

Determining the Patent Eligibility of Inventions Under the New USPTO Guidelines

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Under the U.S. Patent Act, one can patent “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”[1] Common exceptions to what can be patented include laws of nature, natural phenomena, and abstract ideas[2].

In recent years, the U.S. Supreme Court has expanded the scope of the common exceptions to what can be patented. For instance, in *Mayo v. Prometheus (Mayo)*, the U.S. Supreme Court held that methods of administering a drug to a patient, measuring metabolites of that drug, and deciding whether to increase or decrease the dosage of the drug are not eligible for patenting because the methods pertain to natural phenomena[3]. Likewise, the U.S. Supreme Court later held in *Alice Corp. v. CLS Bank International (Alice)* that a computer-implemented electronic escrow service for facilitating financial transactions was not eligible for patenting because it pertained to an abstract idea[4].

The lower courts have been relying on *Alice* and *Mayo* to invalidate many patents related to diagnostic methods and computer-implemented processes. As result, the United States Patent and Trademark Office (USPTO) has issued numerous patent examination guidelines and supporting examples for evaluating the patent eligibility of inventions in view of the aforementioned rulings[5].

However, the previously issued USPTO guidelines were found to lack clarity, consistency and predictability in determining patent eligibility. In fact, the USPTO has admitted that “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.”[6] The USPTO has also admitted that “concerns have been raised that different examiners within and between technology centers may reach inconsistent results” in their patent eligibility analyses[7].

In an effort to address the aforementioned concerns, the USPTO published its “2019 Revised Patent Subject Matter Eligibility Guidance” on January 7, 2019 (“New Guidelines”)[8]. The New Guidelines modify the prior guidelines by directing the Examiners to perform a more detailed and systematic patent eligibility analysis.

The steps involved in determining the patent eligibility of inventions when one combines the prior guidelines with the New Guidelines are illustrated in [Figure 1](#). The steps are also described herein as Steps 1-4.

Step 1: Are the claims directed to a process, machine, manufacture or composition of matter?

In evaluating the patent eligibility of an invention under the New Guidelines, Examiners must first ask whether the claims are directed to one of the following statutory subject matters: (1) a process; (2) a machine; (3) a manufacture; or (4) a composition of matter. If the claims are not directed to any of the following statutory subject matters, then the claims must be rejected under 35 U.S.C. § 101 as not being eligible for patenting. However, if the claims are directed to one of the aforementioned statutory subject matters, then Examiners must proceed to the next step in the patent eligibility analysis (i.e., Step 2)[9].

Step 2: Are the claims directed to the judicial exceptions of natural phenomena, laws of nature, or abstract ideas (e.g., mathematical concepts, certain methods of organizing human activity, mental processes, or another category of abstract ideas)?

Next, Examiners must ask if the claims are directed to one of the following categories of excluded subject matter (i.e., judicial exceptions):

(1) **natural phenomena or laws of nature** (e.g., products of nature, isolated DNA, a cloned farm animal such as a sheep, a correlation between variations in non-coding regions of DNA and allele presence in coding regions of DNA, a correlation that is the consequence of how a certain compound is metabolized by the body, a correlation between the presence of an enzyme in a bodily sample (such as blood or plasma) and cardiovascular disease risk, electromagnetism to transmit signals, qualities of bacteria such as their ability to create a state of inhibition or non-inhibition in other bacteria, single-

stranded DNA fragments known as “primers”, the chemical principle underlying the union between fatty elements and water, or the existence of cell-free fetal DNA (cffDNA) in maternal blood[10]; or

(2) **the following categories of abstract ideas:**

(a) **mathematical concepts** (e.g., mathematical relationships, mathematical formulas or equations, or mathematical calculations);

(b) **certain methods of organizing human activity** (e.g., fundamental economic principles or practices [including hedging, insurance, and mitigating risk]); commercial or legal interactions [including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; and business relations]; managing personal behavior or relationships or interactions between people [including social activities, teaching, and following rules or instructions];

(c) **mental processes** (concepts performed in the human mind [including an observation, evaluation, judgment, and opinion[11]]); or

(d) **a determination by the Examiner that a claim limitation does not fall within the enumerated groupings of abstract ideas but nonetheless should be treated as reciting an abstract idea**[12].

If an Examiner determines that the claims are not directed to any of the aforementioned categories of excluded subject matter, then the claims cannot be rejected under 35 U.S.C. § 101 as not being eligible for patenting. Rather, examination must proceed to determine whether or not the claims satisfy other statutory requirements, such as novelty, obviousness, and compliance with the written description and enablement requirements.

However, if the Examiner determines that the claims are directed to one of the aforementioned categories of excluded subject matter, then the Examiner must proceed to the next step in the patent eligibility analysis (i.e., Step 3).

Step 3: Do the claims integrate the judicial exception into a practical application?

Under this step, an Examiner must ask if the claims integrate a judicial exception into a practical application. According to the New Guidelines, the practical application must be integrated into 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.”[13] More specifically, the new Guidelines indicate that a judicial exception can be integrated into a practical application under any of the following scenarios:

(1) **an additional element reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field;**

(2) **an additional element that applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition;**

(3) **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) **an additional element effects a transformation or reduction of a particular article to a different state or thing;**
or

(5) **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**[14].

The new Guidelines also indicate that a judicial exception cannot be integrated into a practical application under any of the following scenarios:

(1) **when an additional element merely recites the words “apply it” (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea;**

(2) **an additional element adds insignificant extra-solution activity to the judicial exception;** or

(3) **an additional element does no more than generally link the use of a judicial exception to a particular technological environment or field of use**[15].

Moreover, the New Guidelines emphasize that Examiners should give full weight to all elements in a claim, “whether or not they are conventional, when evaluating whether a judicial exception has been integrated into a practical application.”[16]

If an Examiner determines that the claims integrate a judicial exception into a practical application, then the claims cannot be rejected under 35 U.S.C. § 101 as not being eligible for patenting. Rather, examination must proceed to determine whether or not the claims satisfy other statutory requirements, such as novelty, obviousness, and compliance with the written description and enablement requirements.

However, if the Examiner determines that the claims are directed to a judicial exception without integrating the judicial exception into a practical application, then the Examiner must proceed to the next and final step in the patent eligibility analysis (i.e., Step 4).

Step 4: Does the identified judicial exception provide “significantly more” than the judicial exception?

The final step in determining whether or not an invention is patent eligible is to determine whether the identified judicial exception provides “significantly more” than the judicial exception. An identified judicial exception provides “significantly more” than the judicial exception if there are indications that an inventive concept is present in the claimed invention, such as when a specific claim limitation or a combination of claim limitations are not well-understood, routine, or conventional activities in the field[17].

On the other hand, an identified judicial exception does not provide “significantly more” than the judicial exception if a claimed invention “simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception, which is indicative that an inventive concept may not be present.” [18]

However, according to previously presented USPTO guidelines, a specific claim limitation or a combination of claim limitations is not well-understood, routine or conventional unless an Examiner finds, and expressly supports a rejection in writing with, one or more of the following: (1) a citation to an express statement in the specification or to a statement made by an applicant during prosecution that demonstrates the well-understood, routine, conventional nature of the additional element(s); (2) a citation to one or more of the court decisions discussed in M.P.E.P. §2106.05(d)(II) as noting the well-understood, routine, conventional nature of the additional element(s); (3) a citation to a publication that demonstrates the well-understood, routine, and conventional nature of the additional element(s); or (4) a statement that the Examiner is taking official notice of the well-understood, routine, conventional nature of the additional element(s)[19].

If the Examiner determines that the identified judicial exception provides “significantly more” than the judicial exception, then the claims cannot be rejected under 35 U.S.C. § 101 as not being eligible for patenting. Rather, examination must proceed to determine whether or not the claims satisfy other statutory requirements, such as novelty, obviousness, and compliance with the written description and enablement requirements.

However, if the Examiner determines that the identified judicial exception does not provide “significantly more” than the judicial exception, then the Examiner must reject the claims under 35 U.S.C. § 101 as not being eligible for patenting.

Ramifications of the New Guidelines

The New Guidelines direct the Examiners to follow a more systematic approach to evaluating the patent eligibility of inventions by changing the prior guidelines in at least two manners. First, the New Guidelines explain that abstract ideas can be further grouped into mathematical concepts, certain methods of organizing human activity, mental processes, and other categories determined by the Examiner[20]. Second, the New Guidelines explain that a patent claim or patent application claim that recites a judicial exception is not “directed to” the judicial exception if the judicial exception is integrated into a practical application of the judicial exception[21].

Whether or not the New Guidelines will provide more lack clarity, consistency and predictability in the patent eligibility analysis of inventions remains to be determined. For instance, the metes and bounds of when a judicial exception has been integrated into a practical application of the judicial exception may be subject to different interpretations. The metes and bounds of mathematical concepts, certain methods of organizing human activity, mental processes, and other determined categories of abstract ideas may also require further clarification.

In the meantime, patent practitioners and applicants should ensure that Examiners are adhering to the New Guidelines when issuing patent eligibility rejections under 35 U.S.C. § 101. Patent practitioners and applicants should also utilize the New Guidelines to rebut patent eligibility rejections. Finally, the New Guidelines could be utilized as a tool to evaluate the patent eligibility of inventions.

Figure 1 - Click to Enlarge

[1] 35 U.S.C. § 101

[2] 134 S. Ct. 2347, 2354 (2014)

[3] 132 S. Ct. 1289 (2012)

[4] 134 S. Ct. 2347 (2014)

[5] The USPTO guidelines and supporting examples can be found at: <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>. Section 2106 of the Manual of Patent Examining Procedure (M.P.E.P. §2106) also provides patent eligibility guidelines and examples.

[6] 84 Fed. Reg. 50, page 50 (col. 2)

[7] 84 Fed. Reg. 50, page 52 (col. 1)

[8] 84 Fed. Reg. 50. Available at: <https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf>

[9] Step 1 of the subject matter eligibility analysis was previously outlined in M.P.E.P. §2106

[10] See M.P.E.P. § 2106.04(b)

[11] 84 Fed. Reg. 50, page 52 (cols. 2-3)

[12] 84 Fed. Reg. 50, pages 56 (col. 3) to 57 (col. 1)

[13] 84 Fed. Reg. 50, page 54 (col. 3)

[14] 84 Fed. Reg. 50, page 55 (cols. 1-2)

[15] 84 Fed. Reg. 50, page 55 (cols. 2-3)

[16] 84 Fed. Reg. 50, page 55 (col. 1)

[17] 84 Fed. Reg. 50, page 56 (cols. 1-3)

[18] 84 Fed. Reg. 50, page 56 (cols. 1-2)

[19] See USPTO Memorandum of April 19, 2018, "Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*)" (Apr. 19, 2018), available at <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>

[20] 84 Fed. Reg. 50, page 50 (col. 1)

[21] *Id.*