



8 March 2019

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Attention: Carolyn Kosowski, Senior Legal Advisor, Office of Patent Legal Administration

Via email: Eligibility2018@uspto.gov

Re: Comments on USPTO’s 2019 Revised Patent Subject Matter Eligibility Guidance

Dear Ms. Kosowski:

On 7 January 2019 the USPTO issued its most recent guidance memorandum pertaining to patent examination of subject matter eligibility under 35 U.S.C. § 101, the 2019 Revised Patent Subject Matter Eligibility Guidance (“2019 Guidance”). The 2019 Guidance notes that:

Properly applying the Alice/Mayo test in a consistent manner has proven to be difficult and has caused uncertainty in this area of the law. Among other things, it has become difficult in some cases for inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible.

To address these concerns, the 2019 Guidance makes two changes to the examination procedure:

- (1) providing groupings of subject matter that is considered an abstract idea; and
(2) clarifying that a claim is not “directed to” a judicial exception if the judicial exception is integrated into a practical application of that exception.

IPO appreciates the USPTO’s leadership in addressing challenges in examination practice after Alice. In particular, IPO supports the overall intent of the 2019 Guidance to provide examiners with a way of finding eligible subject matter consistent with Supreme Court guidance, rather than articulating myriad ways to reject a claim as ineligible.

Finally, IPO is concerned that the application of the 2019 Guidance to claims directed to certain types of inventions in the life sciences might be inconsistent with the Federal Circuit’s jurisprudence. Thus, although IPO believes the 2019 Guidance will address some of the concerns our stakeholders have had with the patent examination process, we remain concerned that the courts will continue to issue conflicting decisions on subject matter eligibility and might ultimately strike down patents issued under this Guidance. As a result, IPO maintains the view that the best approach is a legislative one that restores patent eligibility law in line with the foundational principles set forth in the 1952 Patent Act, such as proposed by the IPO and AIPLA.

President
Henry Hadad
Bristol-Myers Squibb Co.
Vice President
Daniel J. Staudt
Siemens
Treasurer
Karen Cochran
Shell International B.V.

Directors
Brett Allen
Hewlett Packard Enterprise
Ronald A. Antush
Nokia USA Inc.
Estelle Bakun
Exxon Mobil Corp.
Scott Barker
Micron Technology, Inc.
Thomas Beall
Corning Inc.
Edward Blocker
Koninklijke Philips N.V.
Amelia Buharin
Intellectual Ventures
Management, LLC
Steven Caltrider
Eli Lilly and Co.
John Cheek
Tenneco Inc.
Cara Coburn
Roche, Inc.
John Conway
Sanofi
Robert DeBerardine
Johnson & Johnson
Buckmaster de Wolf
General Electric Co.
Anthony DiBartolomeo
SAP AG
Daniel Enebo
Cargill, Incorporated
Louis Foreman
Enventys
Scott M. Frank
AT&T
Darryl P. Frickey
Dow Chemical Co.
Gary C. Ganz
Evoqua Water
Technologies LLC
Tanuja Garde
Raytheon Co.
Krish Gupta
Dell Technologies
Bill Harmon
Uber
John Harris
Ford Global Technologies LLC
Heath Hoglund
Dolby Laboratories
Thomas R. Kingsbury
Bridgestone Americas
Holding Co.
William Krovatin
Merck & Co., Inc.
Michael C. Lee
Google Inc.
Kelsey Milman
Caterpillar Inc.
Micky Minhas
Microsoft Corp.
Ted Naccarella
InterDigital Corp.
Ken Patel
Procter & Gamble Co.
KaRan Reed
BP America, Inc.
Kevin Rhodes
3M Innovative Properties Co.
Paik Saber
Medtronic, Inc.
Matthew Sarbariora
Oracle Corp.
Manny Schechter
IBM, Corp.
Jessica Sinnott
DuPont
Thomas Smith
GlaxoSmithKline
Todd N. Spalding
Alexion Pharmaceuticals
Brian R. Suffredini
United Technologies, Corp.
Gillian Thackray
Thermo Fisher Scientific
Joerg Thomaier
Bayer Intellectual Property GmbH
James J. Trussell
BP America, Inc.
Mark Wadzzyk
Qualcomm, Inc.
BJ Watrous
Apple Inc.
Stuart Watt
Amgen, Inc.
Ariana Woods
Capital One
Bryan Zielinski
Pfizer Inc.

To assist the USPTO in its efforts to improve examination of subject matter eligibility, we offer the following comments on aspects of the 2019 Guidance that could benefit from further analysis and clarification.

1. Identification of a Claim Reciting a Categorized Judicial Exception

The 2019 Guidance states:

In accordance with judicial precedent and in an effort to improve consistency and predictability, the 2019 Revised Patent Subject Matter Eligibility Guidance extracts and synthesizes key concepts identified by the courts as abstract ideas to explain that the abstract idea exception includes the following groupings of subject matter, when recited as such in a claim limitation(s) (that is, when recited on their own or per se).

The “groupings of subject matter” are the following:

- Mathematical concepts like mathematical relationships, formulas, and calculations
- Certain methods of organizing human activity – fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions);
- Mental processes – concepts performed in the human mind (including an observation, evaluation, judgment, opinion).

The 2019 Guidance goes on to further state that:

Claims that do not recite matter that falls within these enumerated groupings of abstract ideas should not be treated as reciting abstract ideas.

and

For abstract ideas, Prong One represents a change as compared to prior guidance. To determine whether a claim recites an abstract idea in Prong One, examiners are now to: (a) identify the specific limitation(s) in the claim under examination (individually or in combination) that the examiner believes recites an abstract idea; and (b) determine whether the identified limitation(s) falls within the subject matter groupings of abstract ideas enumerated in Section I of the 2019 Revised Patent Subject Matter Eligibility Guidance. If the identified limitation(s) falls within the subject matter groupings of abstract ideas enumerated in Section I, analysis should proceed to Prong Two in order to evaluate whether the claim integrates the abstract idea into a practical application

The identification of “subject matter groupings” at a high level is beneficial, but IPO has several concerns as to the implementation of this identification process. Most importantly, the “groupings” are not rigorously defined. IPO recognizes that avoiding providing specific definitions and long lists of examples might cause examiners to be less inclined to use the

previous “checklist” approach that mapped claims to the ever-growing list of abstract ideas found by the courts. It appears that under the 2019 Guidance, an examiner is to make an immediate decision under Prong 1, based on the actual claim language, and move to a Prong 2 analysis. This is a better approach. However, to the extent that examiners in fact continue to define new categories of abstract ideas, the USPTO should publish an updated list of those categories on a regular basis.

The 2019 Guidance seems to address a problem that the courts have recognized as arising from *Alice*: how far can one go in generalizing a claim by ignoring what it actually “recites”—ignoring specific limitations or the context of the claim—and thereby come to a description of the invention as falling into one of the above categories. As we know, “all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” The 2019 Guidance’s approach appears to preclude examiners from making generalizations at all—which IPO supports. However, without instructions as to how rigorously an examiner must treat what a claim literally “recites” and without clearly defined categories, many claims likely will continue to be improperly categorized as abstract ideas in Step 2A, Prong 1.

IPO suggests the following refinements in the 2019 Guidance to help examiners avoid improper generalizations when deciding whether a claim recites a judicial exception.

a. Mental Processes

As stated in the 2019 Guidance, this grouping is for “concepts performed in the human mind (including an observation, evaluation, judgment, opinion).” The use of “performed” and the selection of examples implies that this category comprises claim steps that are actually performed by humans. IPO believes that is the correct approach for this subject matter grouping. Specifically, a claim should fall into this grouping only where the broadest reasonable interpretation of the claim recites a method that is to be performed mentally by a human. Any limitation, regardless of its conventionality or breadth, that requires the use of a physical apparatus to perform the method takes the claim out of this grouping.

This distinction is not made with the Office’s “2019 PEG Examples 37 through 42,” which attempt to show examples of claims that can be considered mental processes and those that cannot. Example 37 has two claims to an invention for rearranging icons on a GUI, and they differ slightly in a single element:

Claim 1	Claim 2
determining, by a processor, the amount of use of each icon over a predetermined period of time; and	determining the amount of use of each icon by a processor <u>that tracks how much memory has been allocated to each application associated with each icon over a predetermined period of time</u> ;

The Office states that claim 1 recites a judicial exception because “That is, other than reciting ‘by a processor,’ nothing in the claim element precludes the step from practically being

performed in the mind.” On the other hand, the Office states that claim 2 does not recite a judicial exception because “the claimed step of determining the amount of use of each icon by tracking how much memory has been allocated to each application associated with each icon over a predetermined period of time is not practically performed in the human mind, at least because it requires a processor accessing computer memory indicative of application usage.”

This explanation is problematic. First, instead of focusing on claims for inventions that are in fact to be performed by human, this analysis resorts to the notion of a claim that “could be performed” by a human, regardless of whether that is possible or practical. The explanation tells examiners to ignore express claim limitations—“by a processor”—in evaluating the claim.¹ Examiners currently reject claims for inventions that are only implemented in a computer as being merely “mental steps,” contrary to the both express claim limitations and the disclosure in the specification.

Expanding the mental processes grouping from steps that as claimed are to be performed mentally by humans to include those that “could be” performed mentally has the effect of inadvertently lumping in almost every computer implemented algorithm or computation. After all, a human programmer must “mentally perform” the logic of the program and its equations when developing the program. Further, the “could be” standard ignores the fact the speed at which computers can perform algorithms and equations is highly relevant and significant in real world situations.² No human (or even a thousand humans) could possibly perform the calculations used in fields such as image or voice recognition, real time encryption/decryption, audio or video decoding, real time navigation, and other applications.

This analysis of these claims is also problematic because it relies on a distinction that is incorrect—whether or not a human can make the determination—and that can be too easily applied to other claims. A user can readily “track how much memory has been allocated to each application associated with each icon.” More generally, any information that a computer uses to make a “determination” can be exposed to the user to make that “determination” herself.³ Consequently, an examiner could place just about any claim to a computer-implemented method into the mental processes category.

In short, the USPTO’s approach relies on *ad hoc* decision by the examiner as to whether or not a claim recites a mental process: if the examiner can “tell a story” in which a human “could perform” even a single step of a claim, then the claim falls into the mental processes category. This is obviously the wrong outcome, as it relies on a subjective judgment by the examiner

¹ Similarly, footnotes 14 and 15 in the 2019 Guidance cite court decisions and language that expand the grouping to steps that “could be” performed by humans, even if that is not the actual scope of the claim, not as described in the patent specification, or even practically possible.

² As explained by Judge Rich, *In re Benson*, 441 F.2d 682, 688 (CCPA, 1968) (reversed on other grounds, *Gottshalk v. Benson*, 409 US 63 (1972)), the speed of computation is “essential in the practical utilization” of the process, that it was “improbable” that anyone would ever perform the claim mentally.

³ Apropos to this specific example, in Microsoft Windows a user can readily “determine” how much memory is allocated to every executing application using the Task Manager.

Identifying claims to mental processes should be an objective assessment of claim scope based on the literal claim language. IPO recommends that the Office include the following instructions in its examiner training materials and in the MPEP:

When determining whether a claim falls within the mental processes subject matter grouping, examiners should consider the invention as described in the patent specification, as well as the claim language. Where the invention is disclosed as one performed by a human being in practice, such as making or forming a judgment, then the claims are likely to recite mental processes. Where the invention is disclosed and claimed as being performed by a machine, whether a computer or other type of apparatus, and performance by a human is not disclosed, then the claim should not be considered a mental process. Only where a claim as a whole is interpreted as being performed by a human should the claim be considered to be a mental process.

b. Mathematical Formulas

Another concern is the statement that mathematical formulas and calculations are deemed to be abstract ideas. The intent appears to be that the mere presence of a mathematical equation in a claim places the claim into this judicial exception. Again, the Office's "2019 PEG Examples 37 through 42" provide some insights to the Office's intent.

Example 41 pertains to a method of establishing cryptographic communications. The claim here includes the following step:

encoding each of the message block word signals MA to produce a ciphertext word signal CA, whereby $CA = MAe \pmod{n}$;
 where CA is a number representative of an encoded form of message word MA;
 where MA corresponds to a number representative of a message and $0 \leq MA \leq n-1$;
 where n is a composite number of the form $n = p * q$;
 where p and q are prime numbers;
 where e is a number relatively prime to $(p-1) * (q-1)$; and

The Office states:

The claim recites a mathematical formula or calculation that is used to encode each of the message block word signals MA to produce a ciphertext word signal CA, whereby $CA = MAe \pmod{n}$. Thus, the claim recites a mathematical concept. Note that, in this example, the "encoding" step is determined to recite a mathematical concept because the claim explicitly recites a mathematical formula or calculation.

IPO acknowledges that this approach—classifying any claim reciting a mathematical equation as being within the judicial exception—is easily applied in practice, and lets the examiner move on the assessment of a practical application under Prong Two. Nonetheless, IPO suggests that a refinement of the approach will help examiners avoid mis-categorizing claims that, although reciting some form of mathematical concept (whether as an equation in or words), are nonetheless not directed to the judicial exception.

Specifically, what the Supreme Court articulated in *Gottshalk v. Benson* as a judicial exception was claims that recited *pure* mathematics. This is clear from the Court’s definition of *algorithm*:

The patent sought is on a method of programming a general purpose digital computer to convert signals from binary coded decimal form into pure binary form. A procedure for solving a given type of mathematical problem is known as an “algorithm.” The procedures set forth in the present claims are of that kind; that is to say, they are a generalized formulation for programs to solve mathematical problems of converting one form of numerical representation to another.

Gottshalk v. Benson, 409 U.S. 63, 65 (1973) (emphasis added). The Court reaffirmed this narrow definition in *Diamond v. Diehr*, and it is worth quoting the Court at length here, including the important explanation in footnote 9:

Our recent holdings in *Gottschalk v. Benson*, *supra*, and *Parker v. Flook*, *supra*, both of which are computer-related, stand for no more than these long-established principles. In *Benson*, we held unpatentable claims for an algorithm used to convert binary code decimal numbers to equivalent pure binary numbers. The sole practical application of the algorithm was in connection with the programming of a general purpose digital computer. We defined “algorithm” as a “procedure for solving a given type of mathematical problem,” and we concluded that such an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent.⁹

9 The term “algorithm” is subject to a variety of definitions. The petitioner defines the term to mean:

“1. A fixed step-by-step procedure for accomplishing a given result; usually a simplified procedure for solving a complex problem, also a full statement of a finite number of steps. 2. A defined process or set of rules that leads [*sic*] and assures development of a desired output from a given input. A sequence of formulas and/or algebraic/logical steps to calculate or determine a given task; processing rules.” Brief for Petitioner in *Diamond v. Bradley*, O. T. 1980, No. 79-855, p. 6, n. 12, quoting C. Sippl & R. Sippl, *Computer Dictionary and Handbook* 23 (2d ed. 1972).

This definition is significantly broader than the definition this Court employed in *Benson* and *Flook*. Our previous decisions regarding the patentability of “algorithms” are necessarily limited to the more narrow definition employed by the Court, and we do not pass judgment on whether processes falling outside the definition previously used by this Court, but within the definition offered by the petitioner, would be patentable subject matter.

Diamond v. Diehr, 450 U.S. 175, 185-186 (1980) (emphasis added). In short, the Court has limited “algorithms” and more generally the category of “mathematical concepts” to those that involve procedures for solving purely mathematical problems—as opposed to expressing solutions to *engineering* problems. Claims directed to solutions to engineering problems fall into the category of applied mathematics. Indeed, the Office’s 2019 PEG Examples 37 through 42 have excellent examples of this type of claim. Example 38-Simulating an Analog Audio Mixer and Example 39-Method for Training a Neural Network for Facial Detection, are both examples of applied mathematics. In Example 38, the claim recites steps including

“initializing a model of an analog circuit,” and “generating a normally distributed first random value for each circuit element,” and “simulating a first digital representation of the analog circuit based on the first random value and the location of each circuit element within the analog circuit.” In Example 39, the claim recites “applying one or more transformations to each digital facial image including mirroring, rotating, smoothing, or contrast reduction,” and “training the neural network.” All of these steps are inherently mathematical operations.

The Office correctly states that the claims are not directed to a judicial exception, but for the wrong reason: “While some of the limitations may be based on mathematical concepts, the mathematical concepts are not recited in the claims.” In fact, mathematical concepts *are* recited in the claims (e.g., generating random numbers, transforming images, training neural networks, etc.). Rather, these claims are not directed to an abstract idea because the operations are part of solutions to engineering problems, rather than simply solutions to purely mathematical problems as in *Benson*.

In short, claims that use mathematics—whether literally or in more general prose—for the precise description of the operations do not recite the judicial exception as explained by the Supreme Court. IPO urges the Office to refine its analysis of the “mathematical concepts” category accordingly. Further, IPO respectfully recommends that the Office include the following instructions in its examiner training materials or in the MPEP:

The presence of a mathematical relationship, formula, and calculation in a claim, whether literally or in prose, is not a *per se* indication that the claim recites an abstract idea. Only if the mathematical relationship, formula, and calculation represents a solution to a purely mathematical problem is the claim considered to recite an abstract idea. If the claim as a whole does not recite the mathematical relationship, formula, or calculation exclusively for the purpose of disclosing or solving the formula or mathematical relationship itself, then the claim does not recite an abstract idea. No further analysis is necessary to determine whether there is a practical application of the mathematical equation, formula or calculation.

2. Identification of a Practical Application

Moving to the second part of the revised guidance, which appears to apply to all subject matter eligibility analyses, the 2019 Guidance divides Step 2A into two prongs:

In Prong One, examiners evaluate whether the claim recites a judicial exception.

In Prong Two, examiners should evaluate whether the claim as a whole integrates the recited judicial exception into a practical application of the exception. A claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.

The 2019 Guidance explains:

INTELLECTUAL PROPERTY OWNERS ASSOCIATION

Examiners evaluate integration into a practical application by: (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application, using one or more of the considerations laid out by the Supreme Court and the Federal Circuit, for example those listed below. While some of the considerations listed below were discussed in prior guidance in the context of Step 2B, evaluating them in revised Step 2A promotes early and efficient resolution of patent eligibility, and increases certainty and reliability. Examiners should note, however, that revised Step 2A specifically excludes consideration of whether the additional elements represent well-understood, routine, conventional activity. Instead, analysis of well-understood, routine, conventional activity is done in Step 2B. Accordingly, in revised Step 2A examiners should ensure that they give weight to all additional elements, whether or not they are conventional, when evaluating whether a judicial exception has been integrated into a practical application.

As explained here, the “practical application” inquiry is an intermediate step as a way of completing the Step 2A inquiry and finding a claim patent eligible as not being directed to an abstract idea without proceeding to the “inventive step” analysis of Step 2B. The 2019 Guidance instructs examiners that whether a claim element is well-understood, routine, or conventional is not a consideration under Prong Two.

As an initial matter, IPO requests clarification whether this section of the guidance applies to all subject matter eligibility analysis, including those relating to the “natural product” and “natural phenomenon” judicial exceptions. Although IPO believes this approach fits with Supreme Court and Federal Circuit decisions relating to the “natural product” judicial exception, this approach might not be consistent with Federal Circuit decisions addressing the eligibility of diagnostic methods under the “natural phenomenon” judicial exception, as discussed in more detail below.

Except for these concerns, IPO believes that this approach should, *if properly employed by examiners*, reduce the number of improper section 101 rejections.

The 2019 Guidance then provides several general categories of “exemplary considerations” indicating the presence of a practical application:

In the context of revised Step 2A, the following exemplary considerations are indicative that an additional element (or combination of elements) may have integrated the exception into a practical application:

- an additional element reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field;
- an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition;
- an additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim;

- an additional element effects a transformation or reduction of a particular article to a different state or thing; and
- an additional element applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception.

These considerations are a useful starting point, but further refinement would be useful. Suggested clarifications follow.

- *An additional element reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field*

This consideration relies on a finding of an “improvement” by the examiner, but no guidance is given as to what constitutes an improvement or what information would be used as evidence of an improvement. Generally, examination under § 101 should follow the same prosecution practices as examination under §§ 102, 103, and 112. Thus, the specification can be relied upon for explanations of an improvement—but the disclosure of improvements in the specification should not be required. This is primarily because § 112 does not require any discussion of improvements to satisfy the written description and enablement requirements, and so the absence of such a discussion cannot be used against the applicant with regards to § 101.

Evidence of an improvement can also be provided by attorney argument, for example, as supported by citations to literature (e.g., textbooks or treatises) or a Rule 132 declaration/affidavit, just as attorney argument is used to explain how claims are distinguished over prior art references. If the argument is based on sound scientific or engineering principles, the examiner should give it appropriate consideration. The Office’s 2019 PEG Examples provide useful illustrations of the kinds of arguments that applicants should be able to use to demonstrate an improvement.

Finally, as illustrated by the 2019 PEG Examples, the Office does not appear to require that the improvement be literally recited in the claims. IPO agrees that this is the correct approach, and the Office should make this explicit in its examiner training materials.⁴

- *An additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim*

⁴ The Federal Circuit in *Tranxition, Inc. v. Lenovo*, 664 F. App’x 968 (Fed. Cir. 2016), seemed to suggest that literal recitation in the claim was necessary: “[T]he claim is not directed to an improvement to computer functionality. There is nothing in the claim to suggest that, once settings have been transitioned, the target computer will be any more efficient.” First, § 112 does not require any statement of improvements in claim. Second, the Federal Circuit’s approach is at odds with actual claim drafting practice which eschews reciting “benefits” such as “improved efficiency” in the claim itself for the simple reason that such statements are indefinite and do not serve to distinguish the invention from the prior art.

INTELLECTUAL PROPERTY OWNERS ASSOCIATION

The concern here is lack of guidance as to what makes a thing “*particular*.” If a “processor” is not particular, is a “smartphone” a particular machine? *Particularity* is different than *commonality*. A smartphone is a particular machine, just as much as a toaster is a particular machine, even though both are exceedingly common. None of the 2019 PEG Examples address this question.

IPO respectfully recommends that the Office include the following instructions in its examiner training materials or in the MPEP:

Any object for which there is a common noun⁵ will generally qualify as a “particular machine or manufacture.” For example, *member* or *element* are generic nouns; *chair*, *gear*, *memory*, and *switch* are all common nouns that name particular classes of physical objects.

- *An additional element effects a transformation or reduction of a particular article to a different state or thing*

The 2019 Guidance does not explain what a “*particular article*” is or what counts as a “*transformation or reduction*.” Of most concern is whether a particular article can be an intangible article such as information or data. The 2019 PEG Examples do not include any specific examples of a satisfactory transformation or a particular article that is intangible. Example 38, discussed above, includes a step of “encoding” message blocks M_A into ciphertext word signal C_A which IPO understands to be a transformation of a particular thing (message block) to a “different state or thing” (ciphertext), but the Office does not discuss this fact.

Given the importance of data processing, IPO urges the USPTO to address this issue. In particular, IPO recommends that the USPTO prepare a set of examples of claims with transformations that sufficient to integrate a judicial exception into a practical application, as well as examples which are insufficient. The examples should touch upon various exemplary subject matter areas, for example database processing, machine learning, networking, bioinformatics, diagnostics, vaccines, and improvements on products of nature.

IPO recommends that the USPTO include the following instructions in its examiner training materials or in the MPEP:

A particular article can include intangible articles, including information stored in a computer-readable form. For example, particular articles include the following: database records, data schemas and tables, 3D models (e.g., CAD models), 2D images, video files, digital audio files, machine learning models, computer code itself (e.g., source code, object code, scripts, and the like), electronic documents (e.g., word processing documents, spreadsheets), web pages, and so forth.

⁵ “A noun that may occur with limiting modifiers (such as a or an, some, every, and my) and that designates any one of a class of beings or things.” Merriam-Webster definition of “common noun.”

A “transformation or reduction” includes any step(s) that change or alter the content or nature of the particular article.

With further refinement and clarification addressing these concerns, the 2019 Guidance will provide greater certainty to patent holders and the public.

- Whether the application of Step 2A, Prong Two to claims reciting diagnostic methods analyzed with reference to the “natural phenomenon” judicial exception is consistent with Federal Circuit decisions

In the life sciences, in particular, several Federal Circuit decisions suggest that a practical application alone may not be sufficient to avoid patent ineligibility. For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), one of the claims found patent ineligible was not simply drawn to detecting a paternally-inherited nucleic acid, but instead to a “method for performing a prenatal diagnosis on a maternal blood sample....” This appears to be a “practical application” of detecting paternally-inherited nucleic acid, albeit still of broad scope. Similarly, the dependent claims were found ineligible even though they required specific methods of application (PCR) and specific probes—details that would appear to satisfy the “additional elements” aspects set forth above.

Further, in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs. LLC*, ___ F.3d ___ (Fed. Cir. Feb. 6, 2019) (Dkt.2017-2508), the Federal Circuit held that an application of a correlation between a particular antibody and a disease (mysethenia gravis) to “diagnos[e] neurotransmission or developmental disorders related to [MuSK] in a mammal” was patent ineligible. Here too, some claims recited “additional elements” such as specific reagents that were integral to the method (labeled MuSK constructs that would bind to the MuSK antibodies being detected) that would appear to satisfy the Office’s requirements but did not suffice for the Federal Circuit.

These decisions raise serious concerns in the life sciences community and suggest that the “practical application” test at best might not be adequate, and at worst, be inconsistent with the Federal Circuit’s approach. If the Office intends the new Step 2A, Prong Two rubric to apply across the board, it would be helpful if the Office could address these decisions.

We again thank the USPTO for permitting IPO to provide comments and would welcome any further dialogue or opportunity to provide additional information.

Sincerely,



Henry Hadad
IPO President