practice, *not* because the claims were methods of organizing human activity.

IPO members have found that examiners have already started using the introductory statement in the Interim Eligibility Guidance regarding methods of organizing human activity as a pretext to allege that many claims are directed to abstract ideas. Because the only methods of organizing human activities that have been found to be abstract are fundamental economic practices long prevalent in our system of commerce, the PTO should consider removing the language regarding

“certain methods of organizing human activities” from the list of abstract idea examples. At best, this language is duplicative of the “fundamental economic practice” example, and in any event, inclusion of this language fosters erroneous findings that membership in the class of “methods of organizing human activities” is enough to qualify a concept as an abstract idea.

#### **F. Economic Practices**

With respect to economic practices, the final guidance should provide suggestions to examiners on how to determine whether a particular economic practice is “fundamental” and “long prevalent in our system of commerce.” As the Interim Eligibility Guidance points out, the Supreme Court found that the practices at issue in *Bilski* and *Alice* were “longstanding commercial practice[s]” and were “long prevalent in our system of commerce.” In accordance with the way the Supreme Court made that finding, the burden on the examiner should not merely be to identify that the claim involves or has an impact on commerce, but to show that the economic practice at issue is truly “fundamental” and that it is “long prevalent in our system of commerce.” To this end, the final guidance should require examiners to provide documentary evidence for these findings, as the Supreme Court did in *Bilski* and *Alice*. Alternatively, Official Notice may be used to demonstrate that an economic practice is “fundamental” and “long prevalent in our system of commerce,” so long as any takings of Official Notice are subject to the same limitations as takings of Official Notice in the context of prior art rejections.

The final guidance should also indicate that the lack of a prior art rejection suggests that an allegedly offending economic practice is not an abstract idea in the first place. In other words, the inability to apply a prior art rejection is strong evidence that the economic practice is neither “fundamental” nor “long prevalent.” The Interim Eligibility Guidance states that all claims are to be fully examined under 35 U.S.C. §§ 102, 103, and 112, even when a § 101 rejection is to be made. It may be helpful to point out to examiners that when the concept identified in Step 2A of the flowchart is an economic practice, findings that the concept is both a fundamental economic practice long prevalent in our system of commerce and that the claim does not recite “significantly more” are incompatible with a finding that the claim is novel and non-obvious under §§ 102 and 103.

Finally, we endorse the PTO’s observation in the Interim Eligibility Guidance that *Alice* did not create a per se excluded category of business methods or software, or impose any special requirements for eligibility of business methods or software. However, certain technologies dealing with e-commerce, banking, and finance, falling in class 705, are being universally targeted with § 101 rejections, despite the *Alice* Court’s confirmation that there is no per se exclusion of business methods. Other technologies, such as healthcare software-focused technologies are also being swept up in this focus on class 705 even though they are not financially-focused methods. The final guidance should emphasize the lack of a per se exclusion of such claim concepts, and provide examples of economic practice claims that are eligible.

#### **III. Issues Relating to Nature-Based Products and Laws of Nature/Natural Phenomenon**

IPO appreciates that the Interim Eligibility Guidance reflects comments of IPO and others on the March 2014 *Mayo-Myriad* Guidance, and takes a more balanced approach to the eligibility of nature-based product claims. IPO believes that further guidance and clarification is needed regarding the eligibility of “isolated” products and methods that involve or relate to a correlation between a biological marker and a disease, prognosis or course of treatment.

## A. Nature-Based Products

IPO appreciates the PTO's recognition in the Interim Eligibility Guidance that a nature-based product can be patent-eligible if it differs in structure, function and/or other ways from a product of nature. IPO would like the PTO to include additional examples of nature-based products that are patent-eligible based on structure, function and/or utility — especially products eligible based on markedly different function alone.

For instance, new training examples could include:

- a peptide fragment of a naturally-occurring protein that is useful as an antigen in a vaccine (particularly where the peptide is more immunogenic and/or elicits a more protective immune response than the naturally-occurring full-length protein);
- a peptide or peptide fragment conjugated to another moiety (e.g., linker, toxin);
- a small molecule isolated from a natural source with a novel utility (such as a therapeutic or industrial utility that is not relevant in the context of the natural source);
- a human antibody, defined by specific CDR sequences, against a human antigen, where there is no evidence the antibody exists in nature; and
- a pharmaceutical composition comprising a therapeutically effective amount of an isolated compound with therapeutic activity and a pharmaceutically acceptable carrier.

This last category should satisfy the “markedly different” threshold in many different factual scenarios, for example, if the compound found in nature is not therapeutically useful because of impurities that would disqualify it as a pharmaceutical composition, or if a definition for the carrier is provided in the application that effectively excludes the composition that exists in nature. The Interim Eligibility Guidance correctly indicates that nature-based products can be patent-eligible if they are “markedly different” in structure, function and/or other properties” from the corresponding naturally-occurring product. The PTO should clarify that “markedly different” is a lower threshold than the “significantly more” threshold of Step 2B. Alternatively, the PTO could explain that “markedly different” in the context of a nature-based product is tantamount to “significantly more,” to the extent that the Supreme Court endorses a “significantly more” analysis for § 101 analysis.

## B. Process Claims

The Interim Eligibility Guidance provides that process claims should not be “subject to the markedly different analysis for nature-based products used in the process, except in the limited situation where a process claim is drafted in such a way that there is no difference in substance from a product claim (e.g., ‘a method of providing an apple.’).” However, some examiners are rejecting process claims under §101 that specify the use of a naturally-occurring product in an otherwise “conventional” process, such as the use of a newly discovered enzyme in a known industrial process. The PTO should clarify that when such claims do not tie-up the use of the naturally-occurring product *per se*, a § 101 rejection should not be made.

### C. Diagnostic Method Claims

IPO understands that the Interim Eligibility Guidance does not include any examples of detection/diagnostic method claims because the PTO is waiting for additional guidance from the Supreme Court and the Federal Circuit. However, examiners and stakeholders need better guidance on how to – and when not to – apply § 101 to reject such claims.

When developing additional guidance, the PTO should keep in mind that the only Supreme Court decision relating to this type of claim is *Mayo*, where claims recited the use of *known* drugs to treat conditions for which the efficacy of the drugs was *known*, and further recited determining the levels of a drug metabolite that already was *known* to be correlated with safety and efficacy of the drugs. Furthermore, *Mayo* invalidated claims limited to the two steps that were already known and performed in combination – no additional steps were present in the claim as a whole. The PTO should not extend *Mayo* to reject claims directed to diagnosing a specific disease or condition based on the detection of a marker not previously known to be correlated with the disease or condition, because that scenario was not addressed in *Mayo*. IPO urges the PTO to publish examples of diagnostic methods that are patent-eligible.

### D. Detection Method Claims

Additional court decisions will also be helpful in preparing final guidance. The Federal Circuit *Myriad v. Ambry* decision, which issued a few days after the PTO published the Interim Eligibility Guidance, is one such example. IPO believes that *Ambry* generally supports the framework outlined in the Interim Eligibility Guidance, including the principle that a nature-based product can be patent-eligible if it differs in structure, function, or utility from the corresponding naturally-occurring product. This is confirmed by the court’s consideration of *Myriad*’s arguments pertaining to an allegedly different function of its primers, even after the Federal Circuit had decided that the primers did not have a different structure.

When considering the implications of *Ambry*, the PTO must keep in mind the claims that were before the court. The primer pair claims did not specifically recite whether a chemical composition or a kit was claimed, and did not recite specific nucleotide sequences, but primarily defined the “primer pair” by function (“wherein the use of said primers in [PCR] results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.”) Thus, *Ambry* did not address claims directed to specific nucleotide sequences that have a different function than the full-length, naturally-occurring sequence (such as specific primers, detection probes, binding decoy sequences, or RNAi constructs). The detection method claims also did not recite specific sequences or mutations, but broadly recited the detection of any difference from a wild-type sequence. Moreover, the detection method claims did not recite any diagnostic purpose or step. Thus, *Ambry* does not support the rejection of claims directed to detecting specific sequences or mutations, or to methods of diagnosis based on the detection of specific sequences or mutations.

Examples of nucleotide claims that are distinguishable from *Ambry* include:

- claims reciting specific sequences (SEQ ID NOs), particularly if they have a different function and/or are claimed as a chemical composition;
- claims reciting labeled DNA sequences;

- claims reciting chemically modified/conjugated DNA sequences;
- claims reciting DNA sequences with non-naturally occurring sequence mutations; and
- claims reciting recombinant constructs comprising naturally occurring sequences in non-naturally-occurring arrangements.

Examples of method claims that are distinguishable from *Ambry* include:

- claims reciting methods comprising detecting specific sequences or mutations; and
- claims reciting a diagnostic/prognostic step based on the detection of a specific sequence or mutation.

#### **IV. Consistency and Transparency in Examination Are Paramount**

The importance of consistency and transparency in examination cannot be overstated. This includes consistent and transparent (i) examination in all art units; (ii) training; and (iii) review of rejections within the PTO.

In recent months, IPO members have observed varying § 101 examination strategies depending upon art unit. The business methods art units of Technology Center 3600 are scrutinizing applications more strictly than consumer electronic art units by, for example, subjecting withdrawn § 101 rejections to panel level review. Other art units have shown similar inconsistencies. More consistent examination strategies across art units would provide more industry confidence in the PTO's decision making.

The PTO can minimize this difference between art units by ensuring examiner training is consistent across all art units and transparent to the public, even as it may be tailored to specific technologies. With respect to transparency, in particular, any examples that are provided to the examining corps should also be available to the public. For example, although the Interim Eligibility Guidance does not include any examples on diagnostic method claims, some examiners report that they have been instructed on specific claim limitations that will or will not support eligibility. This type of information would certainly be valuable to the industry in understanding how diagnostic method claims will be assessed.

Another concern is the need for consistent and transparent review of rejections within the PTO. Examiners have reported that they are being guided and advised by others within the PTO who are not necessarily their primary or supervisory examiners. This includes specific supervisors, quality assurance specialists, or directors who are apparently setting policies for § 101 rejections within or across specific art units. To the extent these policies go beyond the Interim Eligibility Guidance, applicants should be able to discuss them with the decision makers. Applicants should be able to hold interviews with all decision-makers involved in making a determination under § 101.

INTELLECTUAL PROPERTY OWNERS ASSOCIATION

We thank you for considering IPO's comments and would welcome any further dialogue or opportunity to provide additional information to assist your efforts above in developing guidance on § 101.

Sincerely,

A handwritten signature in black ink that reads "Herbert C. Wamsley". The signature is written in a cursive style with a large initial 'H' and a long, sweeping underline.

Herbert C. Wamsley  
Executive Director