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MEMORANDUM

DATE: May 4, 2016

TO: Patent Examining Corps

FROM: Robert W. Bahr
Deputy Commissioner
For Patent Examination Policy

SUBJECT: Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection

The purpose of this memorandum is to provide examination instructions to the Patent Examining Corps relating to subject matter eligibility of claims under 35 U.S.C. § 101. In particular, this memorandum addresses: (i) how examiners should formulate a subject matter eligibility rejection under § 101, and (ii) how examiners should evaluate an applicant response to such a rejection. These instructions are intended to assist examiners in applying the *2014 Interim Guidance on Patent Subject Matter Eligibility* (*Interim Eligibility Guidance*) and the *July 2015 Update: Subject Matter Eligibility (July 2015 Update)*. Training will be provided to illustrate the points made in this memorandum.

I. Executive Summary

Following a finding of ineligibility under the two-part analysis described in the *Interim Eligibility Guidance*, when an examiner determines that a claim is directed to an **abstract idea** (Step 2A), the rejection should identify the abstract idea as it is recited (*i.e.*, set forth or described) in the claim and explain why it corresponds to a concept that the courts have identified as an abstract idea. Similarly, when an examiner determines that a claim is directed to a **law of nature** or a **natural phenomenon** (Step 2A), the rejection should identify the law of nature or natural phenomenon as it is recited (*i.e.*, set forth or described) in the claim and explain using a reasoned rationale why it is considered a law of nature or natural phenomenon. This is discussed in greater detail in section IIA, pages 2 and 3, of this memorandum.

For the second part of the analysis (Step 2B), the rejection should identify the additional elements in the claim and explain why the elements taken individually <u>and</u> in combination do not amount to a claim as a whole that is significantly more than the exception identified in Step 2A. For instance, when the examiner has concluded that certain claim elements recite well-understood, routine, conventional activities in the relevant field of art, the rejection should explain why the courts have recognized, or those in the field would recognize, the additional elements when taken both individually and as a combination to be well-understood, routine,

conventional activities. This is discussed in greater detail in section IIB, pages 3 and 4, of this memorandum.

Examiners are reminded that examples issued by the Office in conjunction with the *Interim Eligibility Guidance* are intended to show exemplary analyses only and should not be used as a basis for a subject matter eligibility rejection or relied upon in the same manner as a decision from a court. This is noted in section IIC, page 5, of this memorandum.

When evaluating a response by applicant to a subject matter eligibility rejection, examiners must carefully consider all of applicant's arguments and evidence presented to rebut the rejection. If applicant properly challenges the examiner's findings, the rejection should be withdrawn or, if the examiner deems it appropriate to maintain the rejection, a rebuttal must be provided in the next Office action. This is discussed in greater detail in section III, pages 5 and 6, of this memorandum.

II. Formulating a § 101 Rejection

After determining what the applicant invented and establishing the broadest reasonable interpretation of the claimed invention, the eligibility of each claim should be evaluated as a whole using the two-step analysis detailed in the *Interim Eligibility Guidance*. If it is determined that the claim does not recite eligible subject matter, a rejection under § 101 is appropriate. When making the rejection, the Office action must provide an explanation as to why each claim is unpatentable, which must be sufficiently clear and specific to provide applicant sufficient notice of the reasons for ineligibility and enable the applicant to effectively respond. A subject matter eligibility rejection under Step 2 should:

- identify the judicial exception by referring to **what is recited** (*i.e.*, set forth or described) in the claim and **explain why** it is considered an exception;
- identify any additional elements (**specifically point to claim features/limitations/steps**) recited in the claim beyond the identified judicial exception; and
- explain the reason(s) that the additional elements taken **individually**, **<u>and</u>** also taken **as a combination**, do not result in the claim as a whole amounting to significantly more than the judicial exception.

A. When making a rejection, identify and explain the judicial exception recited in the claim (Step 2A)

A subject matter eligibility rejection should point to the specific claim limitation(s) that recites (*i.e.*, sets forth or describes) the judicial exception. The rejection must identify the specific claim limitations and explain why those claim limitations **set forth** a judicial exception (*e.g.*, an abstract idea). Where the claim **describes**, but does not expressly set forth, the judicial exception, the rejection must also explain what subject matter those limitations describe, and why the described subject matter is a judicial exception.

When the examiner has determined the claim recites an **abstract idea**, the rejection should <u>identify</u> the abstract idea as it is recited (*i.e.*, set forth or described) in the claim, and <u>explain why</u> it corresponds to a concept that the courts have identified as an abstract idea. See, for example, the concepts identified on the <u>July 2015 Update: Interim Eligibility Guidance Quick Reference Sheet</u>, page 2. Citing to an appropriate court decision that supports the identification of the

subject matter recited in the claim language as an abstract idea is a best practice that will advance prosecution. Examiners should be familiar with any cited decision relied upon in making or maintaining a rejection to ensure that the rejection is reasonably tied to the facts of the case and to avoid relying upon language taken out of context. Examiners should not go beyond those concepts that are similar to what the courts have identified as abstract ideas. Examiners are reminded that a chart of court decisions is available on the USPTO's Internet Web site.

> Sample explanation: The claim recites the steps of sorting information by X, which is an abstract idea similar to the concepts that have been identified as abstract by the courts, such as organizing information through mathematical correlations in *Digitech* or data recognition and storage in *Content Extraction.*

When the examiner has determined the claim recites a **law of nature** or a **natural phenomenon**, the rejection should identify the law of nature or natural phenomenon as it is recited (*i.e.,* set forth or described) in the claim and explain using a reasoned rationale why it is considered a law of nature or natural phenomenon.

> Sample explanation: The claim recites the correlation of X, and X is a law of nature because it describes a consequence of natural processes in the human body, *e.g.*, the naturally-occurring relationship between the presence of Y and the manifestation of Z.

> Sample explanation: The claim recites X, which is a natural phenomenon because it occurs in nature and exists in principle apart from any human action.

When the examiner has determined the claim recites a **product of nature**, the rejection should identify the exception as it is recited (*i.e.,* set forth or described) in the claim, and explain using a reasoned rationale why the product does not have markedly different characteristics from its naturally occurring counterpart in its natural state.

> Sample explanation: The claim recites X, which as explained in the specification was isolated from naturally occurring Y. X is a nature-based product, so it is compared to its closest naturally occurring counterpart (X in its natural state) to determine if it has markedly different characteristics. Because there is no indication in the record that isolation of X has resulted in a marked difference in structure, function, or other properties as compared to its counterpart, X is a product of nature exception.

B. When making a rejection, explain why the additional claim elements do not result in the claim as a whole amounting to significantly more than the judicial exception (Step 2B)

After identifying the judicial exception in the rejection, identify any additional elements (features/limitations/steps) recited in the claim beyond the judicial exception and explain why they do not add significantly more to the exception. The explanation should address the additional elements both individually and as a combination when determining whether the claim as whole recites eligible subject matter. It is important to remember that a new combination of steps in a process may be patent eligible even though all the steps of the combination were individually well known and in common use before the combination was made (*Diehr*). Thus, it is particularly critical to address the combination of additional elements, because while individually-viewed elements may not appear to add significantly more, those additional elements when viewed in combination may amount to significantly more than the exception by meaningfully limiting the judicial exception.

A rejection should be made only if it is readily apparent to an examiner relying on his or her expertise in the art in the Step 2B inquiry that the additional elements do not amount to claiming significantly more than the recited judicial exception. When making a rejection, it is important for the examiner to explain the rationale underlying his or her conclusion so that applicant can effectively respond. On the other hand, when appropriate, the examiner should explain why the additional elements provide an inventive concept by adding a meaningful limitation to the claimed exception. See the *Interim Eligibility Guidance* for a listing of considerations that courts have found to qualify, and to not qualify, as significantly more than an exception.

For example, when the examiner has concluded that particular claim limitations are well-understood, routine, conventional activities (or elements) to those in the relevant field, the rejection should explain why the courts have recognized, or those in the relevant field of art would recognize, those claim limitations as being well-understood, routine, conventional activities. A prior art search should not be necessary to resolve whether the additional element is a well-understood, routine, conventional activity because lack of novelty (*i.e.*, finding the element in the prior art) does not necessarily show that an element is well-understood, routine, conventional activity previously engaged in by those in the relevant field. For example, even if a particular laboratory technique was discussed in several widely-read scientific journals or used by a few scientists, mere knowledge of the particular laboratory technique or use of the particular laboratory technique by a few scientists is not sufficient to make the use of the particular laboratory technique routine or conventional in the relevant field. Instead, the evaluation turns on whether the use of the particular laboratory technique was well-understood, routine, conventional activity previously engaged in by scientists in the field. If it is determined that the additional element is widely prevalent <u>and</u> its combination with any other additional elements is well-understood, routine, conventional activity, the examiner should provide a reasoned explanation that supports that conclusion.

For claim limitations that recite a generic computer component performing generic computer functions at a high level of generality, such as using the Internet to gather data, examiners can explain why these generic computing functions do not meaningfully limit the claim. The *July 2015 Update* lists some computer functions that the courts have recognized as well-understood, routine, conventional functions when they are claimed in a merely generic manner. This listing is not meant to imply that all computer functions are well-understood, routine, conventional functions, or that a claim reciting a generic computer component performing a generic computer function is necessarily ineligible. Examiners should keep in mind that the courts have held computer-implemented processes to be significantly more than an abstract idea (and thus eligible), where generic computer components are able in combination to perform functions that are not merely generic (*DDR*).

For claim limitations that add insignificant extrasolution activity to the judicial exception (*e.g.*, mere data gathering in conjunction with a law of nature or abstract idea, or that generally link the use of the judicial exception to a particular technological environment or field of use), examiners can explain why they do not meaningfully limit the claim. For example, adding a final step of storing data to a process that only recites computing the area of a space (a mathematical relationship) does not add a meaningful limitation to the process of computing the area. As another example, employing well-known computer functions to execute an abstract idea, even when limiting the use of the idea to one particular environment, does not add significantly more,

similar to how limiting the computer implemented abstract idea in *Flook* to petrochemical and oil-refining industries was insufficient.

C. Examples should not be relied upon in § 101 rejections

The USPTO issued examples in conjunction with the *Interim Eligibility Guidance*, including *Examples: Nature-Based Products; Examples: Abstract Ideas; July 2015 Update Appendix 1: Examples;* and, *Examples: Life Sciences* (issued in May 2016). These examples, many of which are hypothetical, were drafted to show exemplary analyses under the *Interim Eligibility Guidance* and are intended to be illustrative of the analysis only. While some of the fact patterns draw from U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit decisions, the examples do not carry the weight of court decisions. Therefore, the examples should not be used as a basis for a subject matter eligibility rejection. Additionally, while it would be acceptable for applicants to cite an example in support of an argument for finding eligibility in an appropriate factual situation, applicants should not be required to model their claims or responses after the examples to attain eligibility.

III. Evaluating Applicant's Response

In response to a rejection based on failure to claim patent-eligible subject matter, applicant may: (i) amend the claim, *e.g.*, to add additional elements or modify existing elements so that the claim as a whole amounts to significantly more than the judicial exception, and/or (ii) present persuasive arguments or evidence based on a good faith belief as to why the rejection is in error. When evaluating a response, examiners must carefully consider all of applicant's arguments and evidence rebutting the subject matter eligibility rejection.

If applicant's claim amendment(s) and/or argument(s) persuasively establish that the claim is not directed to a judicial exception or is directed to significantly more than a judicial exception, the rejection should be withdrawn. Applicant may argue that a claim is eligible because the claim as a whole amounts to significantly more than the judicial exception when the additional elements are considered both individually and in combination. When an additional element is considered individually by the examiner, the additional element may be enough to qualify as "significantly more" if it meaningfully limits the judicial exception, improves another technology or technical field, improves the functioning of a computer itself, or adds a specific limitation other than what is well-understood, routine, conventional activity in the field or unconventional steps that confine the claim to a particular useful application.

In addition, even if an element does not amount to significantly more on its own (*e.g.*, because it is merely a generic computer component performing generic computer functions), it can still amount to significantly more when considered in combination with the other elements of the claim. For example, generic computer components that individually perform merely generic computer functions (*e.g.*, a CPU that performs mathematical calculations or a clock that produces time data) in some instances are able in combination to perform functions that are not generic computer functions and therefore amount to significantly more than an abstract idea (and are thus eligible).

If applicant properly challenges the examiner's findings but the examiner deems it appropriate to maintain the rejection, a rebuttal must be provided in the next Office action. Several examples of appropriate examiner responses are provided below:

- If applicant challenges the identification of an abstract idea that was based on a court case and the challenge is not persuasive, an appropriate response would be an explanation as to why the abstract idea identified in the claim is similar to the concept in the cited case. If the original rejection did not identify a Supreme Court or Federal Circuit decision in which a similar abstract idea was found and applicant challenges identification of the abstract idea, the examiner would need to point to a case in which a similar abstract idea was identified and explain why the abstract idea recited in the claim corresponds to the abstract idea identified in the case to maintain the rejection. Citation to a case that supports the original rationale would not be considered a new ground of rejection, unless there is a change to the basic thrust of the rejection. See MPEP 1207.03(a) for a discussion of new grounds of rejection.

- If applicant responds to an examiner's assertion that something is well-known, routine, conventional activity with a specific argument or evidence that the additional elements in a claim are not well-understood, routine, conventional activities previously engaged in by those in the relevant art, the examiner should reevaluate whether it is readily apparent that the additional elements are in actuality well-known, routine, conventional activities to those who work in the relevant field. It is especially necessary for the examiner to fully reevaluate his or her position when such additional elements are not discussed in the specification as being known generic functions/components/activities or not treated by the courts as well-understood, routine, conventional activities. If the rejection is to be maintained, the examiner should consider whether rebuttal evidence should be provided to further support the rejection and clarify the record for appeal. Examples of well-understood, routine, conventional claim limitations found by the Supreme Court, include:
    - *Alice Corp.* provides an example of computer functions and components that have been treated as conventional. The court describes the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions as purely conventional computer functions and notes that nearly every computer has a "data processing system" with a "communications controller" and a "data storage unit."
    - *Mayo* provides an example of data gathering that has been treated as well-understood, routine, conventional activity. The court explains that scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds and finding that steps of administering a drug and determining metabolite levels consist of well-understood, routine, conventional activity already engaged in by the scientific community.

- If applicant amends a claim to add a generic computer or generic computer components and asserts that the claim recites significantly more because the generic computer is 'specially programmed' (as in *Alappat*, now considered superseded) or is a 'particular machine' (as in *Bilski*), the examiner should look at whether the added elements provide significantly more than the judicial exception. Merely adding a generic computer, generic computer components, or a programmed computer to perform generic computer functions does not automatically overcome an eligibility rejection. *Alice Corp.*

- If applicant argues that the claim is specific and does not preempt all applications of the

exception, an appropriate response would be to explain that preemption is not a stand-alone test for eligibility. Questions of preemption are inherent in and resolved by the two-part framework from *Alice Corp.* and *Mayo*, as explained by the Federal Circuit in *OIP* and *Sequenom*. Moreover, while a preemptive claim may be ineligible, the absence of complete preemption does not demonstrate that a claim is eligible.